

## EN 15085-2 CERTIFICATION PROGRAM PROCEDURE

### A) DOCUMENT APPROVALS

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## 5. Objective and Scope

The purpose of this procedure is to explain the principles regarding certification activities according to the EN 15085 standard.

This procedure covers the EN 15085 certification activities carried out by the Industrial Services Department within the scope of the EN ISO 17065 standard.

## 6. Definitions

Technical Staff: Lead Auditor, Auditor, Technical Expert, Decision Maker.

ICT: Information and Communication Technologies

APP Software: The web-based software program used

Decision Maker: It is the person in the Certification Committee who makes the certification decision, change and sustainability decisions.

Conformity Assessment Activity: It refers to the activity that provides proof that the specified requirements (specified need or expectation) related to a product, system, person or organization, which is the result of a transaction, are fulfilled.

Conformity Assessment Body (CAB): Organizations providing conformity assessment services are generally referred to as Conformity Assessment Agency (CAB).

Accreditation: It is a part of Conformity Assessment and is a tool that ensures the trust and credibility of reports and certificates issued by accredited conformity assessment bodies.

Annual Inspection: It is the inspection activity that must be carried out at the manufacturer's production site, the conditions of which are determined in the EN 15085 standard.

Audit: It is the Conformity Assessment Activity carried out for Certification Services.

## 7. Responsibilities

The Department Manager, Technical Manager, Planning Coordinator, and qualified Technical Personnel in the relevant field are responsible for the implementation of this procedure.

## 8. Method

### 8.1 Receiving Applications

The application received by the Szutest Industrial Services Department is priced in accordance with the PR.END.03 Industrial Services Pricing Procedure and becomes an agreement in accordance with the PR.END.01 Receiving Applications, Evaluation and Offer Agreement Procedure.

### 8.2 Establishment of the Audit Team and Appointment of the Decision Committee

Following the signing of the contract, the audit team is formed by selecting the Technical Experts/Auditors who are qualified in the relevant field in the FR.K.07 Staff Pool, and the entire process from the application process to the review is formed with an impartial staff member who will take place in the Certification Review and Decision Committee. is assigned with the FR.25 Audit Team Certification Committee Assignment Form in order to monitor and ensure file integrity. A staff member in the audit team cannot take part in the Certification Review and Decision Committee.

The Audit team qualified according to PR.END.02 Qualification Procedure by the Competency Evaluation Specialist and registered in the FR.K.07 Audit Personnel List, the lead auditor (he/she can perform to the audit alone if he/she is also a technical expert) is selected among the technical experts so that they can create a plan suitable for the audit period and appointed with the FR.25 Audit Team and Committee Appointment Form. In case of objections from the audit team to the appointment of auditors, a new audit team is appointed by the Technical Manager, noting the reasons in the FR.25 Audit Team and Committee Appointment Form. The Audit Team can comprise the Lead Auditor+Auditor+Technical Expert. The audit plan is prepared by the auditor and the audit is carried out by the auditor in an audit team that comprises the Auditor+Technical Expert.

### 8.3 Preparation of the Audit Plan

FR.26 Audit Plan is prepared by the Lead Auditor/Auditor, taking into account the field and personnel conditions of the firm. The Lead Auditor/Auditor shares the plan with the Planning Coordinator, and the Planning Coordinator shares it with the firm at least 2 days before the audit and asks the firm for the approval of the audit team and the plan. If the approval is not given, the Planning Coordinator informs the Technical Manager along with the reasons. The Technical Manager informs the Planning Coordinator about changing the audit team, taking into account the reasons. While determining the audit period, PR.END.03 Industrial Services Pricing Procedure and 8.2.3.3 Audit Period Determination Rules should be referred.

### 8.4 Initial Certification Audit

The audit is carried out at the time and address specified in the audit plan, with the participation of company representatives and audit team, over the FR.K.14 15085 Checklist, taking into account the justifications in TL.K.02 EN15085-2 Certification Instruction.

Certification is carried out by meeting the requirements in EN 15085-2:2020 Article 6. When questioning EN 15085-2:2020 Clause 6, the requirements in EN 15085-2:2020 clause 5 are also observed.

