PROCEDURE "APPROVAL OF A FULL QUALITY ASSURANCE SYSTEM"

1. FIELD OF APPLICATION

The working procedure shall apply to the machinery and equipment referred to in Article 6 of the Ordinance on the Essential Requirements and the Assessment of the Compliance of Noise Emission in the Environment by Equipment for Use Outdoors (Article 12 of Directive 2000/14/EC).

2. ORDER OF ACTION

2.1. General provisions

The CTEC review, assess, approve and supervise the manufacturer's full quality assurance system (**FQAS**) in the design, manufacture, control and testing of the final product for compliance with the requirements of Directive 2000/14/EC within a functioning system for full quality assurance, for example implemented in accordance with the criteria of BDS EN ISO 9001.

The actions for the implementation of the procedure for approving the FQAS include:

- Receipt of the technical file of the respective machine and the documentation of the FQAS by the CTEC;
- Review and approval of the submitted documentation;
- Audit of the FQAS on the manufacturer's site;
- Preparation of a report on the results of the audit with a proposal for a decision;
- Submission of the proposal for decision to the Manager for approval;
- Notification of approval/refusal/withdrawal of approval of the manufacturer's FQAS and other authorities for conformity assessment;
- Periodic oversight of the maintenance of the FQAS;

CTEC require the assignor/applicant to notify CTEC of all their intentions for amendments to the approved FQAS.

5.2. Preparation for evaluation. Obtaining the documentation of the FQAS

In order to initiate a procedure for approval of the FQAS of a machine/facility, CTEC require the assignor (the applicant) to submit an application containing:

5.2.1 Application for each product type

All the necessary data for the product category envisaged, including the technical files of all the machinery requested, which are in the design or production phase. The data shall give at least the following information:

- the name and address of the manufacturer or his authorized representative;
- a description of the machine or equipment;
- brand;
- trade name;
- type, series and numbers;
- technical data relevant for the identification of the machine and the assessment of its the noise emission, ncluding drawings, descriptions and explanations necessary for its understanding, if necessary;
- reference to the Ordinance/Directive 2000/14/EC;

- test reports for noise measurements according to the requirements of the Ordinance / Directive 2000/14/EC, the technological processes - the used technical means and the results of assessment of the uncertainties due to the fluctuations in the production processes and their influence on the guaranteed sound power level;
- copy of the declaration of conformity;

5.2.2 Quality system documentation, which includes:

- Quality Manual - with announced quality objectives, organizational structure, responsibilities of the management regarding the quality of the project and the product;
- Documented procedures covering the means and methods of management and verification of the design and product, processes and systematic actions that are applied in the design of the products of the relevant category, the means and methods of production, control and quality assurance;
- Studies and tests carried out before, during and after manufacture, indicating their periodicity;
- Surveillance methods to achieve the required project and product quality (machine or equipment):
- Use of dampers;
- Sound-proofing barriers;
- Prevention of resonance phenomena (resonance-ribbing vibration);
- Opportunities for approving the acoustic behavior of the entire facility in acoustic checks of individual modules.
- Relevant operational documents;
- Quality records - control reports, test and calibration data, staff qualification reports, evidence of the efficient and effective functioning of the quality management system / quality system, which include:
  - ✓ the availability of correct records in connection with the verification and approval of the projects / developments;
  - ✓ the existence of a system and responsibilities for the effective monitoring and strict observation of the requirements valid for the products regulated in the Regulation / Directive 2000/14/EC;
  - ✓ the availability of correct records on the quality of the products delivered;
  - ✓ correct and complete records regarding control during production and final control of the machinery/equipment;
  - ✓ information on the level of customer satisfaction, including coverage and claims made by them and meeting the requirements of valid regulatory and specific customer requirements;
  - ✓ introducing effective corrective and preventive actions in the design and manufacturing phases of the machinery/equipment.

When accepting the application and the technical file the following actions are taken:

- Check the documentation provided (TF) for legibility, cleanliness and clarity (CTEC do not accept TF containing polluted, torn and / or illegible documents. In such cases CTEC require the customer to replace damaged or inaccurate documents).
- Complete the "Protocol for verifying the content of the TF" and
- If the TF does not contain all the documents mentioned (description of the machinery / equipment, trade mark, trade name, type, series, number, technical data necessary for identifying the machinery or equipment and for assessing the noise emission, including drawings and necessary for their understanding descriptions and explanations, if necessary) CTEC do not accept and require the assignor to provide and present missing documents;
- When the content of the TF is complete, CTEC accept the file.
- If a complete compliance is not established, the FQAS documentation is not accepted. The Assignor undertakes to complete the materials within 15 working days. Sending missing documents can also be done by mail / courier;

5.3. Review and approval of the submitted documentation

Within 5 working days, team members present to the team leader a conclusion on the compliance of the FQAS documentation with the full quality assurance requirements. FQAS needs to ensure compliance of the machinery or equipment with the requirements of the Regulation - guaranteed sound power level, marking, declaration of conformity, test reports.
When:
- the documentation is in compliance with the requirements or with non-essential / acceptable deviations, CTEC specifie with the applicant the date / time for conducting an on-site audit;
- the documentation does not comply with the requirements, CTEC inform the applicant in writing of the discrepancies and specify a time limit for their removal.

5.4. Audit on the manufacturer's site to assess the compliance of the FQAS.

The deadline for carrying out the initial audit is up to 1 month after the approval of the documentation under item 5.3.
During the audit, the team collects objective information about the compliance of the audited activities and records with the requirements of the FQAS documentation.
The Team Leader (Lead Assessor) assigned to the Laboratory for Testing of Machines, Equipment and Devices at CTEC a test to determine the compliance of the machines with the requirement for a guaranteed sound power level.
Additional audit is carried out in the event of critical inconsistencies relating to failure to ensure the efficient operation of the manufacturer's quality assurance system, significant failures to ensure traceability at the various stages of the design / development, control and implementation of appropriate corrective and preventive actions, evidence of the removal of which can not be provided in the course of the planned audit.
Only one additional audit is allowed.
The audit ends when it is established that there are no unresolved inconsistencies.

