PRODUCT CONFORMITY ASSESSMENT PROGRAM PROCEDURE

A) DOCUMENT APPROVALS

No	Definition	Action	Approved By	Date
1	Document approved	Approval	Sevda Büyükbaltacı	28.11.2025
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B) REVISION HISTORY

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12	The English version of the document has been added.	Update	28.11.2025	28.11.2025

5. Purpose and Scope

The purpose of this procedure is to determine the principles regarding the realization of product conformity assessment activities within the scope of Directive 2000/14/EC on noise emission in the environment by equipment for use outdoors.

6. Definitions

Ministry: T.R. Ministry of Industry and Technology.

Conformity Assessment: All operations carried out to determine the product's conformity with the relevant technical regulation.

Certificate of Conformity: The written document issued in case the conformity assessment process results positively.

Non-conformity: A finding detected when any of the requirements of **Directive 2000/14/EC** or, if applicable, requirements of harmonized standards are not met.

Non-conformity requiring follow-up audit: Non-conformities that directly affect product safety and require field verification.

Company: The organization that manufactures or distributes the product.

ANNEX VI: Internal Production Control with Assessment of Technical Documentation and Periodic Checks.

ANNEX VIII: Full Quality Assurance.

7. Responsibilities

The **Department Manager**, **Technical Regulation Officer**, and **Lead Auditors/Auditors/Technical Experts** are responsible for the implementation of this procedure.

8. Method

8.1 Application and Contract

Refer to PR.NED.01 Application Evaluation and Contract Procedure.

8.2 Conformity Assessment Program Type

Conformity Assessment Functions and Activities in	Product Certification Module	
Product Certification Program	ANNEX VIII	ANNEX VI
I. Selection		
- Evaluation of application and signing of contract	X	X
- Determination of documents forming the basis for certification (Technical file review)	X	X
II. Determination of Characteristics		
- Internal Production Control	X + T + M	X + T + M
- Management system audit	X + KS	
III. Review		
- Examination of obtained evidence of conformity	X	X
IV. Certification Decision		
- Decision on granting, maintaining, extending scope, suspending, or withdrawing the certificate	X	X
V. Certification, Licensing		
- Granting of the certificate	X	X
- Granting the right to use the Certificate and CE Mark	X	X
- Granting the certificate for a product group	X	X
- Granting the right to use the certificate and CE mark depending on surveillance	X	
- Granting the right to use the Notified Body Identification Number	X	
VI. Surveillance		
- Subjecting samples taken from the factory to tests	X(*)+ T + M	
- Management system audits	X + KS	

(*): Supervises tests taking into account the technical documentation prepared by the manufacturer and the requirements of the directive, and examines and verifies the manufacturer's competence.

X: Indicates mandatory application.

+ T: In the evaluation to be made, for ANNEX VIII, requirements of EN ISO/IEC 17025 Clauses 6 and 7 (excluding clause 7.9) are applied in addition to requirements of EN ISO/IEC 17021-1 standard; for ANNEX VI, requirements of EN ISO/IEC 17025 Clauses 6 and 7 (excluding clause 7.9) are applied in addition to requirements of EN ISO/IEC 17065 standard.

+ M: In the evaluation to be made, for ANNEX VIII, requirements of EN ISO/IEC 17020 Clauses 6.1.2, 6.1.3, and 6.1.6 to 6.1.10 are applied in addition to requirements of EN ISO/IEC

17021-1 standard; for ANNEX VI, requirements of EN ISO/IEC 17020 Clauses 6.1.2, 6.1.3, and 6.1.6 to 6.1.10 are applied in addition to requirements of EN ISO/IEC 17065 standard.
+ KS: In the evaluation to be made, requirements of EN ISO/IEC 17020 Clauses 6.1.2, 6.1.3, and 6.1.6 to 6.1.10 are applied in addition to requirements of EN ISO/IEC 17021-1 standard.
Yellow Color: Indicates that 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.

8.3 Realization of Conformity Assessment

8.3.1 Assignment of Audit Team

Lead Auditor/Auditor/Technical Expert(s) appointed according to PR.NED.02 Qualification Procedure may serve as Team Leader in audits and carry out the audit alone or with another similarly qualified Lead Auditor/Auditor/Technical Expert.
The audit team is appointed via FR.NED.04 Audit Team Appointment Form. If there is an objection to the appointment of the audit team members, the reasons are noted on the FR.NED.04 Audit Team Appointment Form, and a new audit team is assigned by the Technical Regulation Officer.
The following points are considered in the selection of the Lead Auditor/Auditor/Technical Expert:

- Audit objectives, scope, criteria, and determined audit time,
- Competence of the Lead Auditor/Auditor/Technical Expert required to achieve audit objectives,
- Certification conditions (legal or contractual conditions),
- Language and culture,
- Whether the audit team has previously audited the customer's management system.

