

## PRODUCT CONFORMITY EVALUATION PROCEDURE

### A) DOCUMENT APPROVALS

No	Definition	Action	Created By	Date
1	Document approved	Approval	Nurgül Çınar	23.11.2023
2	Translation approved	Approval	Nihan Dağlı Arslan	20.11.2023

### B) REVISION HISTORY

No	Definition	Reason	Approval Date	Release Date
17	Gözetim denetimlerinin APP.SZUTEST yazılımdan takip edildiği bilgisi eklendi, gözetim denetimleri sonrası sertifika süresi uzatılarak gözetim sertifikası verildiği bilgisi eklendi. Modül H kapsamlı işlerde gözetim denetimlerde FR.30 değişiklik formu ile çalışan sayısı bilgisi alındığı bilgisi eklendi. Modül H kapsamlı denetim planlamalarında denetim süresi hesaplaması için PR.PED.01 prosedürüne atıf yapıldı. Modül H Aşama-1'in sahada yapılacağı yazıldı. EN ISO 17021-1 Modül H kapsamında iyileştirmeler yapıldı.	iyileştirme.	23.11.2023	23.11.2023
16	Habersiz denetimlerde kullanılacak rapor numarasına atıf yapıldı, TL.21 Kalibrasyon talimatına yapılan atıflar, PR.25 Cihaz, Ekipman ve Donanım Yönetimi Prosedürü olarak değiştirildi.	iyileştirme	21.06.2023	21.06.2023
15	Improvements were made to the document.	Fr.Ped.64 Audit Team Certification Committe Assigning Form was referred to.	20.03.2023	20.03.2023
14	Transferred to IQMEMO Software.	transfer to new software	15.02.2023	15.02.2023

## 5. Aim and Scope

The purpose of this procedure is to determine the principles regarding the realization of product conformity assessment activities according to the modules listed below and defined according to Annex III of the 2014/68/EU Pressure Equipment Directive and Annex II of the 2014/29/EU Simple Pressure Vessels Directive.

Test and/or Inspection based modules:

- 2014/68/EU Annex III Module A2
- 2014/68/EU Annex III Module B (design type)
- 2014/68/EU Annex III Module B (production type)
- 2014/68/EU Annex III Module F
- 2014/68/EU Annex III Module C2
- 2014/68/EU Annex III Module G

2014/29/EU Annex II Module B (Production type)

2014/29/EU Annex II Module B (Design type)

2014/29/EU Annex II Module C

2014/29/EU Annex II Module C1

2014/29/EU Annex II Module C2

Quality system-based modules:

- 2014/68/EU Annex III Module D1
- 2014/68/EU Annex III Module E1
- 2014/68/EU Annex III Module D
- 2014/68/EU Annex III Module E
- 2014/68/EU Annex III Module H
- 2014/68/EU Annex III Module H1

## 6. Definitions

Ministry: T.C. Ministry of Industry and Technology

Commission: European Union Commission,

Manufacturer: A natural or legal person who manufactures, rehabilitates or introduces himself as a manufacturer by placing his name, trademark or distinctive sign on a pressure vessel and vessel group, if the manufacturer is outside of Turkey, the representative and/or importer authorized by the manufacturer, also, natural or legal person in the supply chain of the pressure vessel whose activities affect the safety characteristics of the pressure vessel

Conformity Assessment: Any activity related to testing, inspection and/or certification of the compliance of the pressure vessel or pressure vessel group with the provisions of this Regulation,

Standard: Characteristics of the product, processing and production methods, related terminology, symbols, packaging, marking, labeling and conformity assessment procedures for common and repeated uses, which are agreed upon, approved by a notified body, aiming to establish order at the most appropriate level under the current conditions.

Harmonized European Standard: The standard prepared by a European Standardization Organization upon the instruction of the Commission and published in the Official Journal of the European Union,

Harmonized National Standard: The standard that harmonizes a harmonized European Standard and is accepted and published as a Turkish Standard by the Turkish Standards Institute,

"CE" Mark: The mark showing that the product complies with all the relevant rules of the technical legislation that requires the "CE" mark to be placed,

Module: Each of the ways that indicate which conformity assessment process will be subjected to the product according to the risks it carries, in accordance with the regulation,

Type: Pressure equipment representing the product planned to be produced,

Technical File: A file containing reports and documents showing that the pressure equipment has been produced in accordance with the requirements of the relevant technical regulation and containing information about the design, production and/or operation of the pressure equipment

Finished Product: Pressure equipment that does not need to undergo any further processing before it can be used and is ready for use,

End Product: The pressure equipment within the scope of the same documents showing conformity with the relevant technical regulation, which is last supplied to the market,

Conformity Assessment Body: Private or public organization that carries out activities related to testing, inspection and/or certification of the conformity of pressure equipment and equipment with the technical regulation related to this Regulation, and authorized by this Regulation and the Regulation on Conformity Assessment Bodies and Notified Bodies No. 2001/3531 and responsible to the Ministry,

Notified Body: The conformity assessment body established in Turkey, whose names are notified to the Commission, and assigned by the authorized body in accordance with the principles determined in the relevant legislation to carry out conformity assessment activities within the scope of technical regulation,

Pressure Equipment: Vessels, piping, safety and pressure accessories, if applicable, pressure equipment, elements connected to pressure parts such as flanges,

nozzles, couplings, supports, lifting eyebolts,

Vessel: A vessel or chambers designed and constructed to contain fluids under pressure, including direct attachments up to the point of attachment to other equipment;

Piping: Pipes designed for the transport of fluids when connected for integration within the pressure system, (Pipes include, in particular, a pipe or piping system, fittings, expansion joints, hoses, or other suitable pressurized parts. Heat exchangers consisting of pipes for cooling or heating the air will also be considered as piping.)

Safety Accessories: Devices designed to protect pressure equipment from exceeding permissible limits, such devices include:

- 1) Direct pressure limiting devices. (Example: safety valve, bursting disc safety devices, bellows, controlled pressure reducing safety systems),
- 2) Limiting devices that either actuate pressure regulating systems or provide shut-down or shut-down and complete stop. (Example: pressure and temperature switches, fluid level switches and all kinds of safety-related measurement, control, and regulation devices.)

Pressurized Accessories: Functional devices with pressure carrier reservoir,

Equipment: Various parts of pressure equipment assembled by a manufacturer to form an integrated and functional unit

ICT: Information and Communication Technology

Major (Major) Nonconformity: Nonconformities that affect the management system's ability to achieve its intended results. that may affect the continuous implementation of the overall system and/or

It is the situation where any of the standard items or sub-headings that adversely affect the fulfillment of the service or product offered under the desired conditions are not adequately defined and/or systematically applied.

Minor (Minor) Nonconformity: Nonconformities that do not affect the ability of the management system to achieve its intended results. They are non-systematic deviations from system standard conditions and/or company documentation requirements that do not affect the overall system.

Observation: It is a situation seen during the examination and can be proven with objective evidence. In case of not taking precautions, determinations that may turn into non-compliance are included in this definition and observations are stated in the audit report.

PMA: Particular Material Appraisal

## 7. Responsibilities

Technical Regulatory Officer and Technical Experts are responsible for the implementation of this procedure.

## 8.Method

### 8.1 Application and Contract

Customer requests are received with FR.SPV.01 Conformity Assessment Application Form for activities within the scope of 2014/29/EU Simple Pressure Vessels Regulation, and FR.PED.01 Conformity Evaluation Application Form for activities within the scope of 2014/68/EU Pressure Equipment Regulation. Applications are evaluated according to PR.PED.01 Application Evaluation and Contract Procedure, and the project starts after the relevant contracts are signed.

### 8.2 Conformity Assessment Program

Compliance in the Product Certification Program		Product Certification Modules												
Assessment Functions and Activities	A2	B (product)	B (design)	C	C1	C2	D	D1	E	E1	F	G	H	H1
<b>I. Selection</b>														
Determining the documents that are the basis for certification	x	x	x	x			x	x	x	x	x	x	x	x
<b>II. Determination of Properties</b>														
Test	x + T	x + T		x + T			x* + T	x* + T	x* + T	x* + T	x + T	x + T	x* + T	x* + T
Technical File Review	x	x	x	x			x	x	x	x	x	x	x	x
Design Approval		x	x									x		x
Inspection	x + M	x + M		x + M			x* + M	x* + M	x* + M	x* + M	x + M	x + M	x* + M	x* + M
Management system audit							x + KS	x + KS	x + KS	x + KS			x + KS	x + KS
<b>III. Review</b>														
Examination of obtained evidence of conformity	x	x	x	x			x	x	x	x	x	x	x	x

IV. Certification Decision													
The decision to issue and maintain the certificate, extend its scope, suspend or withdraw the certificate	x	x	x	x		x	x	x	x	x	x	x	x
V. Licensing													
Issue of the certificate of conformity	x	x	x	x		x	x	x	x	x	x	x	x
Granting the right to use the certificate and the CE mark	x			x		x	x	x	x	x	x	x	x
Issue of conformity certificate for product group	x			x									
Granting the right to use the certificate and the CE mark, subject to surveillance						x	x	x	x			x	x
VI. Surveillance													
Inspection or testing of samples from the factory						x + T	x + T	x + T	x + T			x + T	x + T
Management system audits**						x + KS	x + KS	x + KS	x + KS			x + KS	x + KS

\* If necessary, it supervises the tests and inspections, considering the technical documentation prepared by the manufacturer and the requirements of the regulation, and examines and verifies the competence of the manufacturer.

\*\*Explained on Article 8.3.2.11.1 of this procedure.

+ T: In the assessment to be made, in addition to the requirements of the EN ISO/IEC 17065 standard, the requirements of EN ISO/IEC 17025 Articles 6 and 7 (except article 7.9) are applied. FR.END.89 EN ISO/IEC 17020 and EN ISO/IEC 17025 Applicable Additional Requirements Checklist is used.

+ M: In the assessment to be made, in addition to the requirements of the EN ISO/IEC 17065 standard, the requirements of EN ISO/IEC 17020 Article 6.1.2, 6.1.3, 6.1.6, 6.1.7, 6.1.8., 6.1.9. and 6.1.10 are applied. FR.END.89 EN ISO IEC 17020 and EN ISO IEC 17025 Applicable Additional Requirements Checklist is used.

+ KS: In the assessment to be made, in addition to the requirements of the EN ISO/IEC 17065 standard, the requirements of EN ISO/IEC 17021-1 Articles 7.1.1, 7.1.2, 7.2.4, 7.2.5, 7.2.8, 7.2.10 and Article 9.1, 9.2, 9.3, 9.4 and 9.6 are applied.

Yellow Color: Indicates that the requirements of the EN ISO/IEC 17021-1 standard are applied in the evaluation to be made for the relevant Module, see the table for additional requirements.

Green Color: It indicates that the requirements of the EN ISO/IEC 17020 standard are applied in the evaluation to be made for the relevant Module, see the table for additional requirements.

When the manufacturer presents the Fixed Procedure and Personnel Approval Documents that it has carried out before, it is checked whether the organization that issued these certificates (2014/68/EU Pressure Equipment Directive Annex I- Article 3.1.2.) is a notified body. If the body is not a notified body, the submitted certificates are not accepted.

If there are test reports other than these, it is checked whether the organization performing the test has TS EN ISO / IEC 17025 accreditation, and if there are inspection reports submitted, TS EN ISO / IEC 7020 accreditation is checked, and if this condition is not met, test reports and inspection reports cannot be accepted. If it does not have TS EN ISO / IEC 17025 / TS EN ISO / IEC 17020 accreditation, the laboratory that performs the tests/audits is assessed by performing a TS EN ISO / IEC 17025 / TS EN ISO / IEC 17020 audit.

