

TURKISH STANDARDS INSTITUTION

NEW GLOBAL OLD APPROACH REGULATIONS CONFORMITY ASSESSMENT PROCEDURES AND PRINCIPLES

Board Decision : 29.04.2014 Date 50.-236
Validity date : 05.05.2014

CHAPTER ONE

Objective, Scope, Legal Basis, Abbreviations, and Definitions

Objective

ARTICLE 1 - (1) In addition to the article 1 of Certification Directive;

(2) This has been prepared in order to determine the procedures and principles on Conformity Assessment processes to be applied in the legal metrology area of measurement and measurement devices and in the New/Global/Old Approach Regulations to be applied by the Turkish Standards Institution pursuant to the assignments by Authorized Bodies.

Scope

ARTICLE 2 - (1) These Procedures and Principles cover the conformity assessment processes to be applied to the products under the scope of assignment of the New/Global/Old Approach Regulations prepared by means of harmonizing the European Union New/Global/Old approach directives and include the conformity assessment and certification activities of the products under the legal metrology area of assignment on measurement and measurement devices, and the principles of pricing of the services provided.

Legal Basis

ARTICLE 3 - (1) These procedures and principles have been prepared based on the TSE Certification Directive.

Abbreviations and definitions

ARTICLE 4 - (1) In addition to the article 4 of Certification Directive;

(2) For the purposes of this directive, the definitions in New/Global/Old Approach Regulations and other legislations apply. The relevant definitions in these procedures and principles shall have the meaning adjacent to;

a) AEA: European Economic Area;

b) Authorized Body: a public institution or organization authorized by law or a regulatory act to draw up or implement legislation concerning to a specific product or a product group or to implement Law numbered 4703 and the provisions of the Law with regards to products falling into its area of responsibility;

c) Technical Regulation: Any mandatory legislation laying down one or more of the characteristics or processing and production methods of a product or the related terminology, symbols, packaging, marking, labelling and the conformity assessment procedures;

- d) **Basic Requirements:** The minimum safety conditions of a product with regards to human health, security of life and property, living and health conditions of animal and plants, protection of environment and consumers which are set out by technical regulations;
- e) **New Approach Regulations:** A type of technical regulations meaning national legislation prepared by means of harmonizing the European Union New Approach Directives;
- f) **Global Approach Regulations:** A type of technical regulation meaning national legislation prepared by means of harmonizing the European Union Global Approach Directives;
- g) **Old Approach Regulations:** A type of technical regulation meaning national legislation prepared by means of harmonizing the European Union Old Approach Directives;
- h) **Conformity Assessment:** Any activity to test, inspect and/or certify the conformity of the product with the relevant technical regulation;
- i) **Conformity Assessment Body:** Private or public institution responsible for any activity to test, inspect and/or certify the conformity of the product with the relevant technical regulation;
- j) **Applicant:** Real or legal person requesting the Conformity Assessment service, assuming the responsibilities set forth by the relevant Technical Regulation;
- k) **Conformity Certificate:** The written certificate issued upon successful conclusion of an conformity assessment;
- l) **Examination Report:** The written document issued upon a conformity assessment;
- m) **Company/Certificate/Applicant:** The party requesting the conformity assessment service.

CHAPTER TWO

Certification Bodies

Decision making body

ARTICLE 5 - (1) In addition to the article 8 of Certification Directive;

(2) **Conformity Assessment Committee:** The committee consisting of persons who were proposed by the department, which was assigned for enforcing the conformity assessment activities under these procedures and principles based on the objectivity, independence, and transparency principles, and approved by President of TSE, and who are working at TSE and have experience and knowledge of conformity assessment services.

(3) **Conformity Assessment Committee** is the decision making body which makes general assessment for conformity assessment processes in the fields where TSE is assigned as the Notified Body.

CHAPTER THREE

Certification Processes

Application conditions and admission

ARTICLE 6 - (1) In addition to the article 12 of Certification Directive;

(2) The applications under these procedures and principles are made to TSE by filling out the printed application form prepared by TSE and by attaching the administrative and technical documents stated in the application form.

(3) Application conditions and admission for the conformity assessment activities are held pursuant to procedures below:

a) Each application is assessed by TSE. In case any deficiency is determined in the application documents, the applicant is responsible for completing the deficiencies within 6 (six) months. The applications of those who do not complete their missing documents within 6 (six) months are nullified and application documents are returned upon request.

b) Of the amount paid by the applicants the application of whom were nullified, the amount corresponding to the processes performed until that time is kept and the remaining amount is paid back.

c) When the applicant wants to make another application under the same scope, processes shall be initiated as if a new application.

d) If an inspection was carried out in the production facility; the new applications, scope enlargement, scope reduction or termination requests by the applicant can be taken by hand by the assigned experts and such requests are submitted to the relevant department after arrival. Regarding new applications or scope enlargement requests, an inspection may be carried out if relevant subjects are under the scope assigned to the inspection committee. In the case the period given is not adequate, additional time is requested by contacting the relevant department. The inspection of scope correction or termination requests is drafted accordingly.

e) In the case the certificate owner produces a previously certified product in the same production facility with a trademark/type/model different than the one on the certificate and makes an application for this trademark/type/model as well; along with the application documents, a declaration of uniformity is requested from the applicant to prove that no change/difference has occurred in the trademark/type/model applied for.

f) In the case the previously certified type is produced in the same production facility but on behalf of another person stated on the certificate or declared on the first certification application, an agreement must be signed between the manufacturer and the trademark owner proving that no change/difference has occurred in the type applied for and assuring the sustainability of uniformity, and this agreement must be submitted to the Institution.

g) Assessment is carried out by comparing the relevant technical documents of the product of application to the documents of the certified product and the process of application is finalized with the decision of Conformity Assessment Committee.

h) The new certificate/certificates issued after the declaration of uniformity shall be effective as long as the reference certificate/certificates of comparison are effective.