Observers may also accompany the audits. Observers may be a person observing a member of the audit team or an official from the accreditation body. The customer and audit team members are informed beforehand regarding the participation of observers in the audit, and the customer's approval is obtained. Observers do not interfere with the audit.

Before field audits are planned, an evaluation is made by the Technical Regulation Officer using FR.NED.03 Pre-Audit Technical File Review Report. If it is decided to proceed to the audit stage, the assigned Lead Auditor/Auditor/Technical Expert examines the company's documents and audit preparations using FR.NED.30 Technical File Review Report. If a non-conformity is detected, the Lead Auditor/Auditor/Technical Expert contacts the firm and notifies them of the non-conformities. Notification is made via e-mail. After the non-conformities are resolved, a re-examination is carried out with the FR.NED.30 Technical File Review Report. If the review result is appropriate, the planning stage is started.

The information that must be present in the technical file to be reviewed is as follows:

- Name and address of the manufacturer or their authorized representative established in Turkey,
- Description of the equipment,
- Brand,
- Trade Name,
- Type, series, and numbers,
- Technical data relevant for the identification of the equipment and the assessment of noise emission, including, where appropriate, schematic drawings and any explanations and definitions,
- A reference to this Directive,
- Technical report of noise measurements carried out in accordance with the provisions of this Directive,
- Assessment results of uncertainties arising from production variation and their relation to the guaranteed sound power level,
- A copy of the EC Declaration of Conformity,
- Documents regarding the quality assurance system must be included.

The EC Declaration of Conformity must contain the following information:

- Name and address of the manufacturer or their authorized representative established in Turkey,
- Name and address of the person who keeps the technical documentation,
- Description of the equipment,
- Conformity assessment procedure followed and, where appropriate, name and address of the relevant Notified Body,
- Measured sound power level on an equipment representative for this type,
- Guaranteed sound power level for this equipment,
- A reference to this Directive,
- A declaration that the equipment complies with the requirements of the relevant directive,
- Where appropriate, the declaration(s) of conformity and references to other applied directives,
- Place and date of the declaration,
- Authorized signature circular binding on the manufacturer or their authorized representative established in Turkey.

If the evaluation result is found appropriate, the field audit is planned. If non-conformities are detected, the field audit is planned after the non-conformities are closed. The process up to this stage is accepted as the first stage of the certification audit.
Follow-up audits should be carried out by the team that performed the field audit as much as possible.
Guides may also accompany the audits. A guide is a person who accompanies the audit team to assist them. The responsibilities of the guide may include establishing communication, arranging interviews, organizing site visits, ensuring the implementation of site safety rules, witnessing the audit on behalf of the customer, or providing information requested by the auditor.
The customer and audit team members are informed beforehand regarding the participation of guides and observers in the audit, and the customer's approval is obtained. Guides or observers do not interfere with the audit.

Audit durations should be applied according to the table below:

Audit Type	Audit Duration
ANNEX VI Internal Production Control	½ day
ANNEX VI Annual Periodic Control	½ day
ANNEX VIII Audit	Calculated according to the number of employees within the scope of Annex VIII Module H.
ANNEX VIII Surveillance	Calculated according to the number of employees within the scope of Annex VIII Module H.

ANNEX VIII Module H Certification is evaluated within the scope of the TS EN ISO 17021-1 Standard, and the following criteria must be taken into account when calculating the audit duration:

- Audit durations are calculated considering the times specified in Article 8.3.4.
- Number of employees covers the number of employees within the relevant certification scope.
- A maximum reduction of 30% can be made in the determined audit durations, provided there are necessary reduction justifications.
- The audit duration includes the planning, document review, and reporting time of the auditor or audit team.
- Agreement is reached with the firm regarding timing so that the entire scope of the certificate can be seen during the audit. Season, month, day/date, and shift (if any) are taken into account.
- Part-time employees are handled by comparing them with full-time employees depending on the hours they work. For example, two employees working for 4 hours are counted as 1 effective employee.
- The duration of Stage 1 cannot exceed 30% of the total audit duration.
- Travel times are not included in the calculation.
- Audit duration means the man-day time spent on the audit. One man-day is an 8-hour full-day working period. The number of audit days should not be reduced by programming long audit hours during the planning phase of the audit.
- Surveillance audits during the certification phase are 1/3 of the certification audit on an annual basis. Planned surveillance audits should be reviewed taking into account changes in the firm, maturity of the system, etc.
- Certificate renewal audit duration is 2/3 of the time spent on the certification audit for the same firm. The time spent on certificate renewal audit is above the time spent on routine surveillance audit. The performance of the management system throughout the certification period should be taken into account when determining the certificate renewal audit duration.
- In Management Systems certification, if a large part of the operations is carried out in shifts, the total number of employees is found as follows: Total Number of Employees = Number of People Not Working in Shift + [(Number of people working in shift)/(Number of shifts -1)].
- The number of employees of the firm is taken as a general starting point in determining the necessary audit duration; then, the actual audit duration is determined by considering the differences that may affect the audit duration to perform an effective audit specific to the firm to be audited.

8.3.2 Factors That May Require Increasing Audit Duration:

- Activity being carried out in more than one building and region,
- Staff speaking more than one language (requiring a translator or preventing auditors from working individually),
- Very large sites relative to the number of employees,
- System containing highly complex processes or a relatively large number of individual activities,
- Processes consisting of a combination of hardware, software, process, and service,
- Design responsibility regarding product-related issues,
- Opinions of competent authorities,
- Indirect conditions requiring an increase in audit duration (Example: Relations with headquarters or relations with local competent authorities),
- Additional/different environmental impacts for the sector,
- Extra/different environmental license/conditions for the sector,
- Immature management systems,
- Higher sensitivity for the environment compared to the location specific to the type for the industry sector,
- Technological and regulatory/legal requirements,
- Previous audit results,
- Outsourced activities,
- Activities requiring visits to temporary sites to verify the activities of permanent sites subject to management system certification,
- Risks related to product, process, or organization's activities,
- The organization facing legal proceedings regarding OHS (depending on the severity and impact of the associated risk).

8.3.3 Factors That May Allow Decreasing Audit Duration:

- The organization has been implementing the management system for a long time,
- The firm has prior knowledge about the system (e.g., the organization has been certified by SZUTEST according to another standard),
- Small site relative to the number of employees (e.g., office application only),
- The firm is ready for certification (e.g., certified or approved by another organization),
- Processes consist of a single general activity (e.g., service activity),
- Maturity of the management system,
- A large proportion of employees performing the same simple tasks,

- Outsourced activities,
- Identical activities being performed in all shifts.

8.3.4 Determination of Audit Durations

Module H audit durations within the scope of TS EN ISO 17021-1 standard are calculated based on the table below.

Effective Number of Employees	Certification Audit (Stage 1 + Stage 2)	Surveillance Audit	Certificate Renewal Audit
1-5	1.5	1	1
6-10	2	1	1.5
11-15	2.5	1	2
16-25	3	1	2
26-45	4	1.5	3
46-65	5	2	3.5
66-85	6	2	4
86-125	7	2.5	5
126-175	8	3	5.5
176-275	9	3	6
276-425	10	3.5	7
426-625	11	4	7.5
626-875	12	4	8
876-1175	13	4.5	9
1176-1550	14	5	9.5
1551-2025	15	5	10
2026-2675	16	5.5	11
2676-3450	17	6	11.5
3451-4350	18	6	12
4351-5450	19	6.5	13
5451-6800	20	7	13.5
6801-8500	21	7	14
8501-10700	22	7.5	14.5
>10700	Follow the sequence above		

8.3.5 Lead Auditor/Auditor/Technical Expert Appointment (Planning)

If the pre-audit evaluation result is appropriate, the Lead Auditor/Auditor/Technical Expert(s) qualified according to PR.NED.02 Qualification Procedure are assigned by the Technical Regulation Officer via FR.NED.04 Audit Team Appointment Form. Audit and auditor appointments for the firm are made via the Ministry of Industry's web-based software (ONTEK). The assigned Lead Auditor/Auditor/Technical Expert(s) transmits the FR.NED.05 Audit Plan to the firm.

8.3.6 Pre-Audit General Information

The assigned Lead Auditor/Auditor/Technical Expert carries out audit activities at the address specified by the applicant on the planned date.

Necessary occupational safety measures must be taken by the customer at the customer site during the audit to be performed. Hazards and precautions defined in TL.08 Occupational Health and Safety Rules Instruction must be taken into account by the Lead Auditor/Auditor/Technical Expert.