### 8.3. Performing Conformity Assessment

#### 8.3.1 Performing Test and Inspection Based Conformity Assessment

##### 8.3.1.1 Technical Expert Assignment

If the assessment result of the application described in PR.PED.01 Application Assessment and Contract Procedure is appropriate, Technical Expert(s) qualified according to PR.PED.03 Qualification Procedure are assigned by the Technical Regulatory Officer with the FR.PED.64 Audit Team Certification Committee Assigning.

##### 8.3.1.2. General Information Before Inspection

The Technical Expert, who will carry out the inspection, first records the preliminary examination results of the technical file requested from the customer with the FR.PED.05 Inspection and Pre-Inspection Assessment Form (This form is filled regardless of the module within the scope of the PED.) Then, on the specified

date, it performs the inspection procedures at the address specified by the applicant. Calibration and verification processes of all measuring equipment used in inspection activities must be carried out in accordance with PR.25 Device, Equipment, and Equipment Management Procedure, and calibration and verification evidence must be defined in the inspection report. If non-SZUTEST equipment is used, evidence that the requirements of article 8.4.2 of PR.25 Device, Equipment, and Equipment Management Procedure are met must be retained. The inspection/surveillance results carried out are published with the relevant Inspection Report. During the inspection process to be carried out, the necessary occupational safety measures should be taken by the customer and the Technical Expert should be informed. The hazards and precautions to be taken in TL.08 Occupational Health and Safety Instructions must be taken into consideration by the Technical Expert. Findings related to the situations that do not meet the regulation and standard requirements determined during the inspection are evaluated as a nonconformity.

The maximum inspection activities that can be carried out within a calendar (work) day are determined as specified in article 4.2 of the R.50.01 Guideline on Accreditation of Inspection Bodies published by TURKAK.

However, the inspections carried out according to this instruction cannot be determined with a definite period due to the following reasons.

- The duration of an inspection depends on the firm's well-equipped, qualified, skilled, and competent personnel, the firm's infrastructure (such as the technology it has, the usage status of the machines to do the job).
- The activities to be checked for each module differ significantly depending on the product types to be certified.
- Even when the firm's infrastructure is ready for the inspection and the personnel is sufficiently experienced and knowledgeable, the inspection period may change depending on the product type due to possible problems.
- The inspection period is determined as specified in Article 8.4.1 of PR.PED.01 Application Assessment and Contract Procedure.

### **8.3.1.3 Performing Inspection**

Performing the inspection consists of the following stages:

- Opening Meeting and Pre- Inspection information
- Inspection
- Closing Meeting and Information on Findings

### **8.3.1.4. Pre-Inspection Information**

Pre-inspection briefing starts with the opening meeting held between firm officials and technical experts/experts. At the opening meeting, the topics specified in the FR.27 Opening and Closing Meeting Minutes, the purpose of the inspection, the scope, the method to be used, the confirmation of the completion of the preparations to be made before the inspection, the determination of the firm personnel to accompany the Technical Expert during the inspection, the confirmation of whether the measures related to occupational safety have been taken (The hazards and the precautions defined in the TL.08 Occupational Health and Safety Instructions should be taken into consideration by the Technical Expert) and the procedures and the FR.PED.52 Conformity Assessment Activity Plan are discussed and the audit is started after the briefing.

### **8.3.1.5 Performing Inspection According to Modules (2014/68/EU)**

#### **8.3.1.5.1. Module A2: Internal Production Controls Following Final Assessment**

If the application is within the scope of Module A2, it is verified by the Technical Expert that the product class is the highest Category II, using the Appendix III Conformity Assessment Tables of the Pressure Equipment Directive. Following the conclusion of the contract, the manufacturer is requested to send a written declaration of conformity regarding the pressure equipment in question and the technical file described below. The technical file should be prepared in such a way that conformity assessment of the pressure equipment is carried out with the requirements of the relevant Regulation.

To the extent relevant for this type of assessment, the technical file should cover the design, manufacture and operation of pressure equipment and include:

- A general description of pressure equipment
- Definitions and explanations necessary for understanding the operation of pressure equipment, schematics, conceptual design and manufacturing illustrations, diagrams of parts, sub-parts, circuits, etc.
- List of fully or partially implemented standards specified in Article 5 of the Pressure Equipment Directive and explanations of solutions adopted to meet the essential requirements of the Regulation in cases where these standards are not applied.
- Results of design calculations and inspection performed
- Test reports.
- For the content of the technical file, the FR.PED.48 Pressure Equipment Directive Technical File Content Form should also be consulted.

Following the examination of the technical file, it is determined by the Technical Expert, ex officio, whether the manufacturer has carried out the final assessment in accordance with Annex I Article 3.2. Samples of the pressure equipment are taken from the production or warehouse building to make controls, and after assessment by the Technical Expert, it is decided to have the pressure equipment fully or partially inspected or to have it done. Sample selection is done, where applicable, considering the following criteria:

- The sample is selected so that the product represents the type.
- The sample is selected to represent the production lines.
- Alternatively, in the case of a tank (including a change in welding consumables. For example, a new batch of supplies, etc.) or non-automatic welding after any readjustment, each working day, at least one tank can be selected per welder/operator.

The inspection report is signed by the technical expert and the findings are shared with the applicant. In cases where there is no nonconformity, the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report are issued by the Technical Expert. Following the issuing of the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report by the Technical Expert, the certificate of conformity is issued by the Technical Regulation Officer for the FR.PED.33 EU Certificate (Module A2).

As a result of the final assessment and examination of the samples, the findings are recorded on the FR.PED.16 2014/68/EU Pressure Equipment Directive Audit and Surveillance Report.

#### **8.3.1.5.2. Module B (Production Type): EU Type Assessment**

If the application is within the scope of Module B (Production Type), the manufacturer is requested to send the technical file described below and to prepare the sample representing the type. A "type" may cover many variants of pressure equipment, provided that the difference between the variants does not affect the level of safety. Using the harmonized standard of the product, the Technical Expert determines and notifies the manufacturer if there are other samples needed to perform the test program. The locations of the inspection and necessary tests to be carried out are decided by the Technical Expert together with the applicant.

The technical file should be prepared in such a way that the conformity of the pressure equipment with the requirements of the relevant Regulation is evaluated. To the extent relevant for this type of assessment, the technical file should cover the design, manufacture and operation of pressure equipment and include:

- A general description of pressure equipment
- Conceptual design and manufacturing illustrations, diagrams of parts, sub-parts, circuits, etc.
- Definitions and explanations necessary for understanding the specified illustrations, diagrams, and pressure equipment operation
- List of fully or partially implemented standards specified in Article 5 of the Pressure Equipment Directive and explanations of solutions adopted to meet the essential requirements of the Regulation in cases where these standards are not applied.
- Results of design calculations and inspections performed
- Test reports
- Information about the tests performed in the production
- Information on required properties or approval according to Articles 3.1.2 and 3.1.3. of Annex I.

Reviewing the technical file and verification that the type is produced in accordance with the technical file is performed by the Technical Expert. In particular, the Technical Expert performs the tasks listed below:

- Reviewing the technical file according to the design and production processes
- If the material of the pressure equipment does not comply with the relevant harmonized standard or European approval, the audit of the materials and the certificate issued by the material manufacturer according to Annex I Article 4.3.
- Approving the operation of fixed-connected parts of pressure equipment or checking that it has been previously approved in accordance with Annex I Article 3.1.2.
- Verifying that personnel who handle fixed parts of pressure equipment and perform non-destructive tests comply with Annex I, 3.1.2 or 3.1.3. or are certified.
- In cases where the standards declared in Article 5 of the Pressure Equipment Directive are not applied, performing the appropriate inspections and necessary tests to determine whether the solutions adopted by the manufacturer meet the basic requirements of the Regulation.
- If the manufacturer chooses to apply the relevant standards, perform the appropriate audits and necessary tests to determine whether they have been applied.

Inspection and test procedures are carried out within the framework of TL.PED.01 Inspection and Test Plan for Pressure Equipment and Pressure Vessels if the product in question is a pressure vessel.

#### **8.3.1.5.2.1. Design Review**

Design assessment includes checking the illustrations and calculations prepared by the firm. Controls are made in VVD software for EN 13445, ASME VIII Div.1, AD 2000 - Merkblatt, EN 13480, PD5500, EN 1591 standards. Calculations other than these standards are recorded with the notes taken with a red pen on the firm documents and the "Reviewed" stamps on the documents. The final versions of the calculations and illustrations are sent to the customer with the "Approved" stamp. In this process, for the products within the scope of PED, it is recorded and approved with the FR.PED.43 2014/68/EU Pressure Equipment Directive Type, Design, Production Control Form by the Technical Expert assigned in the design.

As a result of the inspection, the product/products to be inspected for the verification of the design are recorded with the FR.PED.16 Pressure Equipment Directive Inspection and Surveillance Report for the products within the scope of PED. If there are any nonconformities found, 90 days is given and if a follow-up inspection is decided, a follow-up inspection is performed with on-site verification. If it can be proven with photographs and/or documents that the nonconformities have been corrected, the applicant is requested to submit it to the SZUTEST office by proving it with photographs and/or documents after making the necessary corrections. If the correction of the nonconformities cannot be proven with photographs and/or documents, a re-inspection is planned after the necessary corrections are made. The time given for the elimination of nonconformities can be increased with the approval of the Technical Regulatory Officer if there is force majeure and cannot exceed 120 days. If the nonconformities cannot be corrected within this period, the report is issued as negative and the process is completed.

The follow-up of whether the nonconformities are resolved is carried out by the Technical Expert. As a result of closing the nonconformities, the Technical Expert checks the products within the scope of PED with the FR.PED.16 Pressure Equipment Directive Inspection and Surveillance Report and FR.PED.48 Pressure Equipment Directive Technical File Content Form and submits the finished Technical File together with the proofs about the closure of the nonconformities to the Technical Regulatory Officer. If any deficiencies are detected after the control of the Technical Regulatory Officer, the Technical Expert is informed by the Technical Regulatory Officer to correct them.

In cases where there is no nonconformity, the inspection report and technical file checklists are approved and published by the Technical Expert.

If the type is determined to comply with the relevant provisions of the Directive, FR.PED.33 EU Type Examination Certificate (Production Type) is issued to the applicant for the products within the scope of PED. The ten-year renewable certificate contains the following information:

- SZUTEST name and address
- Manufacturer's name and address
- Certificate date
- Conformity assessment results
- Scope of certification
- Data necessary for the determination of the approved type
- Any other information required by the certification program.

#### **8.3.1.5.3. Module B (Design Type): EU Design Review**

If the application is within the scope of Module B (Design Type), the manufacturer is requested to send the technical file described below. The experimental design method given in Article 2.2.4 of Annex I of the Pressure Equipment Directive cannot be used in the context of this module.

The technical file is prepared in such a way that the conformity of the pressure equipment with the requirements of the relevant Directive is evaluated. To the extent relevant for this type of assessment, the technical file should cover the design, manufacture and operation of pressure equipment and should include:

- A general description of pressure equipment
- Conceptual design and manufacturing illustrations, diagrams of parts, sub-parts, circuits, etc.
- Definitions and explanations necessary for understanding the specified illustrations, diagrams, and operation of pressure equipment
- List of fully or partially implemented standards set out in Article 5 of the Pressure Equipment Directive and explanations of solutions adopted to meet the essential requirements of the Directive in cases where these standards are not implemented.
- Necessary supporting evidence regarding the suitability of design solutions, except where the standards set out in Article 5 of the Pressure Equipment Directive are not fully implemented. This supporting evidence should include the results of tests performed by or on behalf of the manufacturer in appropriate laboratories.
- Results of design calculations and inspections
- Information about the tests performed in the production
- Information on required properties or approval according to 3.1.2 and 3.1.3 of Annex I.