This inquiry is reported and recorded with the interview with additional questions appended to the FR.K.14 checklist, or will be limited to the materials and processes used in manufacturing during the inspection and within the scope of certification requested by the manufacturer. can make a technical assessment of the resource coordinator based on questions regarding the implementation of materials and processes. Comments are recorded in the auditor findings and evaluation section of the relevant items in the Checklist. In addition, the test of a source based on an applied WPS can also be applied for this purpose.

In this context;

- An interview to measure the technical knowledge of the welding coordination personnel in line with the EN 14731 standard and EN 15085 series standards (an exam can be applied if necessary).

It; As stated above, questions regarding the implementation of processes within the scope of the relevant certification and the material used may be in the form of interpretation of the welding test accompanied by the welding coordination personnel. The level of the Welding Coordinator, determined according to his duties and competence areas, is indicated on the certificate.

- Conformity assessment of welders and welding operators,
- Conformity assessment of welding procedure specification approvals (PQR),
- Conformity assessment of additional production tests within the scope of EN 15085-4,
- Conformity assessment of technical requirements and welded fabrication
- Inspection of the site, if there is another site related to welded manufacturing,
- Conformity assessment of welded manufacturing quality levels is carried.

Performing the audit; In order to confirm whether the establishment quality system, product and technical documentation are applied in an acceptable way, the basic principles of EN ISO 3834 are made by means of mutual negotiations, examination of documents and records by sampling method, and observing the studies and conditions in the relevant sections under the guidance of standards and regulations.

While sampling, the following points are taken into consideration;

- Sampling from all applied non-destructive testing techniques
- Selecting samples from critical equipment that demonstrates the conformity of the relevant NDT method
- Increasing the number of selected samples, taking into account the number of personnel performing non-destructive testing
- Ensuring that the personnel performing non-destructive testing perform a sample examination.

As a result of the audit performed, minor nonconformities, major nonconformities, positive findings and observations are identified. These findings are recorded in the FR.29 Nonconformity Report.

P (Positive Findings); Positive issues identified in the system

MaN (Major Nonconformities); 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.

MiN (Minor Nonconformities); They are non-systematic deviations from standard conditions and/or firm documentation conditions that do not affect the overall system.

O (Observations); Identifications that cannot be directly associated with the standard or customer documentation, but may turn out to be minor if no action is taken, are referred to in the audit report.

The closing period for identified nonconformities is 90 days for major and minor nonconformities in certification audits. Nonconformities must be closed within the specified period. If the firm makes an application with a letter explaining the justified reason for the delay and requesting additional time, the lead auditor may evaluate the issue and decide to define an additional 30 days. The FIRM, which cannot close the relevant nonconformities, has to repeat the process for certification.

A follow-up audit is required for major nonconformities. However, according to the decision that can be made by the audit team, even if the nonconformity is major, the requirement for follow-up audit may be removed in some cases (where there are nonconformities that can be corrected with a document). If the follow-up audit is not deemed necessary by the audit team regarding minor nonconformities, the corrective action evidence is sent to the lead auditor within the period specified by the firm. If a follow-up audit decision is made, a follow-up audit is scheduled from the date on which the manufacturer reports that it has closed the relevant nonconformities. Follow-up audits should be performed within the nonconformity closing periods. Observations identified during the audit are re-examined in the next audit. If measures have been taken

regarding the detected observations and the system has been improved, it is stated in the report. If no precautions are taken regarding the observations and some defects will affect the operation of the system, it is reported as minor/major nonconformity according to the decision of the audit team.

The audit file completed by the Audit Team is evaluated by the certification committee assigned with the FR.25 Audit Team/Certification Committee Appointment Form and recorded with the FR.K.16 EN ISO 3834-EN 15085 Review and Decision Report. If the certification decision is positive, the firm's certificate is issued, and if the decision is negative, the firm is informed in writing by stating the reasons.

## 8.5 Surveillance Audits

It is the periodical audits that SZUTEST carries out to verify that the firm it has certified continues to comply with the certification requirements. Surveillance audits are planned with reference to the last day of the decision date.