8.4 Performing Audit

Performing the audit consists of the following stages:

8.4.1 For ANNEX VI

It starts with a preliminary briefing by the Technical Expert with the participation of the firm official. It is not mandatory for this briefing to be in the form of a meeting. In the pre-audit briefing, the Technical Expert informs the firm about the following issues and expresses their requests:

- Introduction.
- Explanation of the audit purpose (explaining for which module and scope they are at the firm).
- Confirmation that preparations required before the audit are completed.
- Determination of the firm personnel who will accompany the Technical Expert during the audit.
- Confirmation of whether occupational safety measures have been taken (Hazards and precautions defined in**TL.08 Occupational Health and Safety Rules Instruction** must be taken into account by the Technical Expert).
- Performing the audit.
- Notification of detected findings.

8.4.2 For ANNEX VIII

- Opening meeting.
- Performing the audit.
- Audit team meeting and reporting.
- Notification of detected findings.
- Closing meeting.

8.4.3 Opening Meeting

It starts with the opening meeting held under the chairmanship of the audit team leader, attended by the audit team and firm officials. Topics in FR.NED.06 Opening/Closing Meeting Minutes Form are discussed at the opening meeting.

8.4.4 Stage 1 Audit

Stage 1 audits are carried out to control whether the firm, whose initial certification or recertification will be performed, is ready for the Stage 2 audit by reviewing the organization's documents.
The Stage 1 audit must be carried out at the customer's site address.
The audit team records Stage 1 audit results in FR.NED.28 Stage 1 Audit Report Form. If a non-conformity is detected in the Stage 1 audit, the Stage 2 audit is planned after verifying that the detected non-conformities are closed. While evidence of closure is requested from the firm for major non-conformities, an action plan is sent for minor non-conformities, and the verification of actions taken regarding non-conformities is carried out by the audit team during the Stage 2 audit.
The time between Stage 1 audit and Stage 2 audit can be a maximum of 6 months.

8.4.5 Audit

8.3.4.5.1 For ANNEX VI

The audit is carried out to meet the items specified in FR.NED.05 Audit Plan and the articles of TL.NED.01 2000/14/EC Annex VI Instruction and TL.NED.03 2000/14/EC Directive Noise Test Rules Instruction. When a situation arises where it is not possible to comply with the audit plan, the Lead Auditor/Auditor/Technical Expert informs the team leader. During the execution of the audit, the Lead Auditor/Auditor/Technical Expert must record findings, suggestions, and other important points related to the audit, for example, information such as name, code, identification of samples selected during the audit, in the FR.NED.09 Conformity Assessment Final Report in a way that guarantees that non-conformities and observations are detected based on sufficient objective evidence. In this way, information regarding audit objectives, scope, and criteria is collected and verified with appropriate sampling to become audit evidence. Methods used to collect information may be interviews, review of practices, documents and records, observation, measurement, etc.

SZUTEST:

- Performs periodic checks to verify the continuing conformity of the manufacture of equipment manufactured according to the requirements of Directive 2000/14/EC and technical documents. Particular attention is paid to the following points:
    - Whether the equipment is marked correctly and completely according to Article 9 of this Directive (2000/14/EC),
    - Whether the EC declaration of conformity has been issued according to Article 8 of this Directive (2000/14/EC),
    - Assessment results of uncertainties arising from technical equipment used and production variation and their relation to the guaranteed sound power level.

The manufacturer of the product or their authorized representative established in Turkey must allow SZUTEST free access to all internal documents supporting these, such as actual results of internal audits and corrective actions taken if any.

Only if the above checks give a non-conforming result, SZUTEST, according to its own decision and experience, subjects the relevant equipment either to a simplified noise test or to a noise test by fulfilling the provisions specified in Annex III completely.