The technical file is reviewed by the Technical Expert. In particular, the Technical Expert performs the following tasks:

- If the material of the pressure equipment does not comply with the relevant harmonized standard or European approval, to inspect the materials and to check the certificate issued by the material manufacturer according to Annex I Article 4.3.
- Approving the operation of fixed-connected parts of pressure equipment or checking that it has been previously approved in accordance with Annex I Clause 3.1.2.
- Verify that personnel who handle fixed parts of pressure equipment and perform non-destructive tests comply with Annex I Article 3.1.2 or 3.1.3 or are certified.
- In cases where the standards declared in Article 5 of the Pressure Equipment Directive are not applied, to carry out or have the appropriate inspections and necessary tests carried out in order to determine whether the solutions adopted by the manufacturer meet the basic requirements of the Regulation.
- If the manufacturer chooses to apply the relevant standards, to perform or have the appropriate audits and necessary tests carried out to determine whether they have actually been applied.

#### **8.3.1.5.3.1. Design Review**

Design assessment includes checking the illustrations and calculations prepared by the firm. Controls are made in VVD software for EN 13445, ASME VIII Div.1, AD 2000 - Merkblatt, EN 13480, PD5500, EN 1591 standards. Calculations other than these standards are recorded with the notes taken in red on the firm documents and the "Reviewed" stamps on the documents. In this process for the PED, FR.PED.43 2014/68/EU Pressure Equipment Directive Type, Design, Production Control Form is filled by the Technical Expert assigned in the Design and submitted to TDS for examination. After the examination is completed, the relevant forms and inspection report are signed by the Technical Expert and the findings are shared with the applicant. The final versions of the accounts and illustrations are sent to the customer with the "Approved" stamp.

A period of 90 days is given to close the nonconformities found as a result of the inspection, and if the follow-up inspection is decided, a follow-up audit is performed with on-site verification. If it can be proven with photographs and/or documents that the nonconformities have been corrected, the applicant is requested to submit it to the SZUTEST office by proving it with photographs and/or documents after making the necessary corrections. If the correction of the nonconformities cannot be proven with photographs and/or documents, a re-inspection is planned after the necessary corrections are made. The time given for the elimination of nonconformities can be increased with the approval of the Technical Regulatory Officer if there is force majeure and cannot exceed 120 days. If the nonconformities cannot be corrected within this period, the report is issued as negative and the process is completed.

The follow-up of whether the nonconformities are resolved is carried out by the Technical Expert. As a result of closing the nonconformities, the Technical Expert checks the products within the scope of PED with the FR.PED.16 Pressure Equipment Directive Inspection and Surveillance Report and FR.PED.48 Pressure Equipment Directive Technical File Content Form and submits the finished Technical File together with the proofs about the closure of the nonconformities to the Technical Regulatory Officer. If any deficiencies are detected after the control of the Technical Regulatory Officer, the Technical Expert is informed by the Technical Regulatory Officer to correct them.

In cases where there is no nonconformity, the inspection report and technical file checklists are approved and published by the Technical Expert.

If it is determined that the design complies with the relevant provisions of the Regulation, FR.PED.34 EU Type Examination Certificate (Design Type) is issued to the applicant for the products within the scope of PED. The ten-year renewable certificate contains the following information:

- SZUTEST name and address
- Manufacturer's name and address
- Certificate date
- Conformity assessment results
- Scope of certification
- Data necessary for the determination of the approved type
- Any other information required by the certification program.

#### **8.3.1.5.4. Module C2: Conformity to Type**

If the application is covered by Module C2, a written declaration of conformity for the pressure equipment in question and an EU Type Examination Certificate are requested from the manufacturer. With the unexpected visit by the Technical Expert, it is determined whether the manufacturer has carried out the final assessment in accordance with Annex I Article 3.2. Samples of the pressure equipment are taken from the production or warehouse building to make controls, and after assessment by the Technical Expert, it is decided to have the pressure equipment fully or partially inspected or to have it done. Sample selection is done, where applicable, considering the following criteria:

- The sample is selected so that the product represents the type.
- The sample is selected to represent the production lines.
- Alternatively, in the case of a tank (including a change in welding consumables. For example, a new batch of supplies, etc.) or non-automatic welding after any readjustment, each working day, at least one tank can be selected per welder/operator.

As a result of the final assessment and examination of the samples, the findings are recorded on the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report. The audit report is signed by the technical expert and the findings are shared with the applicant.

A period of 90 days is given to close the nonconformities found as a result of the inspection, and if the follow-up inspection is decided, a follow-up inspection is performed with on-site verification. If it can be proven with photographs and/or documents that the nonconformities have been corrected, the applicant is requested to submit it to the SZUTEST office by proving it with photographs and/or documents after making the necessary corrections. If the correction of the nonconformities cannot be proven with photographs and/or documents, a re-inspection is planned after the necessary corrections are made. The time given for the elimination of nonconformities can be increased with the approval of the Technical Regulatory Officer if there is force majeure and cannot exceed 120 days. If the nonconformities cannot be corrected within this period, the report is issued as negative and the process is completed.

The follow-up of whether the nonconformities are corrected is carried out by the Technical Expert. As a result of closing the nonconformities, the Technical Expert submits the audit report to the Technical Regulation Officer, together with the proofs regarding the closure of the nonconformities. If any deficiencies are detected after the control of the Technical Regulatory Officer, the Technical Expert is informed by the Technical Regulatory Officer to correct them. In cases where there is no nonconformity, the inspection report is approved and published by the Technical Expert.

If it is determined that it complies with the relevant provisions of the Directive, FR.PED.35 EU Certificate (Module C2) is issued to the applicant for the products within the scope of PED. The ten-year renewable certificate contains the following information:

- SZUTEST name and address
- Manufacturer's name and address
- Certificate date
- Conformity assessment results
- Scope of certification
- Data necessary for the determination of the approved type
- Any other information required by the certification program.

#### **8.3.1.5.5. Module F: Product Verification**

If the application is under Module F, a written declaration of conformity for the pressure equipment in question and an EU Type Examination Certificate or an EU Design Inspection Certificate are requested from the manufacturer. The technical expert inspects each of the pressure equipment separately, records it on the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report and confirms that they comply with the type defined on the Type Examination Certificate (Design Type/Production Type). perform the tests and inspections specified in the relevant harmonized standards, or their equivalent, to verify that they fulfill the specified requirements in the Directive.

In particular, the Technical Expert performs the following tasks:

#### **8.3.1.5.6. Module G: EU Unit Verification**

If the application is within the scope of Module G, the manufacturer is requested to send the technical file described below:

The technical file is prepared in such a way that the conformity of the pressure equipment with the requirements of the relevant Regulation is evaluated. To the extent relevant for this type of assessment, the technical file should cover the design, manufacture and operation of pressure equipment and should include:

- A general description of pressure equipment
- Conceptual design and manufacturing illustrations, diagrams of parts, sub-parts, circuits, etc.
- Definitions and explanations necessary for understanding the specified illustrations, diagrams, and operation of pressure equipment
- List of fully or partially implemented standards specified in Article 5 of the Pressure Equipment Directive and explanations of solutions adopted to meet the essential requirements of the Regulation in cases where these standards are not applied.
- Results of design calculations and inspections performed
- Test reports.
- Appropriate details on qualifications and approvals of relevant personnel, approval of production and testing processes in accordance with Annex I Article 3.1.2 and 3.1.3.

The Technical Expert examines the design and construction of the pressure equipment and performs the tests specified in the harmonized standard or equivalent tests and inspections to ensure that it fulfills the requirements specified in the regulation. In particular, the Technical Expert performs the following tasks:

- Reviewing the technical file according to the design and production processes
- In case the material of the pressure equipment does not comply with the relevant harmonized standard or European approval, to inspect the materials and to check the certificate issued by the material manufacturer according to Article 4.3 of the Annex.
- Approving the operation of fixed-connected parts of pressure equipment or checking that it has been previously approved in accordance with Annex I Article 3.1.2.
- Verify that personnel who handle fixed parts of pressure equipment and perform non-destructive tests comply with Annex I Articles 3.1.2 or 3.1.3 or are certified.
- To carry out the final audits reported in Annex I Article 3.2.1, to carry out or have the durability tests reported in Annex I Article 3.2.2, to inspect the safety equipment, if any

Inspection and test procedures are carried out within the framework of TL.PED.01 Inspection and Test Plan for Pressure Equipment and Pressure Vessels, if the product in question is a Pressure Vessel.

-The design examination includes checking the illustrations and calculations prepared by the firm. These controls are recorded with the red pencil notes on the firm documents and the "Approved" and "Reviewed" stamps on the documents.

In this process, FR.PED.43 2014/68/EU Pressure Equipment Directive Type, Design, Production Control Form is used. The checklists are used in conjunction with the relevant standard. The standards, which are within the scope of the activity but for which a specific checklist has not been prepared, will be prepared and used based on the application in that field.



Inspection and test procedures are carried out within the framework of TL.PED.01 Inspection and Test Plan for Pressure Equipment and Pressure Vessels if the product in question is a Pressure Vessel. As a result of the inspection of the samples, the findings are recorded in the inspection report. The inspection report is signed by the technical expert and the findings are shared with the applicant. In cases where there is no nonconformity, the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report are published by the Technical Expert. After the approval of FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report, FR.PED.37 EU Certificate (Module G) is issued by the Technical Regulation Officer.

### **8.3.1.6. Performing Inspection According to Modules (2014/29/EU)**

#### **8.3.1.6.1. Module B: EU Type Examination**

The EU Type Examination is part of the conformity assessment procedure, in which the technical design of the vessel is examined and it is verified and certified through checklists or regulation essential safety requirements that the technical design of the vessel fulfills the requirements of this Regulation applied to the vessel. The EU Type Examination will be carried out in accordance with Article 13 of the regulation by one of the following methods:

- Assessment of the adequacy of the technical design of the vessel (production type) through examination of the technical documentation and supporting evidence mentioned below, plus an examination of a prototype of the entire vessel representative of the anticipated production.
- Assessment of the adequacy of the technical design of the vessel (design type) by reviewing the technical documentation and supporting evidence mentioned below without a prototype vessel examination.

The manufacturer will apply for an EU Type Examination to a single notified body that has been chosen.

The application will include:

- (a) The name and address of the manufacturer and, if the application is made by an authorized representative, the name and address of the authorized representative
- (b) Written declaration that the same application has not been made to any other notified body
- (c) The technical documentation shall make it possible to assess the compliance of the vessel with the relevant requirements of this Regulation and shall include an adequate analysis and assessment of the risks. Relevant requirements will be specified in the technical documentation and will cover the design, manufacture and operation of the vessel in relation to assessment. The technical documentation shall include at least the following elements, where possible:

- General description of the vessel
- Conceptual design and production illustrations and component diagrams, etc.
- Illustrations and diagrams as well as explanations needed to understand the operation of the vessel
- Descriptions of solutions implemented to meet the essential safety requirements of the regulation, including a list of harmonized standards whose references are published in the Official Journal of the European Union and applied in part or in full, and a list of other relevant technical specifications applied where these harmonized standards are not applied. In the case of partial application of harmonized standards, the technical documentation should specify which parts are applied.
- The results of the design calculations made, the examination performed, etc.
- Test reports
- Instructions and safety information referred to in Annex III, Article 2
- A document describing the following:
  - Selected materials,
  - Selected welding methods,
  - Selected controls,
  - Any information about vessel design

(d) Where appropriate, prototype vessels represent the anticipated production. SZUTEST may request additional prototype vessels if needed for the execution of the test program.

(e) Supporting evidence for the adequacy of the technical design solution. This supporting evidence includes any documents that have been used, particularly where harmonized standards have not been fully implemented. If necessary, the supporting evidence should also include the results of tests performed by the manufacturer's relevant laboratory or by another test laboratory on its behalf and under its responsibility, in accordance with other relevant technical specifications.