In case surveillance audits cannot be carried out within 12 months from the decision date of the certification audit, the certificate of the firm is suspended from the date of the expiry of the 12-month period.

For the second and subsequent surveillance audit, a postponement of up to three months can be made for temporary situations (such as Fair, Conference, Business Trip, Heavy Workload, Temporary Health Problems, Temporary Shutdown of Production and Service), provided that the justification for the postponement requests from the organizations is stated. Postponement request is received in writing (e-mail or fax).

Surveillance audits should include the following:

- a) Verification of the actions taken for the nonconformities detected in the previous audit
- b) Complaints
- c) Progress of planned activities aimed at continuous improvement
- d) Reviewing the changes
- e) Use of marks or other references to certification
- f) Whether there are changes in the content of technical documentation
- g) Examination of the standard-specific requirements,
- h) Control of the continuity of process and service conditions

The surveillance audit period can be determined as less than 12 months upon the request of the firm.

For surveillance audits, the Planning Coordinator contacts the firm regarding surveillance audit at least 2 months before the expiry of the validity period of the certificate, taking the surveillance period specified in the agreement as reference. Performing and reporting the audit, closing and monitoring of nonconformities are performed as in the certification audit.

Nonconformities identified during surveillance audits are recorded in the FR.29 Nonconformity Report. The closing period for nonconformities for surveillance audits is 60 days. Submitting the Firm's corrective action plans is sufficient for minor nonconformities. In the next audit, SZUTEST evaluates for minor nonconformities and on-site verification of nonconformities that were detected in the previous audit and closed without on-site verification, control of mark and certificate use, and whether the corrective actions are carried out effectively. Minor nonconformities identified during the audits and decided to be closed in the next audit, provided that the corrective action plan is approved, are categorized as major nonconformities if they are not closed or repeated during the next audit. The maximum period determined for the implementation and fulfillment of the corrective action in such nonconformities is one month. If it is determined that the nonconformity is still not resolved in the audit carried out after one month, the certificate of the FIRM is suspended. If they can provide a suitable justification, they are given an additional 3 months to close the

nonconformities. At the end of these periods, if the nonconformities are still not closed, a follow-up audit is performed.

In case the nonconformities cannot be closed before the specified dates, the certificate of the firm is suspended and the firm is notified with a suspension notification letter. The continuation of the validity of the certificates of the companies that close all nonconformities before the specified dates is decided by the decision-maker. The final decision regarding the maintenance of the certificate belongs to the decision-maker, as in the certification audit. In surveillance audits, the committee decision is recorded with the FR.K.16 EN ISO 3834-EN 15085 Review and Decision Report. The surveillance certificates are shared with the firm by extending the surveillance period on the certificates of the companies whose certificate validity is decided by the committee.

## 8.6 Follow-Up Audits

It is carried out in order to determine that the reasons for the suspension of the firm's certificate, the major nonconformities that emerged during the certification, surveillance and change audits, and the minor nonconformities that require on-site audit have been resolved and that corrective actions have been implemented effectively.

If a follow-up audit is performed after the audit, the audit can be performed as a full audit. Follow-up audits are carried out by the audit team that performed the main audit unless there is a situation that requires otherwise (illness, death, conditions that may affect impartiality, etc.).

The follow-up audit activity is carried out on a jointly planned date with the firm after the corrections determined in the FR.29 Nonconformity Report are made. If the firm cannot complete its preparations within the time given to the firm for the follow-up audit after the audit and/or cannot prove that it has corrected the nonconformities during the follow-up audit, the application or certificate of the firm is withdrawn. In the audits performed less than 30 days before the certificate validity period expires, the nonconformity closing period is given at least 7 days before the certificate validity period. This time is necessary for the committee to meet and complete its reviews. If there is any nonconformity that cannot be closed within this period, the certificate of the firm is withdrawn. After the nonconformities are verified by the lead auditor, the audit file is sent to the certification committee.