8.4.5.2 For ANNEX VIII

Audits within the scope of Annex VIII (applying the requirements of EN ISO/IEC 17021-1 standard) consist of Stage 1 and Stage 2. Details of Stage 1 audit are specified in Article 8.3.4.4. The audit is carried out to meet the departments/processes and articles specified in FR.NED.05 Audit Plan. The audit is carried out in accordance with the methods specified for each equipment in TL.NED.03 2000/14/EC Directive Noise Test Rules Instruction. When a situation arises where it is not possible to comply with the audit plan, the Lead Auditor/Auditor/Technical Expert informs the team leader. Each Lead Auditor/Auditor/Technical Expert is responsible for auditing the areas specified in the audit program and must inform the team leader so that necessary arrangements can be made if audit durations go beyond the plan. Experts who are not Lead Auditors/Auditors/Technical Experts in the audit team must be with the Lead Auditors/Auditors/Technical Experts during the audit. During the execution of the audit, each auditor must record findings, suggestions, and other important points related to the audit, for example, names of persons interviewed, procedure article numbers related to findings, information such as name, code, identification of samples selected during the audit, in the FR.NED.07 Audit Report in a way that guarantees that non-conformities and observations are detected based on sufficient objective evidence. In this way, information regarding audit objectives, scope, and criteria is collected and verified with appropriate sampling to become audit evidence. Methods used to collect information may be 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 depending on the need. If findings that will be a problem in achieving audit objectives are reached or when an urgent and significant risk (such as safety) occurs, the team leader determines the appropriate action and reports this situation to the Technical Regulation Officer and, where possible, to the customer. Such activity may include reconfirmation or modification of the audit plan, change in audit objectives or audit scope, or termination of the audit. The decision taken is notified to the Technical Regulation Officer by the Audit Team Leader. When a change in the audit scope is considered, this situation is decided together with the customer.

8.4.6 Audit Team Meeting and Reporting

When the audit is completed, team members hold a meeting to review the findings. Review meetings are also held at the end of each day during the audit. In this meeting, audit checklists are reviewed, and the audit team compares notes. Audit findings and other appropriate information collected during the audit are reviewed against audit objectives. Agreement is reached on audit conclusions, taking into account the uncertainty inherent in the audit process. The suitability of the audit plan is confirmed, or any desired change

(e.g., scope, audit duration or date, surveillance frequency, competence, etc.) is determined. The audit report is prepared. Detected non-conformities are classified and recorded with FR.NED.10 Non-Conformity Report.

8.4.7 Notification of Detected Findings

Findings related to situations that do not meet the regulation and standard requirements detected during the audit are evaluated as non-conformities, and the customer is informed by reading these non-conformities one by one to obtain their approval. Non-conformities notified to the customer with FR.NED.10 Non-Conformity Report at the end of the audit are approved by the person authorized to represent the customer firm.

Non-conformities constitute an obstacle to certification. If the non-conformity is not resolved within 90 days, a certification or reporting decision cannot be made.

After non-conformities are resolved, depending on whether the non-conformities require on-site examination (valid only for Annex VIII), a certification decision is made by reporting if no findings are detected by repeating the entire or a part of the audit.

8.4.8 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 topics specified in FR.NED.06 Opening/Closing Meeting Minutes are discussed. The purpose of the closing meeting is to present the audit conclusions, including the recommendation regarding certification.

Non-conformities are negotiated with the firm to ensure that the evidence is correct and the non-conformities are understood. The report prepared for the official acceptance of non-conformities by the firm is submitted to the approval of the firm representative by the team leader. Following the presentation of non-conformities to the firm representative, FR.NED.10 Non-Conformity Report is signed by the firm representative as confirmation of the firm's acceptance of the findings.

All identified non-conformities must be accepted by the firm representative before the audit team leaves the firm. If the firm representative does not want to accept the non-conformities, it is stated that certification will not be possible if the non-conformities are not resolved and that they can apply to SZUTEST in writing regarding their objection if they wish.

The team leader leaves a copy of FR.NED.10 Non-Conformity Report to the firm and provides necessary information regarding the closure of the found non-conformities.

The audit team cannot make any promise or commitment regarding the date of certificate issuance in any way.

8.5 Surveillance/Annual Periodic Control Audits

Surveillance/annual periodic control audits are planned at 12-month intervals to evaluate the continuity of the system; however, audit frequency may be increased in line with customer complaints reaching SZUTEST, the degree of non-conformities, and the opinions of the certification team. The date of the first surveillance/periodic control to be carried out after the initial certification is planned not to exceed 12 months based on the certification decision date.

8.5.1 For Annex VI

In case of exceeding this period, the application and conformity assessment process is restarted from the beginning.

8.5.2 For Annex VIII

In case of exceeding, the suspension process is initiated by the Technical Regulation Officer. In other surveillance audits to be carried out after the 1st surveillance audit and in surveillance audits to be carried out after certificate renewal audits, the deviation from the planned audit date is at most +3 months. For postponement requests, a written justification (e.g., Relocation, Fair, Conference, Business Trip, Heavy Workload, Temporary Health Problems, Temporary Stoppage of Production and Service, etc.) is requested from the certified customer.