When examining a prototype vessel, the technical documentation should also include:

- Documentation regarding welding processes and appropriate qualifications of welders or welding operators,
- Inspection label of materials used in the manufacture of parts or components that contribute to the resistance of the vessel,
- A report of the examinations and tests performed or a description of the suggested controls.

For the vessel:

- Technical documentation and supporting evidence are reviewed to assess the adequacy of the technical design of the vessel.

For prototype vessel(s):

- It is verified that the prototype vessel(s) are produced in accordance with the technical documentation, can be used safely under the intended operating conditions, and elements designed according to the relevant harmonized standard provisions as well as those designed according to other relevant technical specifications are determined.

To check whether the methods chosen by the manufacturer to implement the solutions in the relevant harmonized standards are applied correctly, the relevant audits and tests are carried out. In cases where the solutions in the relevant harmonized standards are not applied, the relevant inspections and tests are carried out or carried out to control the solutions implemented by the manufacturer by applying other relevant technical specifications to fulfill the basic safety requirements of this Regulation. The product to be manufactured is determined by stamping SZUTEST on the technical illustrations (picture) and diagrams. These documents are valid during SZUTEST controls. The location where the inspection and tests will be carried out must be agreed upon with the manufacturer.

SZUTEST issues an assessment report that records the activities carried out in accordance with the above-mentioned activities and their results. Without prejudice to its obligations to the certification bodies, SZUTEST only publishes the content of this report in part or in whole after agreement with the manufacturer. In cases where the type complies with the requirements of this Regulation, SZUTEST issues the FR.SPV.09 EU Type Examination Certificate for the manufacturer. This certificate contains the following information:

- SZUTEST name and address
- Manufacturer's name and address
- Certificate date
- Conformity assessment results
- Scope of certification
- Data necessary for the determination of the approved type
- Any other information required by the certification program.

The EU Type Examination Certificate may contain one or more annexes. The EU Type Examination Certificate and its annexes contain all relevant information that allows the compatibility of the manufactured vessels with the type under examination to be evaluated and allows audit during use. It shall also specify any conditions to which the regulation may be subject, accompanied by the descriptions and drawings necessary to determine the approved type. In cases where the type does not fulfill the relevant requirements of this Regulation, SZUTEST does not accept the issuance of the EU Type Examination Certificate and informs the applicant by stating the detailed reasons for the rejection. SZUTEST should be aware of any changes to the latest generally accepted version, which indicates that the approved type may no longer comply with the relevant requirements of this Regulation and decides whether these changes require additional research. If required, SZUTEST informs the manufacturer on this matter.

### **8.3.1.6.2. Module C1 - Type Conformity Subject to Internal Production Inspection Plus Supervised Vessel Test**

Subject to internal production inspection plus supervised vessel testing, type conformity is a part of the conformity assessment procedure in which the manufacturer ensures and declares that he fulfills the obligations set out below, and that, under his sole responsibility, the relevant vessels comply with the type described in the EU-Type Examination Certificate and fulfill the regulatory requirements applicable to these vessels.

Production: The manufacturer shall take all necessary measures to ensure that the production process and the follow-up of the produced vessels comply with the type described in the EU-type examination document and the regulatory requirements applicable to these vessels.

Before starting production, the manufacturer presents all the necessary information, in particular, the following.

Technical documentation should also include:

- Documentation regarding welding processes and appropriate qualifications of welders or welding operators,
- Inspection label of materials used in the manufacture of parts or components that contribute to the resistance of the vessel,
- Report of the examinations and tests performed,
- Inspection document describing the appropriate examinations and tests to be carried out during production, along with the frequency of their performance and the relevant procedures,
- EU type examination certificate.

#### **8.3.1.6.2.1. Vessel Controls**

For each vessel produced, SZUTEST inspection personnel conducts the appropriate examinations and tests in order to verify the conformity of the vessel with the type described in the EU Type Examination Certificate and the relevant requirements of this regulation, in accordance with the following points:

- (a) The producer presents his vessels in uniform batches and takes all necessary measures to ensure the uniformity of the production process for each batch produced.
- (b) When a lot is examined, the notified body ensures that the vessels are manufactured and inspected in accordance with the technical documentation and performs a Ph hydrostatic test or equivalent effect pneumatic test at a pressure equal to 1.5 times the design pressure to check the strength of the vessel on each vessel in the lot. Pneumatic testing is subject to acceptance of test safety procedures by the EU Member State where testing is performed.
- (c) Furthermore, the SZUTEST technical expert performs tests on samples taken from a representative production test piece or vessel, at the manufacturer's choice, to examine the weld quality. The tests are performed on longitudinal welds. However, where different welding techniques are used for longitudinal and circumferential welds, the tests are also repeated on circumferential welds.

For vessels subject to the experimental method referred to in Article 2.1.2 of Annex I of the Regulation, instead of these tests, a hydrostatic test is performed on five randomly selected vessels from each group to check whether they comply with the basic safety requirements set out in Article 2.1.2 of Annex I of the Regulation. In the case of accepted batches, the SZUTEST Technical Expert adds or adds the identification number to each vessel and prepares a written certificate of conformity regarding the tests performed. The nameplate of the vessels checked and accepted by SZUTEST is stamped with the SZUTEST logo. All vessels in the lot may be placed on the market, except for vessels that fail the hydrostatic or pneumatic test. In case of rejection of the lot, SZUTEST takes measures to prevent the relevant lot from being placed on the market. If lots are rejected frequently, SZUTEST may suspend statistical verification. In line with the request of the relevant authorities, the manufacturer can submit the conformity certificates given by SZUTEST, which are mentioned in 8.3.1.6.1. Module B: EU Type Examination article (e). SZUTEST sends a copy of the audit report to the approved EU Member State and, upon request, to other notified bodies, the other EU Member States and the Commission.

Inspection and test procedures are carried out within the framework of TL.PED.01 Inspection and Test Plan for Pressure Equipment and Pressure Vessels if the product in question is a Pressure Vessel. As a result of the examination carried out on the samples, the findings are recorded in the inspection report. The inspection report is signed by the technical expert and the findings are shared with the applicant. In case of absence of nonconformities, FR.SPV.02 2014/29/EU Simple Pressure Equipment Directive Inspection and Surveillance Report are published by the Technical Expert. Following the publication of the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report, the certificate of conformity FR.SPV.12 EU Certificate (Module C1) is issued by the Technical Regulation Officer.

### **8.3.1.6.3. Module C2 - Type Conformity Subject to Internal Production Inspection Plus Supervised Vessel Test at Random Time Periods**

Type conformity, subject to internal production inspection plus supervised vessel testing performed at random intervals, is part of the conformity assessment procedure in which the manufacturer ensures and declares that he has fulfilled the obligations set out below and, under his sole responsibility, the relevant vessels comply with the type described in the Type Examination Certificate and fulfill the requirements of the Regulation applied to these vessels. The manufacturer takes all necessary measures to ensure that the production process and the follow-up of the produced vessels comply with the type described in the Type Examination Certificate and with the regulatory requirements applied to these vessels.

Before starting production, the manufacturer provides all the necessary information described below, in particular, the following;

- Technical documentation, which will include the following:
- Documentation on welding processes and appropriate qualifications of welders or welding operators
- Inspection label of materials used in the manufacture of parts or components that contribute to the strength of the vessel
- Report of the examinations and tests carried out
- Type Examination Certificate
- A document describing the production processes and all predetermined systematic measures taken to ensure the conformity of the vessels with the type described in the Type Examination Certificate.

SZUTEST Technical Expert examines these documents to certify their conformity with the Type Examination Certificate before the start date of any production. These documents are as follows.

- i. Description of production methods and controls on the conformity of the manufacture of vessels
- ii. An audit document describing the appropriate examinations and tests to be carried out during production, along with the frequency of their performance and associated procedures.
- iii. Commitment to carry out inspections and tests according to the inspection document and to have a hydrostatic test on each manufactured vessel or pneumatic test at test pressure equal to 1.5 times the design pressure, subject to agreement of the EU Member State. These examinations and tests will be carried out under the responsibility of qualified personnel independent of the production personnel and a corresponding report should be prepared.
- iv. The addresses of the production and storage locations and the date of the start of production

#### **8.3.1.6.3.1. Vessel Controls**

The SZUTEST Technical Expert ensures that vessel checks are carried out on random samples and at random time intervals determined by him in order to verify the quality of the internal controls on the vessel, taking into account the technological complexity of the vessel and the production amount. A sufficient number of samples taken from the final vessels are examined by the notified body before the vessel is placed on the market. The relevant tests specified by the relevant parts of the harmonized standards and/or the equivalent tests specified in the relevant technical specifications are also carried out in order to check the conformity of the vessel with the type described in the Type Examination Certificate and the relevant requirements of this regulation.

The SZUTEST Technical Expert also ensures the control of the vessels produced in accordance with 8.3.1.6.2.1. Vessel Controls article (c). The nameplate of the vessels checked and accepted by SZUTEST is stamped with the SZUTEST logo. In cases where a vessel does not comply with the acceptable quality level, SZUTEST takes the relevant measures. It is applied according to the sampling instruction to determine whether the manufacturing process of the vessel is carried out within acceptable limits in order to ensure the compatibility of the vessel. SZUTEST sends a copy of the audit report to the EU Member State that has approved it and to other notified bodies, the other EU Member States and the Commission upon request.

Inspection and test procedures are carried out within the framework of TL.PED.01 Inspection and Test Plan for Pressure Equipment and Pressure Vessels if the product in question is a Pressure Vessel. As a result of the examination carried out on the samples, the findings are recorded in the inspection report. The inspection report is signed by the technical expert and the findings are shared with the applicant. In case of absence of nonconformities, FR.SPV.02 2014/29/EU Simple Pressure Equipment Directive Inspection and Surveillance Report are published by the Technical Expert. Following the publication of the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report, the certificate of conformity FR.SPV.13 EU Certificate (Module C2) is issued by the Technical Regulation Officer.

- Verify that the personnel handling the fixed connected parts of the pressure equipment and performing the non-destructive tests comply with Annex I, 3.1.2 or 3.1.3 or are certified.
- To verify the certificate prepared by the material manufacturer in accordance with Annex I Article 4.3,
- To carry out or have the final inspection and durability test performed as stated in Annex I Article 3.2 and to inspect the safety equipment, if any,

Inspection and test procedures are carried out within the framework of TL.PED.01 Inspection and Test Plan for Pressure Equipment and Pressure Vessels if the product in question is a Pressure Vessel. As a result of the audit made on the samples, the findings are recorded in the audit report. The inspection report is signed by the technical expert and the findings are shared with the applicant. In cases where there is no nonconformity, the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report are approved and published by the Technical Expert. After the approval of the FR.PED.16 2014/68/EU Pressure Equipment Directive Inspection and Surveillance Report, FR.PED.36 EU Certificate (Module F) is issued by the Technical Regulation Officer as a certificate of conformity FR.SPV.13 EU Certificate (Module C2) is issued by the Technical Regulation Officer.

#### **8.3.1.6.4. MODULE C - Type Compliance Subject to Internal Production Control**

Subject to internal production inspection, type conformity is part of the conformity assessment procedure in which the manufacturer fulfills the obligations defined below and ensures and declares that the relevant vessels comply with the type described in the EU type examination document and fulfill the regulatory requirements applicable to these vessels. The manufacturer takes all necessary measures to ensure that the production process and the follow-up of the produced vessels comply with the approved type described in the EU type examination document and the regulatory requirements applied to these vessels.