## 8.7 Special Audits:

### 8.7.1 Change Audits

The firm should inform SZUTEST that there has been a fundamental change regarding the content of the certificate (expansion, reduction, change in title, change in product and production method, address, welding coordination personnel/staff, a representative with equal rights, change of substitute representative).

Change requests are received from the companies in writing with the FR.30 Certification Change form. A decision is made by the decision-maker whether to conduct a certificate review or field audit and is noted on the form. Whether the field audit is necessary is determined by the decision-maker depending on the new scope requested and the content of the scope owned.

#### 8.7.1.1 Scope Extension Change

Change audit should be performed in cases such as adding new activities to the scope, changing product and production methods, etc. In such cases, a change in the periodic audit date may be required. If changes are required, both periodic and scope change audits are carried out together.

If the documents and audit report are approved by the decision-maker, changes are made and noted in the FR.30 Certification Change Form. The revised certificate is submitted to the firm by making changes to the certificate. If the certification change is not deemed appropriate, the firm is notified in writing. The current certificate validity period of the firm does not change in certificate changes. In this case, the certificate

amendment fee specified in the PR.END.03 Industrial Services Pricing Procedure is requested.

### **8.7.1.2 Certificate Owner Title Change**

In case the firm has a title change request, the FR.30 Certification Change Form is shared with the customer by the Planning Coordinator. According to the new title, the certificate holder sends the trade registry newspaper and the signature circular as an attachment. In the event that the certificate owner has a title change decision, if there is no change affecting the product, production and factory production control system, a revision is made on the existing certificate with the decision of the Certification Committee based on the relevant information and the previous certificate is requested to be sent. In this case, the certificate amendment fee specified in the PR.END.03 Industrial Services Pricing Procedure is requested.

### **8.7.1.3 Address Change**

In case the firm requests a change of address, the Planning Coordinator will share the FR.30 Certification Change Form with the customer. In case of a change of production location, a change audit is carried out to examine the new production site of the certificate owner. If the adequacy of the Factory Production Control system is determined in the examination, the certificate of the organization is revised according to the new production location address, with the decision of the Certification Committee. In this case, the certificate amendment fee specified in the PR.END.03 Industrial Services Pricing Procedure is requested.

### **8.7.1.4 Change in welding coordination personnel(s), co-authorized representatives, substitutes**

In case the firm requests a change, the FR.30 Certification Change Form is shared with the customer by the Planning Coordinator. An appointment letter/proficiency certificate of the personnel to be appointed additionally is requested from the firm. After the necessary documents are delivered, the appointed Lead Auditor conducts technical interviews with the personnel to be appointed. If the result of the technical interview is sufficient, necessary changes are made on the firm certificate and its revision is carried out on the existing certificate. In this case, the certificate amendment fee specified in the PR.END.03 Industrial Services Pricing Procedure is requested.

### **8.7.2 Short Notice Audits**

In the case of complaints containing objective evidence against the firm, the Technical Manager may decide to conduct an extraordinary audit by contacting the firm, although it is not in the program. In such audits, the firm is informed and the audit is carried out in a time that will not allow the firm to change the current situation (maximum 1 day before).

In audits, the following are examined,

- Subject of complaint
- Results of previous surveillance visits,
- The need to monitor corrective actions,
- Where appropriate, special conditions for system validation,
- Significant changes in the organization of the manufacturing process, metrics or techniques.

While assigning the audit team to perform the audit, the Technical Manager assigns an audit team that is different from the previous audit team and capable of interpreting the subject of the complaint. If the subject of the complaint is related to the previous audit team, a different team is assigned.

If the firm does not accept the audit, the certificate is suspended and the firm is notified in writing. SZUTEST has stated that it can take this decision in the agreement signed before providing service to the firm.

### **8.8 Acceptance Criteria for Test Reports Affecting the Certification**

The following criteria will be sought for the acceptance of the reports of Destructive/Non-Destructive tests, welding method procedure approvals and welders' personnel documents for certification purposes, which are

examined in the conducted audits.