While planning the surveillance audit, the audit history specified in the certification audit report is taken as a reference. The execution, reporting, and closure and follow-up of non-conformities of the audit are carried out as in the certification audit.

On-site verification of non-conformities detected in the previous audit and whose corrective action plans were approved, control of CE mark, brand, and certificate use are carried out during the surveillance audit. If a non-conformity is found as a result of on-site verification, it is evaluated by the audit team as a non-conformity requiring follow-up audit in the non-conformity report, and the firm is left for a follow-up audit.

The final decision regarding the maintenance of the certificate belongs to the Technical Regulation Officer, as in the certification audit. If non-conformities requiring follow-up audit cannot be closed before the specified dates, the firm's certificate is suspended by the decision of the Technical Regulation Officer. The situation is notified to the firm in writing. In case corrective action plans regarding non-conformities not requiring follow-up audit are approved by the team leader, the continuation of the validity of their certificates is decided by the Technical Regulation Officer. This decision is recorded with FR.NED.09 Conformity Assessment Final Report.

8.6 Certificate Renewal Audits (For ANNEX VIII)

8.6.1 Certificate renewal audits are audits performed to recertify firms when the validity period of the certificate expires. Firms are warned by the Planning Officer (e-mail or telephone) at least 3 months before the end 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 certificate, the certificate loses its validity at the end of the certificate validity period.

8.6.2 If the firm wants to be certified again after the certificate validity period expires, the application is handled as certification, not recertification.

8.6.3 If the firm requests certificate renewal, a certificate renewal audit is carried out. A new contract is made with the firm in accordance with pricing rules. The Conformity Assessment Application Form is filled out again by the firm; the firm's old file number is valid. Planning of the recertification audit, appointment of the audit team, execution of the audit, reporting of the audit, closure of non-conformities, and making the certification decision are the same as in the certification audit. However, provided that recertification activities are completed, if the certification decision is taken and the certificate is made active within 6 months after the expiration of the certification period, the valid date on the certificate becomes the recertification date or later, and the previous certification cycle is taken as the basis for the validity period; otherwise, the process is accepted as initial certification.

8.6.4 During recertification, non-conformities detected in the previous audit and corrective actions are examined. Audit scope, new documents, brand and certificate use are controlled, and transactions are carried out as in the surveillance audit. As a result of the audit, the evaluation is made as in the certification audit.

8.7 Audit Program

The audit program recorded with FR.NED.29 Audit Program covers the initial audit containing stage 1 and stage 2 audits, surveillance audits in the first and second years, and the recertification audit in the third year before the validity of the certificate expires. The three-year certification cycle begins with the certification or recertification decision. In

determining the audit program and each subsequent arrangement, the proven level of management system efficiency, as well as the size of the customer organization, the scope and complexity of the management system, products and processes, and previous audit results are taken into account.
In addition, the following points are taken into account during the modification or development of an audit program. If there are changes affecting the certification process, these changes are obtained from the firm with FR.NED.20 Change Notification Form. The activity to be followed is determined by the Technical Regulation Officer according to the change. Considering the effect of changes on the field audit, if necessary, the audit plan can be changed depending on the following situations:

a) Scope and complexity of the customer management system,
b) Products and processes (including services),
c) Size of the customer organization,
d) Sites to be audited,
e) Language, spoken and written languages of the customer organization,
f) Requirements of the sector or regulatory bodies,
g) Needs and expectations of the customer and their customers,
h) Number of shifts and timing,
i) Necessary audit duration for each audit activity,
j) Competence of each member of the audit team,
k) Need for auditing temporary sites,
l) Results of other previous audits or stage 1 audit,
m) Results of other surveillance activities.

The following activity sequence is taken into consideration in the preparation of the audit program:
a) Certification Audit Stage 1
b) Certification Stage 2
c) Surveillance Audit
d) Follow-up Audit (if any)
e) Certificate Renewal Audits

8.8 Other Situations Regarding Conformity Assessment Process

8.8.1 Suspension of Audits

Suspension of the conformity assessment activity can only be in question when the following conditions occur:

- If it is detected that requirements regarding the product within the scope of conformity assessment or legal sanctions are not fulfilled,
- If conditions during conformity assessment negatively affect the health of the audit team or pose a danger,
- If serious problems preventing the continuation of conformity assessment are detected in the implementation of the system and it is understood that a follow-up audit is inevitable (Suspension of conformity assessment under these conditions is an exceptional situation and should be resorted to as a last resort. In such cases, renewal of conformity assessment becomes mandatory).
- If serious problems are encountered in accessing relevant personnel, relevant department or work, records related to product or service, or if a bribe is offered.
- Also, if the firm requests the suspension of conformity assessment due to firm-originated reasons, it can be suspended provided that the conformity assessment is repeated.