Before starting production, the manufacturer provides SZUTEST, which has issued the EU Type Examination Certificate, with all the necessary information, in particular:

- (a) Documentation relating to welding processes and the appropriate qualifications of welders or welding operators
- (b) Inspection label of materials used in the manufacture of parts or components that contribute to the resistance of the vessel
- (c) Report of examination and tests performed
- (d) A document describing the production processes and all the predetermined systematic measures taken to ensure the conformity of the vessels with the type described in the EU Type Examination Certificate.

This document includes:

- i. Description of production methods and controls on the conformity of the manufacture of vessels
- ii. An audit document describing the appropriate examinations and tests to be carried out during production, along with the frequency of their performance and associated procedures.
- iii. Commitment to carry out examinations and tests according to the inspection document and to have a hydrostatic test on each manufactured vessel or pneumatic test at test pressure equal to 1.5 times the design pressure, subject to agreement of the EU Member State. These examinations and tests are

carried out under the responsibility of qualified personnel independent of the production personnel and a report is prepared about them.  
iv. The addresses of the production and storage locations and the date of the start of production

SZUTEST will examine these documents to certify their compliance with the EU Type Examination Certificate before the start date of any production. FR.SPV.02 2014/29/EU Simple Pressure Equipment Regulation Inspection and Surveillance Report is published by the Technical Expert in cases where there is no nonconformity as a result of the examination. Following the publication of the FR.PED.16 2014/68/EU Pressure Equipment Regulation Inspection and Inspection Report, the certificate of conformity is issued by the FR.SPV.10 EU Certificate (Module C) Technical Regulation Officer.

### **8.3.1.7. Information on Findings and Assessment of Nonconformities (2014/68/EU and 2014/29/EU)**

The findings regarding the situations that do not meet the regulations and standard requirements determined during the inspection are evaluated as nonconformity and the customer is informed. Nonconformities are recorded in the FR.29 Nonconformity Report. As a result of the inspection, the nonconformities are approved by the person authorized to represent the customer firm. Nonconformities hinder certification. If the nonconformity is not corrected within 90 days, a certification or reporting decision cannot be made. The time given for the elimination of nonconformities can be increased with the approval of the Technical Regulatory Officer if there is force majeure and cannot exceed 120 days.

After the nonconformities are eliminated, the whole or part of the inspection is repeated depending on the nonconformities requiring on-site examination, and if no finding is detected, a certification decision is made by reporting.

### **8.3.2 Operations Performed According to Quality Management System Based Modules (Module E, E1, D, D1, H, H1)**

#### **8.3.2.1. Review of the Technical File**

The technical file submitted to SZUTEST after signing the contract and the content of which is stated below is examined by the Technical Expert, and the results of the examination are recorded with the FR.PED.05 Pre-Inspection and Audit Assessment Form. **In Module H Certification audits, this control is carried out in the Stage-1 audit.**

#### **File Content**

The technical file is prepared in such a way as to demonstrate the compliance of the pressure equipment with the requirements of the regulation. The technical file should cover, as far as possible, the design, production, and operation of pressure equipment for this type of assessment and should include:

- A general description of the type
- Conceptual design and production illustrations, diagrams of parts, sub-parts, circuits, etc.
- Definitions and explanations necessary for understanding the mentioned illustrations, diagrams and pressure equipment operation
- List of fully or partially implemented standards specified in Article 5 of the Pressure Equipment Directive and, where these standards are not applied, explanations of the solutions adopted to meet the essential requirements of the Regulation
- Checking the implementation of Annex-1 Basic Requirements of the Regulation
- Control of material certificates specified in Annex-1 Basic Requirements of the Regulation, Chapter 4. If a PMA is required and a pre-approved PMA is available, its compliance must be checked. Relevant PMA documents must be approved by the TE.
- Results of design calculations and inspections
- Test reports. (These tests should be done in a laboratory with a recognizable accreditation, if the firm performs the tests in its laboratory, it must be approved by the technical expert that the firm's laboratory meets the ISO/IEC 17025 accreditation requirements)
- Information about the tests performed in the production
- Information on the required properties or approval in accordance with 3.1.2 and 3.1.3 of Annex I.
- Regarding the content of the Technical File, the FR.PED.48 Pressure Equipment Directive Technical File Content Form document should be consulted.

Technical File review is recorded by the Technical Expert with the FR.PED.48 Pressure Equipment Directive Technical File Content Form.

#### **8.3.2.2. Assignment of Audit Team and Planning of Audit**

The appropriate audit team is determined by the Technical Regulation Officer through the FR.PED.08 Pressure Equipment Directive Auditor Pool and the appointment is registered with the FR.PED.64 Audit Team Certification Committee Assigning. The FR.PED.52 Conformity Assessment Action Plan and the resumes of the personnel in the team (if requested) are sent to the firm at least 3 days before the audit. The approval of the audit team is requested from the firm, and if approval is not given, the firm is requested to state its reason. The Technical Regulatory Officer may change the audit team, taking into account the reasons. The audit team should definitely be replaced when there is a violation of the provisions of the Commitment to Confidentiality and Impartiality. The determination of the audit team for the companies for which the audit decision is taken is made by the Technical Regulation Officer through Ontek System. **In Module H services, the audit duration is determined by taking into account the article 8.4.1.3 Determination of Audit Periods of the PR.PED.01 Application Evaluation and Contract Procedure for man/day calculation.**

The following points are taken into account in the selection of a Technical Expert;

- Audit objectives, scope, criteria and determined audit time,
- The competence of the Technical Expert required to achieve the audit objectives,
- Certification requirements (legal or contractual terms),
- language and culture,
- Whether the audit team has previously audited the client's management system,

Inspections may also be accompanied by observers. Observers may be the person observing a member of the audit team, or they may be an official of the accreditation agency. The client and audit team members are informed about the participation of the observers in the audit and the client's approval is obtained. Observers do not interfere with the audit.

#### **8.3.2.3. Performing the Audit**

Performing the audit consists of the following stages:

- Opening meeting

- Audit
- Audit Team meeting and reporting
- Closing meeting

#### **8.3.2.4. Opening Meeting**

Audits carried out in the field start with the opening meeting held under the chairmanship of the audit team leader, attended by the firm officials and the audit team. At the opening meeting, the subjects specified in the FR.27 Opening and Closing Meeting Minutes, the purpose and scope of the audit, the methods and procedures to be used and the FR.PED.52 Conformity Assessment Activity Plan are discussed. If deemed necessary by the team leader, a quick field tour can be held with the representatives of the organization in order to collect preliminary information from the field and a preliminary situation assessment for the site, process and products to be audited.

#### **8.3.2.5. Stage 1 Audit**

Stage 1 audit is the audit performed to check whether the company, whose initial certification and re-certification will be carried out, is ready for Stage 2 audit, for the review of the documents of the organization.

**Stage 1 audit must be carried out at the customer's workplace since the products within the scope of Module H are considered in the high-risk product category.**

The inspection team records the Stage 1 inspection results in the FR.PED.05 Inspection and Pre-Inspection Evaluation Form. If nonconformities are detected in the Stage 1 audit, a Stage 2 audit is planned after confirming that the detected nonconformities are closed. While proof of closure is requested from the company for major nonconformities, the action plan is sent for minor nonconformities and the actions taken regarding the nonconformities are verified by the audit team in the stage 2 audit.

There can be a maximum of 6 months between Stage 1 audit and Stage 2 audit.

#### **8.3.2.6. Certification Audit-Stage 2**

The audit is carried out to meet all the departments/processes and articles specified in the FR.PED.52 Conformity Assessment Action Plan. Each Technical Expert is responsible for the inspection of the areas specified in the plan and should inform the team leader in case the inspection periods exceed the plan so that the necessary arrangements can be made. During the performance of the audit, each Technical Expert will provide information about the audit findings, recommendations and other important points, such as the names of the audited persons, the procedure article numbers regarding the findings, the name, code, identification of the samples selected during the audit, to ensure that nonconformities and observations are detected based on sufficient objective evidence and record on the FR.PED.03 Conformity Assessment Report (2014/68/EU Pressure Equipment Directive). In this way, information about audit objectives, scope and criteria is collected and verified by appropriate sampling to become audit evidence. The methods used to gather information are interviews, review of processes, practices, documents and records, observation, etc.

During the audit, the audit team evaluates the progress of the audit and exchanges information as needed. In case of findings that will cause problems in meeting the audit objectives or when an urgent and important risk (such as security) occurs, the team leader determines the appropriate action and reports this situation to the Technical Regulatory Officer and, where possible, to the customer. Reaffirmation or change of such an operating audit plan may include a change in audit objectives or audit scope or termination of the audit. The decision taken is reported to the Technical Regulation Officer by the audit team leader. When considering changes in the scope of the audit, this is agreed upon with the customer.

For Module H1 audits, pre-audit design calculations and results are recorded with FR.PED.43 2014/68/EU Pressure Equipment Directive Type, Design, Production Control Form.

#### **8.3.2.7. Audit Team Meeting**

Following the completion of the audit, the audit team reviews the audit findings at the meeting they hold among themselves, classifies the deviations from the standard conditions of the firm's quality management system, regulations and firm documentation, and records them with the FR.50 Nonconformity Report.

The audit team evaluates the findings as nonconformity and observation. Nonconformities can be evaluated in two classes as Major (Major) and Minor (Minor):

- Major Nonconformity; It is the situation where any of the standard or regulation conditions or sub-headings are not adequately defined and/or not applied systematically, which may affect the continuous implementation of the system in general and/or adversely affect the service or product offered to the customer to meet the desired conditions.
- Minor (Minor) Nonconformity; They are non-systematic deviations from regulation and standard conditions and/or firm documentation requirements that do not affect the overall system.
- Observation: Detections that cannot be directly related to the standard or customer documentation, but which may turn out to be minor if precautions are not taken, are called and specified in the audit report.

#### **8.3.2.8. Identifying Corrective Actions**

All nonconformities are recorded with the FR.29 Nonconformity Report, supported by objective evidence documented by the audit team. It is also defined which article of the standard or directive/regulation the nonconformity corresponds to. It is decided that the recorded nonconformities will be evaluated in the field or in the office, depending on their content. Follow-up audits are planned for the nonconformities that are decided to be verified in the field. For the certification decision, all non-conformances must be confirmed within 90 days. The time given for the elimination of nonconformities can be increased with the approval of the Technical Regulation Officer if there is force majeure and cannot be more than 120 days.

#### **8.3.2.9. Arrangement of the Audit Report**

After the audit is completed, the FR.PED.03 Conformity Assessment Report (2014/68/EU Pressure Equipment Directive) containing the recommendation decision on certification is prepared by the team leader together with the audit team.

#### **8.3.2.10. Informing the Firm Representative**

If the audit lasts more than one day, the firm representative is verbally informed about the findings of that day at the end of the day. The findings obtained during the audit are shared with the firm and signed by mutual agreement at the closing meeting.

In one-day audits, the findings obtained during the audit are shared with the firm and signed by mutual agreement at the closing meeting.

### 8.3.2.11. Closing meeting

After the completion of the audit, a closing meeting is held under the chairmanship of the team leader with the participation of firm representatives, where the issues specified in the FR.27 Opening and Closing Meeting Minutes are discussed. The purpose of the closing meeting is to present the audit results, including the recommendation regarding certification.

Nonconformities are negotiated with the firm to ensure that the evidence is correct and that nonconformities are understood. The report prepared for the official acceptance of the nonconformities by the firm is submitted to the approval of the firm representative by the team leader. Following the presentation of the nonconformities to the firm representative, the FR.29 Nonconformity Form is signed by the firm representative as confirmation of the firm's acceptance of the determinations. The team leader leaves a copy of the FR.29 Nonconformity Report to the firm and gives the necessary information about closing the found nonconformities. It is stated that the corrective action plans should be forwarded to the team leader within 10 days. The audit team can in no way make any promises or commitments regarding the document issuance date.