- Whether the destructive tests are carried out by an accredited organization according to EN ISO/IEC 17025 Standard or by an organization audited by Szutest according to EN ISO/IEC 17025 standard and included in Szutest's approved laboratory list. If the relevant laboratory does not meet one of these two conditions, then it is questioned whether the institution performing the tests inspects the test laboratory at least in terms of traceability, the accuracy of test methods, calibrations of the devices performing the tests and personnel qualification. If the manufacturer provides objective evidence that the laboratory has been audited according to the EN ISO/IEC 17025 standard, test reports from that organization may also be accepted.

- Whether the non-destructive tests and welding method procedure approvals have been performed by an accredited organization according to EN ISO/IEC 17020 Standard or by an organization audited by Szutest according to EN ISO/IEC 17020 standard and included in Szutest's approved laboratory list. If the relevant laboratory does not meet one of these two conditions, then it is questioned whether the institution performing the audit inspects the test laboratory at least in terms of traceability, the accuracy of test methods, calibrations of the devices performing the tests and personnel qualification. If the manufacturer provides objective evidence that the laboratory has been audited according to the EN ISO/IEC 17020 standard, test reports from that organization may also be accepted.

- Welder certificates must be obtained from organizations accredited according to the EN ISO/IEC 17024 standard.

This assessment is reported and recorded through the audit checklist.

## 8.9 Recertification Audits

The firm must make a request to SZUTEST for a recertification audit 3 months before the expiry of the certificate validity period for the audit to be scheduled within the certificate validity period. If no application is received, the certificate loses its validity at the end of the validity period of the certificate.

For recertification activities, a signed FR.K.01 EN ISO 3834 - EN 15085-2 Application Form is requested from the organization and a new price offer is submitted and the activities begin with signing the agreement as in the first certificate.

After the correction and corrective actions for the nonconformities identified as a result of the audit are carried out, it is verified that it complies with the requirements of the relevant standard, and the necessary studies are completed, as in the first certification, and a new certificate is issued.

## 8.10 Certification

If there is no nonconformity as a result of the audit or if the found nonconformities are closed within the specified period, a certificate is issued to the firm in accordance with the PR.END.04 Certificate and Reporting Procedure over the FR.K.08 EN 15085 Certificate format. The certificate is signed by the Department Manager. Published certificates are added to the FR.END.73 Certified Firms List and published on the [www.szutest.com.tr](http://www.szutest.com.tr) website.

Information about the use of certificates and marks is sent to the companies for which a certificate decision has been taken, via the web page with the PR.10 Certificate and Mark Usage Procedure. The FR.24 General Conditions Text includes reference to this procedure.

## 8.11. Suspension of Certificate and Narrowing the Scope

In the event that the following conditions occur, the entire or part of the scope of the firm's certificate may be suspended, provided that it does not exceed three (3) months from the date of the decision. The firm may request an extension of the suspension period for justified reasons. With the approval of the decision-maker,



the suspension period may be extended, provided that it does not exceed six (6) months.

The suspension decision may be taken by the Department Manager in cases where technical evaluation is not required, such as not fulfilling financial obligations, request for voluntary suspension by the firm, not closing the nonconformities in a timely manner.

- Some nonconformities have not been corrected within the specified period determined during the audits,
- Identification that non-standard requirements or legal sanctions regarding the product/service covered by the audit are not fulfilled,
- The firm submits a written request for voluntary suspension of certification.
- Any misuse of SZUTEST certificate and mark,
- Failure to comply with the agreement, relevant standards and regulations,
- Failure to fulfill financial obligations,
- Failure to notify SZUTEST of significant changes in the firm's organization and products,
- Failure to implement the system as documented and audited,
- Failure of the firm to allow surveillance audits to be conducted as often as necessary.
- Failure of the firm to take the necessary corrective action against the complaints submitted to the firm.
- Not providing Szutest with the information requested by Szutest regarding the scope of certification.

When the organization shows a persistent or serious failure to meet the certification requirements for a part of the certification scope, SZUTEST narrows the customer's certification scope to exclude the part that does not meet the requirements.

The firm is notified that the certificate has been suspended and that the suspension has been lifted. The organization's suspended certificate is invalid.