When the team leader decides to suspend the conformity assessment, they must contact the firm representative and explain the reason. At the decision-making stage, the team leader should consult the **Technical Regulation Officer** if needed. The team leader explains the reason for the suspension of the conformity assessment by calling the firm's senior management to a meeting. If the firm's request for certification is still valid, it is stated that a repetition of conformity assessment will be made later provided that the relevant non-conformity is resolved. All details regarding the suspension of conformity assessment must be specified in the report. The relevant report is sent to the firm in writing.

8.8.2 Follow-up of Detected Non-Conformities

8.8.2.1 For ANNEX VI

The responsibility for following up on non-conformities belongs to the manufacturer firm. The closure period for non-conformities is a maximum of 60 days. In case of exceeding this period, the application and conformity assessment process is restarted from the beginning.

8.8.2.2 For ANNEX VIII

The firm representative is requested to define the necessary activity to eliminate the non-conformity and the preventive activity to prevent its recurrence in the Non-Conformity Report and send it to SZUTEST within 10 business days. The team leader verifies and signs by checking that the activity specified in the form is sufficient to eliminate the non-conformity and prevent its recurrence and complies with the given periods. However, if it is understood that the activity defined by the firm is not sufficient to prevent the recurrence of the non-conformity, it is returned to the firm without approval by the team leader, stating the reason, to be reviewed again in the Non-Conformity Report.
The maximum time allowed for the realization of correction and corrective actions for the closure of all non-conformities is a maximum of 60 days from the date the non-conformity was written, regardless of the magnitude of the non-conformity (it must be ensured that the time to be determined in the certificate renewal audit is before the date the certificate validity period expires).

8.8.3 Closing Non-Conformities via Follow-up

8.8.3.1 For Annex VI

The firm representative requests a re-audit by describing that the non-conformities have been eliminated with the FR.NED.10 Non-Conformity Form. By performing an on-site audit where the described non-conformity has been eliminated and collecting objective evidence, the FR.NED.09 Conformity Assessment Final Report is filled out again.

8.8.3.2 For ANNEX VIII

A follow-up is planned for non-conformities requiring on-site verification. The appointment and planning process for follow-up is carried out as in the normal conformity assessment process.
Follow-ups are carried out by the Lead Auditor/Auditor/Technical Expert who served as Team Leader in the initial assessment as much as possible. If corrective actions are found appropriate in follow-up audits, the certification stage is proceeded to in certification and certificate renewal audits, and the continuity of the certificate is ensured in surveillance audits.

8.8.4 Unannounced Audits (For Annex VIII)
SZUTEST may perform unexpected audits on the product's manufacturing/assembly area or the firm. During these audits, SZUTEST may perform or request tests to check the proper functioning of the quality assurance system and the product if necessary; it must give the audit report and, if a test has been performed, the test reports to the firm.
In particular, a visit control plan is created considering the following factors:

- Category of the equipment,
- Results of previous audit visits,
- Need for corrective action,
- Special conditions connected with the approval of the system,
- Significant changes in production organization, policy, and technique.

Also, when there are complaints containing objective evidence regarding the firm, or if a non-conformity is detected in Market Surveillance and Inspection carried out by the Ministry, the Technical Regulation Officer may decide to perform an audit even if it is not in the program.
When appointing the audit team to perform the audit, the Technical Regulation Officer assigns an audit team that is different from the previous audit team and competent to interpret the subject of the complaint.

If the firm does not accept the audit, its certificate is suspended by the decision of the Technical Regulation Officer, and the situation is notified to the firm in writing. SZUTEST has stated in the contract signed before the service that it can take this decision.
If SZUTEST detects that the conditions constituting the basis for the certificate it has issued do not exist as a result of the audit it has performed, it suspends or cancels the certificate according to the nature of the unfulfilled conditions. It provides necessary information for market surveillance and inspection purposes to the authorized branch of the Directorate General for Industry of the Ministry of Industry and Technology and the authorized body performing market surveillance and inspection related to the subject, and if envisaged in the relevant technical regulation, to the authorized bodies of European Union member countries. It presents information regarding assessment procedures to the commission if requested.