### 8.3.2.12. Unannounced / Unexpected Visits

SZUTEST may make unexpected visits to the manufacturing or assembly site and accompany sampling and/or final inspection, within the framework of specified quality assurance procedures. During such inspections, SZUTEST may, if necessary, carry out or have tests carried out to check the proper functioning of the quality assurance system and the product. It provides the company with the inspection report and, if an experiment has been carried out, the test report. The number of unexpected visits must be at least 2 for products in categories III and IV in the first year of production (annual surveillance inspection is also included in this number). This is not an obligation for products with a lower category group but certified from a higher category, and the frequency of visits is determined based on the directive articles.

The need and frequency of inspections are determined by the following factors.

1. Results of previous inspection visits: If a follow-up inspection was carried out or if more than 5 major nonconformities were detected in the previous inspection, an ex officio inspection is carried out at least once until the next surveillance inspection.
2. The need to continue corrective action: In case of corrective actions, the results of which cannot be seen before 6 months, an ex officio inspection is carried out at least once until the next surveillance inspection.
3. Where applicable, special conditions associated with the approval of the system: In case of significant changes regarding the structure of the quality assurance system (for example, change of management, change of all responsible persons in the quality assurance system, etc.), an ex officio audit is carried out at least once until the next surveillance audit.
4. Significant changes in manufacturing organization, policy and technique: In case of changes in the manufacturing processes and methods of the product, at least one ex officio audit is carried out until the next surveillance audit.

If there is less than 1 month between the periodic surveillance time and the need for ex officio inspection, periodic surveillance and ex officio inspection are combined and the surveillance inspection is carried out as follows.

Inspections are reported to the organization at most 1 week before the inspection. The planning officer forms the audit team, as in the initial certification.

Technical Expert FR.PED.52 prepares the Audit Plan. **If the company does not accept the audit, its certificate is suspended by the decision of the Technical Regulation Officer and the situation is notified to the company in writing.**

The scope of audit consists of product tests and experiments, taking into account the factors that create the need for audit.

The results of the audit are recorded in the FR.PED.03 Audit Report.

The certificate may be suspended or canceled in cases where products are found to be non-conforming or the operation of the quality system does not meet the requirements of the regulation. This situation is reported to the ministry.

### 8.3.2.13. Surveillance Audits

- These are the periodic audits carried out by SZUTEST to verify that the firm it has certified continues to comply with the certification requirements. Surveillance audits are carried out in periods of maximum of 12 months, with reference to the last day of the certification audit date. If the first surveillance audit cannot be made within 12 months from the last day of the certification (field audit) audit, the firm's certificate is suspended by the Technical Regulation Officer as of the expiry of the 12-month period. **Surveillance audits are tracked periodically under the "Surveillances" module in the APP.SZUTEST software. The Planning Coordinator contacts companies whose surveillance audit deadline is approaching at least 2 months in advance.**

Postponement requests from companies for the second surveillance audit are evaluated by the Technical Regulation Officer, provided that the reason is stated. For temporary situations (such as Moving, Fair, Conference, Business Trip, Heavy Workload, Temporary Health Problems, Temporary Cessation of Production and Service), a maximum of three months can be postponed. Postponement request is received in writing (e-mail or fax).

**In EN ISO 17021-1 Module H comprehensive Surveillance audits, the FR.30 Document change form is shared with the customer while planning, with this form the current number of employees information is requested and the application is reviewed every year. Inspection period calculation is determined by taking into account article 8.4.1.3 Determination of Inspection Periods of PR.PED.01 Application Evaluation and Contract Procedure.**

-Surveillance audits should include the following:

The purpose of surveillance is to ensure that the manufacturer is fully meeting the obligations outside the approved quality assurance system.

-SZUTEST conducts an audit at least once a year to ensure that the firm maintains and implements the quality assurance system. As a result of the audits, an audit report is given to the firm.

SZUTEST can make unexpected inspections of the production or assembly location. During such audits, SZUTEST may, if necessary, carry out or have tests performed to control the proper functioning of the quality assurance system and the product. It gives the firm the inspection report and, if the test has been done, the test report.

- While assigning the audit team to carry out the surveillance audits, at least one person from the audit team must be appointed in the relevant product location.

- Special postponement requests from companies related to force majeure related to surveillance audits are evaluated by the Technical Regulation Officer and a maximum of 6 months can be postponed.

- Regarding surveillance audits, the firm is contacted about the surveillance audit at least 3 months in advance, taking as reference the surveillance period specified in the contract. The Technical Regulatory Officer determines the audit periods and the appropriate audit team in accordance with the audit time determination rules and submits it to the audit team with the FR.PED.64 Audit Team Certification Committee Assigning. In case of objections to the assignments made by the audit team, the reasons are noted on the audit team assignment form and a new audit team is appointed by the Technical Regulation Officer. If the

audit team does not object to the appointments, the audit team and the firm are contacted and the FR.PED.52 audit plan prepared by the audit team leader and the resumes of the personnel in the team (if requested) are sent to the firm at least 3 days before the audit. The approval of the audit team is requested from the firm, and if the approval is not given, the situation is conveyed to the Technical Regulation Officer along with the reasons. The Technical Regulatory Officer may change the audit team, taking into account the reasons.

-While planning the surveillance audit, the audit history specified in the stage 2 audit report is taken as a reference. Performing the audit, reporting, and closing and following up nonconformities are performed as in the certification audit.

- On-site verification of nonconformities that were detected in the previous audit and closed without on-site verification, control of CE marking, trademark, and certificate use, is carried out during the surveillance audit. If a nonconformity is found as a result of on-site verification, it is evaluated as a major nonconformity in the nonconformity report by the audit team and the firm is left to follow-up audit regarding the nonconformity.

- The final decision regarding the maintenance of the certificate belongs to the certification committee, as in the certification audit. In case the nonconformities cannot be closed before the specified dates, the certificate of the firm is suspended with the decision of the Technical Regulation Officer. The firm is notified of the situation in writing. The continuation of the validity of the certificates of the companies that close all nonconformities before the specified dates are decided by the certification committee.

After the surveillance audit, the surveillance periods on the certificates of the companies for which the committee decides to maintain document validity are extended and the surveillance certificates are shared with the company.

#### **8.3.2.14. Recertification Audits**

- Certification renewal audit is the audit to re-certify companies when the validity period of the certificate expires. Companies are warned by the Planning Officer (e-mail or telephone) at least 3 months before the expiry of the certificate validity period and a response is requested from the firm. If the firm does not respond or does not request the continuation of the document, the document loses its validity at the end of the validity period.

- If the firm wants to be re-certified after the expiry of the document validity period, the application is considered as certification, not as re-certification.

- If the firm requests recertification, a recertification audit is carried out. A new contract is made with the firm in accordance with the pricing rules. The Conformity Assessment Application Form is filled again by the firm, the old file number of the firm is valid. Planning the recertification audit, assigning the audit team, performing the audit, reporting the audit, closing the nonconformities and making the certification decision are the same as in the certification audit.

However, provided that the re-certification activities are completed, the certification decision can be taken and the document can be activated within 6 months after the certification period expires. The valid date on the document is the re-certification date or later and the validity period is based on the previous certification cycle, otherwise the process is considered as the first certification.

- During re-certification, nonconformities and corrective actions identified in the previous audit are examined. The scope of the audit, new documents, trademark and certificate use are controlled and the procedure is done as in the surveillance audit. As a result of the audit, the assessment is made as in the certification audit.

#### **8.3.2.15. Audit Program**

The audit program recorded with the FR.PED.63 Audit Program includes the initial audit, which includes stage 1 and stage 2 audits, surveillance audits in the first and second years, and re-certification audit in the third year before the validity of the certificate. The three-year certification cycle begins with the certification or recertification decision. The size of the client organization, the scope and complexity of the management system, products and processes, as well as the results of previous audits, as well as the demonstrated level of management system efficiency, are taken into account in determining the audit program and each subsequent arrangement.

In addition, the following points are taken into account when changing or developing an audit program. In case of changes that will affect the certification process, these changes

from the company with the FR.30 Certification Change Form. According to the change, the activity to be followed by the Technical Regulation Officer is determined. Impact of changes on field audit

Depending on the situation, the audit plan can be changed depending on the following situations;

- a) The scope and complexity of the customer management system,
- b) Products and processes (including services),
- c) The size of the client organization,
- d) Areas to be inspected,
- e) The language, oral and written languages of the client organization,
- f) The conditions of the sector or regulatory bodies,
- g) The needs and expectations of the customer and their customers
- h) The number and timing of shifts,
- i) Audit time required for each audit activity,
- j) The competence of each member of the audit team;
- k) The need for inspection of temporary sites,
- l) Results of other previous audits or stage 1 audits,
- m) Results of other surveillance activities,

In the preparation of the audit program, the following sequence of activities is taken into account;

- a) Certification Audit Stage 1
- b) Certification Stage 2
- c) Surveillance Inspection
- d) Follow-up Audit (if any)
- e) Document Renewal Controls

### **8.3.3 Other Circumstances Related to the Conformity Assessment Process**

#### **8.3.3.1. Suspension of Audits/Inspections**

Suspension of the conformity assessment activity can only occur when the following conditions are met:

- If conditions during conformity assessment adversely affect or endanger the health of the inspection team.
- If serious problems that prevent the continuation of conformity assessment are detected in the application of the system and it is understood that follow-up inspection is inevitable (Under these circumstances, suspension of the conformity assessment is an exceptional situation and should be the last option.

In such cases, it is necessary to renew the conformity assessment).

- If serious problems are encountered in accessing the relevant personnel, the relevant department or the records of the work, product or service, or bribes are offered.
- In addition, if the firm requests the suspension of the conformity assessment due to firm-related reasons, it can be suspended on the condition that the conformity assessment is repeated.

When the team leader decides to suspend the conformity assessment, he/she should reach the firm representative and explain the reason. During the decision-making phase, the team leader should consult the Technical Regulatory Officer when necessary. The team leader explains the reason for suspending the conformity assessment by calling the firm's top management to a meeting. If the firm's request for certification is still valid, it is stated that a conformity assessment will be repeated later, provided that the relevant nonconformity is eliminated. All details regarding the suspension of conformity assessment should be stated in the report. The related report is sent to the firm in writing.

### 8.3.3.2. Follow-up of Detected Nonconformities

It is requested in the Nonconformity Report of the firm representative to describe the necessary action to eliminate the nonconformity and prevent its recurrence and to send it to SZUTEST within 10 working days. The team leader verifies and signs, checking that the activity specified in the form is sufficient to eliminate the nonconformity and prevent its recurrence and that it complies with the given deadlines. However, if it is understood that the activity described by the firm is not sufficient to prevent the recurrence of the nonconformity, it is returned to the firm by the team leader to be reviewed in the Nonconformity Report, without being approved by stating the reason.

Regardless of the size of the nonconformity, the maximum time allowed for the implementation of corrections and corrective actions to close all nonconformities is maximum of 90 days from the date of writing the nonconformity (it must be ensured that the period to be determined in the recertification audit is earlier than the expiry date of the certificate).

### 8.3.3.3. Closing Nonconformities with Follow-up

Follow-up is planned for nonconformities that require verification in the field. The process of assignment and planning for follow-up is carried out as in the normal conformity assessment process.

Follow-up is carried out by the Technical Expert, who acts as the Team Leader in the first assessment, whenever possible. If corrective actions are found appropriate in the follow-up audits, the certification phase is started in the certification and recertification audits, and the continuity of the certificate is ensured in the surveillance audits.

### 8.3.3.4. Unannounced Audits

SZUTEST may perform unexpected audits on the production/assembly site of the product or on the firm. (It has been seen that the English directive has taken the expression "may" in this regard.) Therefore, the necessity and frequency of these additional unannounced audits are determined based on the control system implemented by SZUTEST. In particular, the following factors are determined based on the visit control system.