In case the certified organization cannot solve the problems within the given time, the firm's certificate is withdrawn by the decision-maker or its scope is narrowed. In case of suspension or withdrawal of the certificate, the validity status of the certificate is announced to the public on the website. The firm is obliged to stop the use of certificates and marks from the date of suspension of the certificate. The certificate cannot be used during the time it is suspended.

## 8.12 Reinstatement of the Certification

Firms whose certificates have been suspended notify SZUTEST in writing that the reasons for suspension have been eliminated. In order to confirm that the reason for the suspension has been eliminated, an audit is carried out by SZUTEST when deemed necessary in the firm. The type, content and duration of the audit carried out within the scope of suspension are determined depending on the reason for the suspension of the certificate. At the end of the audit, the certificate of the firm, whose conformity is verified, is reinstated by the decision-maker.

In case the reasons for suspension are not eliminated within the suspension period, the certificate is withdrawn.

## 8.13 Withdrawal of Certificate and Its Consequences

The certificate is withdrawn by the decision of the Department Manager or the decision-maker in the event of the following conditions. In cases where there is no need to evaluate the effectiveness of the firm, such as the reasons for suspension cannot be resolved within the specified time, the firm's bankruptcy or termination of its activities or the firm's termination of the agreement, the Department Manager may take a withdrawal decision. In other cases, the certificate is withdrawn by the decision of the certification committee.

- The firm does not accept the suspension reasons or does not resolve them within the specified time,
- The firm's bankruptcy or termination of its activities

- Failure of the firm to use the certificate for the scope and address specified on it.
- The firm's giving false and misleading information during the audit
- In the audits, it is determined that the firm management system and product compliance have been completely lost.
- The firm's destruction of documents and annexes
- The firm's desire to terminate the agreement

In case of withdrawal of the certificate, the status of the certificate is announced to the public on the Szutest website. Re-applications of companies whose agreements and certificates have been withdrawn can be processed at least 30 days later. When re-application is made, the initial certification procedures are applied.

## 8.14 Other Matters

### 8.14.1 Suspension of Inspection

Suspension of audit activity may occur only when the following conditions are met:

- If it is determined that the conditions within the scope of the certification activity are not fulfilled
- If conditions during the audit adversely affect or pose a threat to the health of the audit team.
- If serious problems are encountered in accessing records related to the relevant personnel, the relevant department or the job or service.
- In addition, if the company requests that the conformity assessment be stopped due to reasons originating from the company, it can be stopped on the condition that the conformity assessment is repeated.

When the Team Leader decides to stop the conformity assessment, he/she should reach the company representative and explain the reason. During the decision making phase, the Team Leader should consult the Department Manager when needed. The Team Leader explains the reason for stopping the conformity assessment by calling the top management of the company for a meeting . If the company'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 also be notified to the company in writing.

## 8.15 Certification Program

The certification program has been established as follows, based on ISO/IEC 17067 Table 1.

Product Certification System Elements		Product Certification System
<b>I</b>	<b>Selection</b> (Identification of mandatory documents that will form the basis for certification)	X
<b>II</b>	<b>Evaluation of services</b>	X
<b>III</b>	<b>Reviewing</b> (evaluation)	X
<b>IV</b>	<b>Certification Decision</b> (Granting, extending, continuing, suspending, withdrawal)	X
<b>V</b>	<b>Licensing</b>	
	a- Publication of the certificate of conformity	X
	b- Granting the certificate and the right to use Szutest mark	X
	c- Granting the certificate of conformity for the product group	-
	d- The continuation of the certificate and the right to use	X

	the Szutest mark depends on the surveillance.	
VI	<b>Surveillance</b>	
	a- Testing or audit of samples taken from the market	-
	b- Testing or audit of samples taken from the factory	-
	c- Evaluation of production, delivery of service or operations	X
	d- Audit of the management system	X

## 8.16. Remote Audit

Considering the adequacy of the connection quality (live video, audio, etc. transmission, internet access, remote access to the database and management system, etc.) while planning the remote audit, the necessity of increasing the audit time will be taken into consideration. In case Turkak performs an audit with remote auditing techniques, this period is increased from 1 to 1.5 times in order to carry out an effective audit.