5.5. Report on audit results

Within 10 (ten) days of completing the audit, the Team Leader compiles and submits to the audited entity an "Audit Repor of the FQAS".
The report is in two copies (one for the applicant and one for the CTEC).

5.6. Approval / withdrawal of approval of the

The decision to approve / refuse to approve the FQAS of the evaluated machine / equipment is taken by the Manager of the CTEC based on the report by the team leader and the documents used during the audit.
An "Approval of the FQAS" is prepared in two copies when the decision is the FQAS to be approved;
A "Cover Letter" is prepared, which contains the reasons for the decision taken - approval or refusal to approve the FQAS;
By the decision of the manager, the notification of the outcome of the procedure (the sending of the cover letter and / or the transmission of the certificate) to the contracting authority (the applicant) may be withheld (for example, in the case of unsettled financial relations).

5.7. Periodic monitoring of the maintenance of the FQAS

5.7.1 Proposals for Modification of an Approved COP

The manufacturer / applicant, in fulfilling the obligations arising out of the approved quality system and maintaining its correct and efficient operation, shall notify the CTEC of any intended modification thereof. The team of auditors who carried out the quality system evaluation shall be convened to a working meeting by a head of department who discusses the proposals for change. The team leader documents the decision whether, after the quality system changes, it still complies with the requirements to ensure that the product (machine or equipment) is in compliance with the requirements of the Ordinance or a reassessment is required. When the solution is:

- ✓ the system continues to meet the requirements to ensure compliance of the product (machine or equipment) with the requirements of the Ordinance / Directive 2000/14 / EC, the documented decision of the team is added to the file of the assignor (the applicant) together with the reviewed documents and the team leader notifies the manufacturer / applicant for the approval of the proposals for change;
- ✓ the system does not continue to meet the requirements for compliance of the product (machine or equipment) with the requirements of the Regulation / Directive 2000/14 / EC, a new assessment is necessary, the team leader shall undertake an extraordinary audit under this procedure.

5.7.2 Supervision

CTEC shall carry out, in consultation with the applicant / manufacturer, periodic supervision to verify the maintenance of the approved FQAS intended to ensure the accurate performance of the manufacturer's obligations under the approved quality system.
Periodic supervision is carried out through supervisory audits conducted at least once a year within a period of ± 2 months compared to the month of the previous audit.

For the purpose of surveillance, the manufacturer shall provide CTEC with access to the locations of design, manufacture, control, testing and storage and with all necessary data:
- documentation of the quality system;
- quality records related to design, analysis results, calculations, tests, etc.;
- quality records related to production - control reports, test data and calibration of the technical measuring and testing equipment, qualification reports of the personnel, etc.
The audit manager shall provide the manufacturer with an audit report.
The validity of the approval in the performance of the manufacturer's obligations under the approved quality system is 3 years. The decision to maintain the approval or the withdrawal of the approval of the FQAS is taken by the manager on the basis of the report of the team leader on the procedure set out in this procedure.
If a decision is taken by the manager to withdraw the approval, CTEC shall notify the other notified bodies.

5.7.3 Unannounced on-the-spot checks

In addition to planned periodic audits, CTEC also performs unannounced inspections at the manufacturer's site, following a proposal made by the head of department and an order of the CTEC Manager. Unannounced inspections are carried out in the event of signals on the compliance of a machine / facility or the functioning of the FQAS with the requirements of the Ordinance. These inspections are carried out and documented by the team according to the general audit rules under this procedure, in order the CTEC to be sure that the manufacturer correctly maintains and applies the approved FQAS.
The team decides wether there is a need for testing. If such a need arises, a team leader assigns a test to the Laboratory for Testing of Machines, Equipment and Devices at CTEC or to the manufacturer to check the conformity of the machine / equipment. When the test is conducted by the manufacturer, it is supervised by the audit team.
The team leader shall provide the applicant / manufacturer with a inspection report and test report when a test has been performed.
In the event of discrepancies, a regular surveillance audit shall be carried out.

5.8. Recognition of certificates for implemented quality management systems

When the manufacturer / applicant has a Quality Management System (QMS) certified in accordance with BDS EN ISO 9001, the assessment performed by the NB-team is based on records and material evidence for the efficient functioning of the QMS and evidence of the correctly performed control of the machinery / equipment as required by the Regulation / Directive 2000/14 / EC.
In the presence of an efficiently functioning QMS, the team focuses on the collection of evidence for the implementation of the QMS in the production and realization of the machine / equipment subject to evaluation. The evaluation includes:
- assessment of this part of the Sofia University degree, which corresponds to the requirements of the Regulation / Directive 2000/14 / EC;
- an on-site audit in a reduced timeframe focusing on:
  - ✓ verification of the entire production cycle;
  - ✓ project / development verification;

- ✓ control activities in all phases of product realization;
- ✓ effective corrective and preventive actions with a reduction in the sound power level of the machines / equipment.

- questionnaire with excluded general questions, the team prepares appropriate specific questions that comply with the requirements of the Regulation / Directive 2000/14 / EC;
- review and evaluation of the results of the tests carried out by the manufacturer and, by the Laboratory for Testing of Machines, Equipment and Devices at CTEC, when applicable;
- verification of records showing conformity of the evaluated machine / equipment with the requirements of the Ordinance/Directive 2000/14/EC, internal audit results, management reviews, analysis of statistical evaluations related to the requirements of the Ordinance/Directive 2000/14/EU.