\*Previous audit results,

\*The need to continue the corrective action,

\*Substantial changes in production organization, policy or technique,

\*Complaint warning letters from third parties (Customer, Public Institutions),

\*Detection of other similar factors that may affect impartiality by SZUTEST.

During these audits, SZUTEST may, if necessary, conduct or request tests to check the proper functioning of the quality assurance system and the product; it should provide the firm with the inspection report and, if the test has been carried out, the test reports.

In particular, a visit control plan is created by considering the following factors.

- category of equipment,
- the results of previous inspection visits,
- The need for corrective action,
- Special conditions in connection with the approval of the system,
- Significant changes in production organization, policy and technique.

In addition, in the case of complaints containing objective evidence against the firm, in case nonconformity is detected in the Market Surveillance and audits carried out by the Ministry, the Technical Regulation Officer may decide to carry out an audit even though it is not in the program.

While assigning the audit team to perform the audit, the Technical Regulation Officer assigns an audit team that is different from the previous audit team and capable of interpreting the subject of the complaint.

In the unannounced inspections, the question items of the FR.PED.03 Conformity Assessment Report numbered 3,12,15,17,18,19,20,25,26,29,31 are questioned.

If the firm does not accept the audit, the certificate is suspended with the decision of the Technical Regulation Officer and the firm is notified in writing. SZUTEST has stated in the contract signed before the service to the firm that it can take this decision.

If SZUTEST determines that the conditions that form the basis of the certificate it has given as a result of its audit are not present, it suspends or cancels the certificate according to the nature of the unfulfilled conditions. It provides the necessary information for market surveillance and audit to the authorized branch of the Ministry of Industry and Technology, General Directorate of Industry, and to the authorized institution performing market surveillance and audit, and to the authorized bodies of European Union member countries, if stipulated in the relevant technical regulation. If requested, it provides information about the assessment procedures to the commission.

### 8.3.3.5. Changes in Certified Products

In case of a change in the design, technical file and components of a certified product, this change should be evaluated by SZUTEST by following the steps below.

1. The customer submits the change to SZUTEST using the FR.30 Certification Change Form.
2. The change is evaluated by the Technical Regulation Officer and the necessary technical or legal documentation is requested from the firm.
3. Relevant documents sent by the customer are reviewed by the Technical Regulation Officer. The effect of changes on the essential safety requirements of the regulation is checked. Changes that may cause deviations from the conditions specified in the basic requirements are controlled by performing the necessary tests and inspections in the laboratory. The process is carried out as described in articles 8.3.1 or 8.3.2.

## 8.4 Review and Decision



It is performed according to PR.PED.04 Certification Procedure.

## 8.5 Reporting and Certification

It is performed according to PR.PED.04 Certification Procedure.

## 8.6. Remote Audit

**8.6.1.** This article is only considered within the scope of conformity assessment processes defined in 8.3.2.

Remote audit techniques cannot provide the outputs of an on-site audit in all cases. For this reason, SZUTEST's primary approach is to carry out field audits. The period between the subsequent certification/recertification dates and the audit date cannot exceed 15 months. However, if SZUTEST decides that on-site inspection is not applicable due to extraordinary events and conditions, it can use the remote audit technique to achieve the same purpose as on-site audit.

**8.6.2.** The level of application of remote audit techniques can be determined according to the structure of the organization, the level of cooperation with SZUTEST, the risk of the organization's activities, the certification experience, the complaints and objections, and the first certification and surveillance outputs if previously certified.

**8.6.3.** Remote audits cannot be performed in the first certification audit. However, it can be used as part of the initial certification audit when deemed necessary. After the extraordinary events and conditions end, field audits are carried out. In the event that extraordinary events and conditions continue, the certification process is continued until the end of the situation.

**8.6.4.** For surveillance audits, remote audit techniques may be preferred according to article 8.6.2 due to extraordinary events and conditions. Following the end of extraordinary events and conditions, field audits are carried out by the same audit team.

**8.6.5.** The audit team and the management representative/factory production control officer must have remote access including the opening meeting and closing meeting. Interim meetings can be held when the audit team needs it, by disabling the audited party's access. Each audit team member and audited party officials share audit records electronically. Before the audit, a trial connection should be made and the compliance of the connection conditions of the audited party and the audit team should be confirmed by the parties. Before, during and after the audit, the audited party submits the documents and records that the audit team needs to review in the audit electronically. These documents and records will be stored electronically on the SZUTEST server for 10 years. Reporting of the audit, findings and practices will be carried out and completed in accordance with Articles 8.3,8.4 and 8.5.

**8.6.6.** During the implementation of the remote audit, if the audited party cannot maintain the processes specific to this audit technique or the audit team cannot perform the remote audit sufficiently, the remote audit can be repeated, a new remote audit can be made for the missing parts, or an on-site audit can be performed depending on the decision of SZUTEST.

## 8.7 Temporary alternative emergency measures and arrangements for on-site audits

These temporary alternative emergency measures include the following principles and regulations:

Postponing on-site surveillance audits for force majeure.

Replacing on-site audits with remote audits using the most advanced Information and Communication Technologies as appropriate under information security and data protection legislation.

Off-site assessment of all relevant and necessary documents/records by SZUTEST.

The possibility of utilizing temporary alternative emergency measures for on-site audits should be carefully evaluated by SZUTEST on a case-by-case basis, documented and realized using a risk-based approach. In particular, the risk assessment determining the possibility of using these alternative measures should take into account the experience with the body to be certified. For example, with regard to production/operational control for organizations with multiple and/or critical histories of nonconformities, taking such interim measures may have an impact on the organization's compliance. However, in these cases, as a temporary measure, an alternative measure such as an on-site audit should be implemented after the travel restrictions are lifted.

In order to evaluate which alternative extraordinary measure is most appropriate, SZUTEST should evaluate the manufacturer's status and files related to the audit in question, such as the area to be audited, the quality management system and the level of compliance with previous audits. First of all, the organization should be contacted and the following information should be evaluated by the Planning Coordinator with the FR.END.96 Form. It must be approved by the Department Manager.

Does the organization have a history of multiple and/or critical nonconformities or critical weaknesses in the previous audit report or critical processes that are recommended to be reviewed at the next audit?

Has a "follow-up or suspension audit" been performed in the organization's recent history?

When will the organization be able to function normally?

When can the organization ship or perform the products or services defined in the current certification scope?

Will the organization need to use alternative production and/or distribution sites? If so, are they currently covered by the current document or do they need to be evaluated?

Does the certified organization have a disaster recovery plan or emergency response plan, has the certified organization implemented this plan and is it effective?

Will some of the transactions and/or services performed or products shipped be subcontracted to other organizations? If so, how will the activities of other organizations be controlled by the certified body?

To what extent has the functioning of the management system been affected?

Has the certified body made an impact assessment?

A definition of control that the organization has the necessary infrastructure to support the use of the proposed ICT.

In cases where the postponement cannot be justified, the Planning Coordinator and the Department Manager should evaluate which alternative extraordinary measures should be taken (remote audit, off-site document review, conference calls with the personnel of the relevant institution, etc.).

For remote audits, both SZUTEST and the manufacturer must have and install the necessary information and communication technologies or tools (document sharing web conferences, an inspection of production lines, etc.). Confidentiality of intellectual property rights must be protected. SZUTEST must clearly document and communicate such requirements for its audits, together with its auditors, including the necessary data protection and cyber security measures, which must be shared before and during these audits. The technological capability of the organization to enable such an audit should be verified by the Planning Coordinator before the audit.

Competent Authorities may wish to observe/witness such remote audits through existing and established information and communication technologies or tools. When creating the audit plan, SZUTEST should arrange the review period of the sites in the audit plan, together with the overall duration of the audit, in coordination with the manufacturer to use this alternative effectively. The audit plan should also clearly outline what alternative emergency measures will be used and what will be carried out remotely. When issuing audit reports, SZUTEST should clearly state that the audit is being carried out remotely and also specify the method(s) used for these audits.

Remote surveillance audits should cover all surveillance tasks that can be verified remotely, including on-site inspection of all documents that would normally be evaluated on-site.

Following such an alternative extraordinary measure, SZUTEST should review and adjust the audit program for each manufacturer.

## 8.7.1 I. Surveillance Audit

Normally, the first surveillance audit after the first certification audit should be conducted within 12 months of the last day of the first stage 2 audit. If it is not possible to carry out the Surveillance audit in its normal period due to the Covid 19 pandemic, SZUTEST must first conduct a remote audit before the 12-month period expires. If a remote audit is not possible, the 1st audit can be extended for 6 months, that is, it can be done 18 months after the last day of the first certification date. Evidence of this should be recorded by SZUTEST.

Otherwise, the certificate should be suspended or reduced in scope.

There may be certain circumstances where SZUTEST may justify adjusting the timing of the next surveillance audit. If an organization needs complete closure for a limited period (less than 6 months), SZUTEST may delay an audit scheduled at the time of closure until the organization resumes its activities. The organization should inform SZUTEST when it starts operating so that SZUTEST can carry out the audit immediately. The organization should be informed about this issue.

## 8.7.2 II. Surveillance Audits

A surveillance audit scheduled for 2020 may be postponed to any date in 2020 due to the Covid 19 pandemic (the last audit date is late 2020). II. Surveillance audit is carried out by remote audit, it is decided to maintain the certificate and field audit is carried out within the calendar year.

## 8.7.3 Recertification Audit

SZUTEST must first perform and complete the re-certification audit before the previous certification period expires. If this is not possible due to the above-mentioned Covid 19 pandemic situation, a remote audit must first be carried out in accordance with current internal regulations so that the re-audit can be carried out and scheduled. This remote audit may cover up to 50% of the calculated onsite audit time and should include an audit of key standard requirements such as management review, internal audits, partial checks for corrective and preventive actions. (Especially for nonconformities and deviations from previous audits). After this remote audit, an on-site inspection (field inspection) is carried out by SZUTEST to prove the conformity of the certified product. In case of a positive certification decision, a new certificate valid for three more years can be issued (Certificate is issued for 6 months). A field audit should be performed by SZUTEST within 6 months after the certification date.

Normally, a recertification audit must be completed to avoid certificate loss and a recertification decision must be made before the expiration date. However, a period of extension may be considered to assure that the certified management system is effective, provided sufficient evidence as above has been collected. This period normally cannot exceed 6 months after the original expiry date.

Recertification should be done within this long period allowed. If not, a new initial audit should be made. The expiration of the renewed certificate should be based on the original recertification cycle.

## 8.7.4 Informing the Competent Authority

All deviations from the Certification/Conformity assessment program must be justified, documented and submitted to Competent Authorities upon request.

## 8.7.5 Mandatory check before moving on to remote inspection

Remote audit compliance: It should be checked that the standard and/or the relevant article is appropriate / authorized for remote auditing.

Past experience of the organization: It should be checked that the results of previous audits, recent restructuring or long-standing onsite audit do not disqualify the customer for remote auditing.

Technical feasibility: Given the availability of the required ICT infrastructure, customers should be checked for suitability for remote auditing.

It should be checked whether the connection has been tested before the audit.

Audit Team Preparation: Auditors or technical experts who will participate in remote auditing should have the ability to understand and use information and communication technologies used to obtain information and communication technologies while using ICT. They should be knowledgeable about ICT and its impact on the validity and limitations of information collected using this methodology. They should be aware of the risks and opportunities of the ICT used and their impact on the validity and impartiality of the information collected.

Remote audit period: It is checked whether the planned duration is in accordance with the maximum allowed time considering the scope of the audit. If ICT is used for audit/assessment purposes, it should be taken into account when planning the total audit/assessment time as additional planning may be required which may affect the audit/assessment time.