### 8.16.1.

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

### 8.16.2.

The level of application of remote auditing 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 documented.

### 8.16.3.

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, on-site audits are carried out. In the event that extraordinary events and conditions continue, the certification process is continued until the end of the situation.

### 8.16.4.

For surveillance audits, remote audit techniques may be preferred in accordance with Article 8.15.2 due to extraordinary events and conditions. After the end of extraordinary events and conditions, on-site audits are carried out by the same audit team.

### 8.16.5.

The audit team, including the opening meeting and closing meeting, must have remote access to the management representative/factory production control supervisor. 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 the audit records in the electronic environment. 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 transmits the documents and records that the audit team needs to review in the audit electronically. These documents and records will be electronically stored on the SZUTEST server for 10 years. Reporting of the audit, findings and applications will be carried out and completed according to Articles 8.2, 8.3, 8.4 and 8.5.

### 8.16.6.

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.

## **8.17 Applications of Audits to be Performed within the Scope of Temporary Emergency Measures**

### **8.17.1 Arrangements for temporary alternative emergency measures and 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 in accordance with information security and data protection legislation.

Off-site evaluation of all relevant and required 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 gained with the body to be certified. For example, with regard to production/operational control for organizations with multiple and/or critical histories of non-compliance, 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 emergency 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 recent history of the organization?

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 covered by the current certificate or should they be considered?

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 organization made an impact assessment?

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

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

For remote audits, both SZUTEST and the manufacturer must have and install the necessary information and communication technologies or tools. (For example, document sharing web conferences, audit of production lines). The confidentiality of intellectual property rights should 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 areas 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 an on-site audit 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.

### **8.17.2 1st 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, i.e. 18 months after the last day of the first certification date. Evidence of this matter must 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.

### **8.17.3 2nd and Subsequent 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 the end of 2020). The 2nd surveillance audit is carried out by remote audit, the continuation of the certificate is agreed and on-site audit is carried out within the calendar year.

### **8.17.4 Recertification Audit**

SZUTEST must first perform and complete the recertification audit before the end of the previous certification period. If this is not possible due to the above-mentioned COVID-19 pandemic, 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 take up to 50% of the calculated on-site 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 audit (field audit) 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). An on-site audit should be carried out 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 documented management system is effective, provided that sufficient evidence has been collected as above. This period will normally not exceed 6 months after the original expiry date.

Recertification must be done within this long period of time allowed. If not, a new initial audit should be

made. The expiration of the renewed certificate should be based on the original recertification cycle.

### **8.17.5 Informing the Competent Authority**

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

### **8.17.6 Mandatory control before moving on to remote audit**

Remote audit compliance: The conformity/authorization of the standard and/or the relevant article for remote auditing should be checked.

Past experience of the organization: It should be checked that the results of previous audits, recent restructuring or long-standing on-site audit do not disqualify the client 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 audit 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 effect 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 its effect 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/evaluation purposes, it should be taken into account when planning the total audit/evaluation time as additional planning may be required which may affect the audit/evaluation time.

### **8.17.7 Points to be considered while performing the audit**

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

During remote auditing, the security and confidentiality of information transmitted electronically are particularly important when using ICT for audit/evaluation.

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.

Simultaneous use of applications that are not suitable for ICT should not be allowed on the supervisor's computer.

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 was used and to what extent, and the effectiveness of 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 remote auditing, all necessary measures should be taken to ensure audit confidentiality of the organization and audit team.

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

### **8.17.8 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 audits/evaluations.

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

- Meetings; via teleconferencing facilities, including voice, video and data sharing
- Auditing/evaluation 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 approved by SZUTEST such as Skype, Snagit, Google, Microsoft. Communication tools not approved by SZUTEST cannot be used.

### **8.17.9 Prohibited Applications**

It is forbidden:

- To conduct a remote audit in public places (eg. 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.

### **8.17.10 Decisions regarding certification**

Remote audits for recertification purposes must 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 onsite 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 should be suspended or expired.