8.8.5 Change Audits (For Annex VIII)
These are audits carried out to control changes such as change of firm title, change of firm activity scope, change of firm address and branches. If the official status of the firm has changed (address, title, etc.) before change audits, the service contract is renewed.
Change requests are obtained from firms via FR.NED.20 Change Notification Form. It is decided by the Technical Regulation Officer whether a document review or field audit will be performed, and it is noted on the form. In scope extension and address change audits, in addition to document review, a field audit is carried out in the required time depending on the scope and production place and recorded with an audit report. In change audits where a field audit is not required, the Technical Regulation Officer may decide on the certificate change themselves, provided that it depends on objective evidence. (Example: Scope reduction, changes made by local administration such as street, avenue, door number).

8.8.6 Transfer Process
Transfer Audits cover examination and verification activities carried out to confirm the accuracy and validity of the certificate for the purpose of moving a valid and accredited Directive 2000/14/EC conformity certificate issued by another certification body to SZUTEST.
The transfer process aims to protect the customer's current certification status and maintain the certification cycle uninterrupted.
Transfer Audit Initiation Conditions
Certificate transition is evaluated as a transfer audit if the following conditions are met.

The certificate issued by the transferring certification body must:

1. Be accredited by an IAF member accreditation body,
2. Be in valid (not suspended) status,
3. The candidate firm's scope of activity must be compatible with SZUTEST's accreditation scope,
4. The last audit of the firm applying for transfer must have been carried out at most 12 months before the transfer audit date,
5. Major non-conformities reported by the previous certification body must have been closed, and acceptable correction plans must be presented for minor non-conformities.

Transfer Application and Preliminary Review Process

- Copy of valid certificate,
- Previous audit reports (initial certification, last surveillance or recertification),
- Non-conformity reports and closure records,
- Complaint records and actions taken,
- Statement regarding the firm's reason for transfer,
- Certificate scope and address information,
- Ongoing proceedings with current legal or regulatory authorities (if any),
- Previous audit dates.

Transfer applications are received in the same format as certification audit applications. The above documents are requested from the candidate firm.

Audit Type and Necessity

SZUTEST primarily conducts the evaluation for the transfer process over documentation. These documents include the firm's current certificate, previous audit reports, non-conformity records, and scope information. If all information is clear and consistent, the entire process is completed as a desk review.

- However, a preliminary transfer visit may be made in the field in the following cases:
  - Uncertainty of open major non-conformities,
  - Doubt about the validity of the certificate,
  - Insufficiency of previous audit reports.

  Note: The visit made in the field is only for evaluating the transfer, and this operation is not reported as a separate audit.

Certification Decision

1. When all conformity conditions are met, a new certificate is prepared and published by SZUTEST in accordance with the validity period of the transferred certificate.
2. In this process, the current certification cycle is preserved. For example:
   - If the transfer operation coincides with a period between surveillances, the surveillance audit is performed according to the current plan.
   - If the certificate is about to expire, a recertification audit is performed.
3. Persons performing the transfer evaluation and persons making the certification decision must be different.

Rejection of Transfer

The transfer is rejected, and the applicant is evaluated as a new customer in the following cases:

- The certificate is not valid (suspended, withdrawn, etc.),
- Previous audit reports cannot be presented,
- Major non-conformities have not been closed,
- Activities not fitting SZUTEST's scope,
- Audit date limit has been exceeded (>12 months),
- If the certificate does not carry IAF accreditation.

The rejection decision is documented with reasons and notified to the customer in writing.

Notification Obligation

After completing the transfer process and issuing the new certificate, SZUTEST sends a written notification to the transferred certification body. This notification includes:

- Customer name,
- Transfer date,
- Reference and duration of the new certificate.

8.9 Changes Occurring in Certified Products

In case of a change in the design, technical file, or components of a certified product, this change should be evaluated by SZUTEST following the steps below. The customer transmits the change to SZUTEST using FR.NED.01 2000/14/EC Conformity Assessment Application Form and FR.NED.20 Change Notification Form.
The change is evaluated by the Technical Regulation Officer, and necessary technical or legal documentation is requested from the firm.
Relevant documents sent by the customer are examined by the Technical Regulation Officer. The effect of changes on the basic requirements of regulations and standards is checked. Changes that may cause deviation from the conditions specified in basic requirements are checked by performing an audit. The process for Annex VIII is carried out as described in article 8.3. The process for Annex VI starts again with an application.

8.10 Review and Decision

It is carried out according to PR.NED.04 Certificate and Report Operations Procedure.

8.11 Reporting and Certification

It is carried out according to PR.NED.04 Certificate and Report Operations Procedure.