## 8.7.6 Matters to be considered while performing the audit

The planned approach is approved by the auditor at the audit planning followed by the opening meeting.

During remote control,

The security and confidentiality of electronically transmitted information is particularly important when using ICT for audit/assessment.

It may not be possible to record call/video recordings of the entire audit process during the audit. However, at least the opening and closing meetings, as well as other cases deemed appropriate by the audit team, call/video recordings of the audit should be recorded.

The simultaneous use of applications that are on the supervisor computer and which are not suitable for ICT should not be allowed.

It is highly recommended to use security/privacy tools i.e. customization screens, headsets etc. and use a separate room.

It is preferable to use customer invitation when using tools such as Skype, Teams etc.

Audit report: The Audit Report should clearly describe which ICT is used to what extent in the performance of the audit and the effectiveness of the ICT in achieving the audit objectives.

The Audit Report is filled with the records of the persons participating in the remote audit.

During the implementation of the remote audit, all necessary precautions should be taken to ensure audit confidentiality of the organization and the audit team.

All necessary audit documents should be filled in accordance with the relevant procedures.

## 8.7.7 ICT methods that can be applied in audits

Information and communication technologies are the use of technology to collect, store, retrieve, process, analyze and transmit information. It includes software and hardware such as smartphones, handsets, laptops, desktop computers, drones, video cameras, wearable technology, artificial intelligence, and others.

ICT can be suitable for both local and remote audit/assessment.

Examples of ICT use during audits/assessments may include, but are not limited to:

- Meetings; via teleconferencing facilities, including voice, video and data sharing
- Auditing/assessment of documents and records via synchronous (real time) or asynchronous (if available) remote access
- Recording information and evidence with still video, video or audio recordings
- Providing audio/visual access to remote or potentially hazardous locations

In the audits, the Audit Team must use reliable communication tools such as Skype, Snagit, Google, Microsoft approved by SZUTEST. Communication tools not approved by SZUTEST cannot be used.

## 8.7.8 Prohibited Applications

It is prohibited:

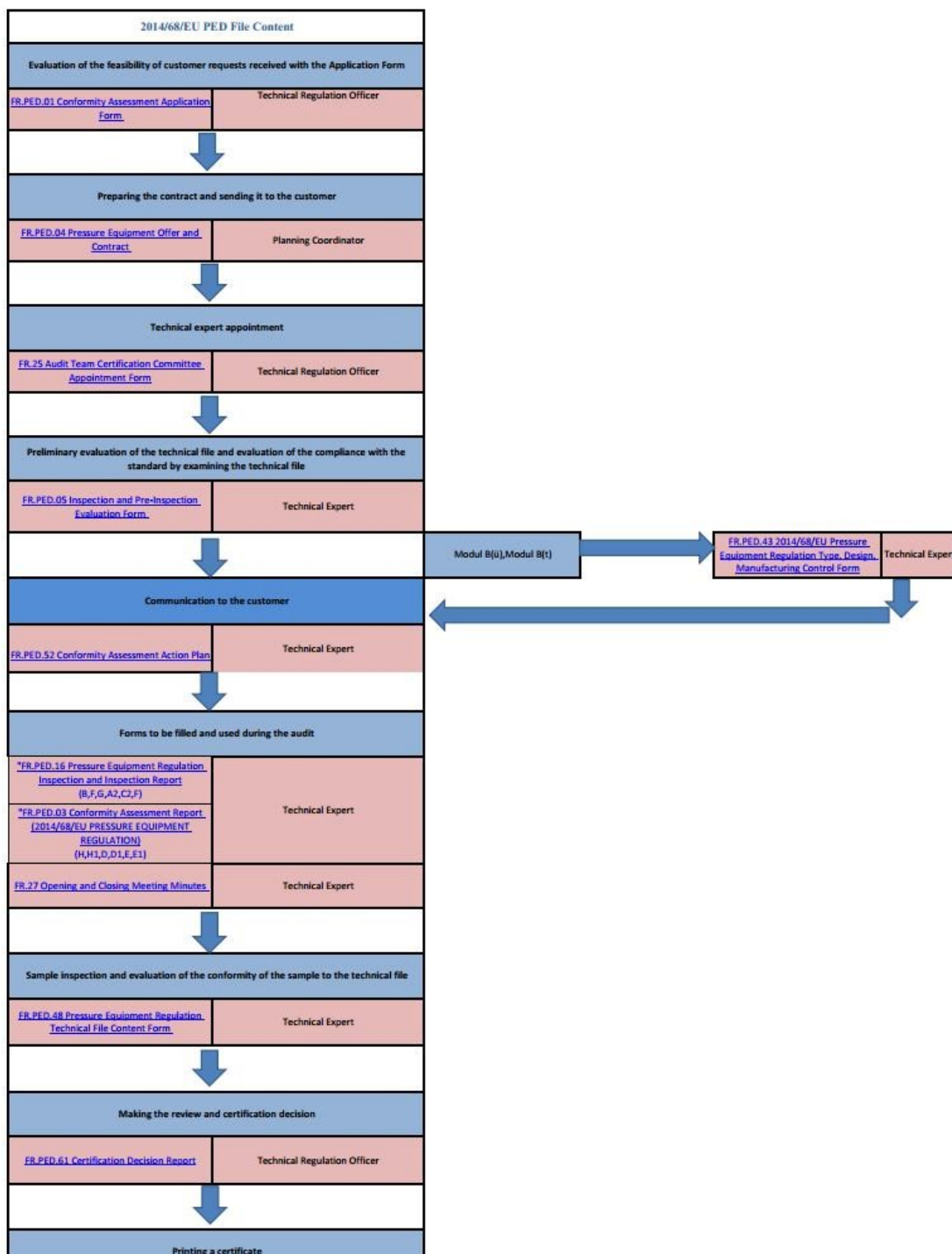
- To conduct remote audits in public places (train, cafe, etc.).
- To conduct a remote audit in a room with others who are not part of the audit team.
- To store the records obtained during the audit on personal computers other than the computers registered to SZUTEST.

## 8.7.9 Decisions regarding certification

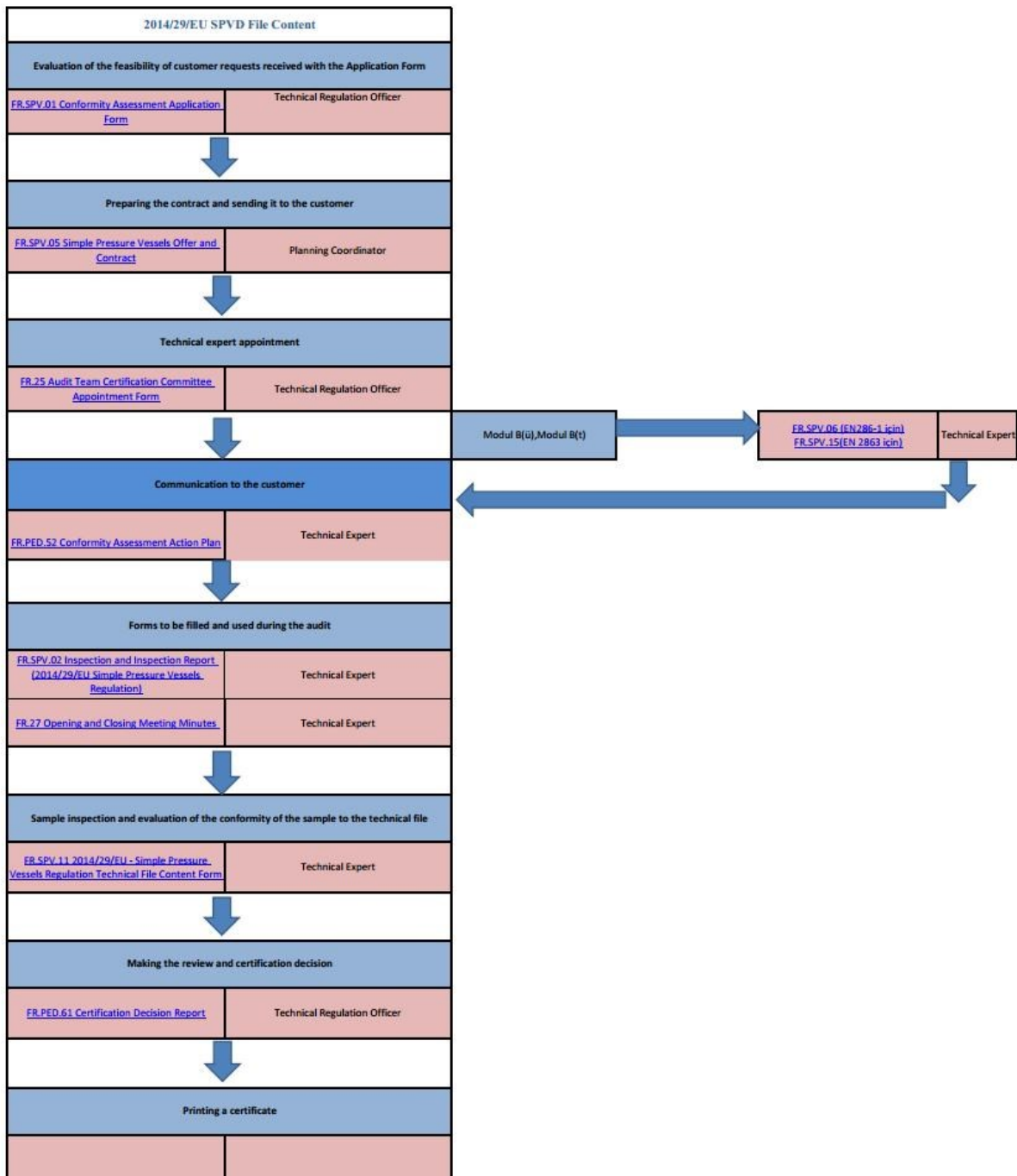
Remote audits for recertification should cover all mandatory recertification tasks that can be verified remotely. After a successful remote audit, SZUTEST may reissue the certificate, provided that these assessments are followed by an on-site validation audit at the next appropriate opportunity to verify elements that cannot be remotely evaluated. The planned timeline for the on-site verification audit should be justified by SZUTEST.

Upon SZUTEST's request, the organization may provide SZUTEST with the necessary records on a continuous or regular basis. If the recertification remote audit fails, the certificate must be suspended or expired.

## 8.8. Documentation Flowcharts



<a href="#">FR.PED.32 Certificate - A2</a> <a href="#">FR.PED.33 Certificate - B(t)</a> <a href="#">FR.PED.34 Certificate - B(u)</a> <a href="#">FR.PED.40 Certificate-E</a> <a href="#">FR.PED.40 Certificate-E</a> <a href="#">FR.PED.35 Certificate - C1</a> <a href="#">FR.PED.36 Certificate - F</a> <a href="#">FR.PED.37 Certificate - G</a> <a href="#">FR.PED.38 Certificate - H1</a> <a href="#">FR.PED.39 Certificate-D1</a> <a href="#">FR.PED.14 Certificate-D</a> <a href="#">FR.PED.13 Certificate - H</a>	Technical Regulation Officer
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# SZUTEST

**Document Code :** PR.PED.02  
**Revision No/Date :** 17 / 23.11.2023  
**Status :** Effective  
**Effective Date :** 23.11.2023  
**Confidentiality :** Internal  
**Gdpr :** Does Not Contain Personal Data

<a href="#">FR.SPV.09 EU Type Examination Certificate (Design Type)</a> <a href="#">FR.SPV.14 EU Type Examination Certificate (Production type)</a> <a href="#">FR.SPV.12 Certificate - Module C1</a> <a href="#">FR.SPV.13 Certificate - Module C2</a>	Technical Regulation Officer
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