Sampling/providing sample and transfer

ARTICLE 7- (1) Sampling, providing sample and transfer processes are performed pursuant to the procedures below:

a) In the case the samples representing the product of application are to be submitted by the applicant, such samples can be submitted to the laboratories designated by TSE by the applicant.

b) In the case the samples are to be taken from the production facility by TSE, the samples taken can be submitted to the laboratories designated by TSE without making any changes on seal, marking, and labels.

Surveillance and assessment

Article 8 - (1) The assessment results of the conformity assessment of the product are finalized by the Conformity Assessment Committee. The agreement based on the conformity certificate issued upon positive decision of the Conformity Assessment Committee is signed mutually.

(2) In the case there non-conformities in the reports prepared based on the Conformity Assessment and no additional time is given by the Conformity Assessment Committee, the applicant shall be responsible for satisfying the non-conformities within 3 (three) months at the latest. Unless the non-conformities are satisfied within the designated period, it is submitted to the Conformity Assessment Committee for final decision and notifications assumed by the relevant technical regulations are made.

(3) In the case the examination and tests carried out pursuant to the relevant regulations for type approval under the old approach regulations give a positive result, examination and test reports and the type approval documents to be issued according to the relevant regulations shall be submitted to the relevant ministry. The fees realized before this submission procedure must be collected before the process. One copy of those sent shall be kept in the Institute. One copy of the examination and test report is also sent to the applicant.

CHAPTER FOUR

Processes after the Conformity Assessment

Scope Change

ARTICLE 9 - (1) In addition to the article 19 of Certification Directive;

(2) In the case a scope change is requested for the certificate, the process is finalized in the framework of the decision to be taken by the Conformity Assessment Committee following the completion of processes decided upon the assessments by TSE.

(3) The date of submission of the first certificate is based for the effective date of the certificate and a new agreement is signed for the modification made.

Modifications on application and conformity certificate details

ARTICLE 10 - (1) In addition to the article 20 of Certification Directive;

(2) In the case any change has been applied to the application documents of the applicant who procured a conformity assessment service from TSE, the applicant shall be responsible for notifying TSE of the documents to be prepared again including the details of the changes within 30 (thirty) days and for submitting such documents thereof.

(3) As a result of the assessment by TSE, if it is decided that the changes do not affect product responsibility and do not modify the product, new conformity certificate is issued without repeating the conformity assessment processes. Otherwise, conformity assessment processes are fully or partially repeated. All relevant changes are notified to the Authorized Body and other relevant institutions.

(4) If the validity period of the certificate issued upon the CE marking conformity assessment processes was defined, certificate renewal inspection shall be carried out before this term expires upon request of the certificate owner.

(5) This term can be deferred up to 4 (four) months in case of force majeure (i.e. acts of God, economic crisis, heavy health problems etc.). If the application for certificate renewal inspection is made within the Certificate validity period and up to 4 (four) months following the certificate validity period, file / document inspection fee is not collected.

(6) For the applications made out of the periods given above, certificate renewal inspection is not carried out, in this condition, the certification process must be initiated with the application form again and the fees are collected as if it is a new application.

(7) If no application is made to renew the certificate, documents can be returned on condition that the correspondences are conserved in the archives.

Changes related to product and system

Article 11 - (1) In the case any change is made on a product or production process with conformity certificate, the application documents including the details of the changes shall be submitted to TSE within 30 work days at the latest. Application examination is performed on such documents. As a result of the examination held, the validity of conformity certificate is maintained without repeating the conformity assessment processes if the changes do not affect the conformity of the product (conformity to basic requirements of relevant technical regulations) and/or system (conformity to basic conditions of relevant technical regulations). Where required, conformity assessment processes are fully or partially repeated.

Surveillance (interim audit)

ARTICLE 12 - (1) In addition to the conditions stated below according to article 21 of Certification Directive; surveillance activities shall be carried out in line with the regulation of Conformity Assessment.

(2) In case it is required by the conformity assessment process, quality system modules certificate renewal inspection every 3 years and periodic controls shall be carried out to control whether the sustainability of quality assurance system or factory production system or conformity with the certified type, which were approved by TSE, is maintained or not. This condition may change based on the current status of regulations.

(3) If non-conformities were determined during the periodic control, the activities to correct such non-conformities shall be decided and relevant period shall be allocated for realizing such activities. Unless the non-conformities are corrected within the given period, the certificate is suspended pursuant to the Agreement signed and the situation is notified to the Authorized Body.

(4) The non-conformities are expected to be corrected during the suspension period and certificate owner and the market surveillance mechanism is notified of that the product shall not be released to the market in this period.

Notifications

Article 13 - (1) The relevant notifications of products with conformity assessment done shall be made pursuant to “Regulation On The Notification Of The Technical Legislation And Standards Between Turkey And The European Union”.

(2) If the certificate’s owner awarded with the CE/π marking as a result of the conformity assessment services by TSE uses this CE/π marking or Notified Number wrongly or any non-conformity with the agreement is determined, TSE shall make relevant notifications to the organization responsible for market surveillance.

Changes on the technical document basis for the certification

ARTICLE 14 - (1) In addition to the article 23 of Certification Directive;

(2) Changes on principles of conformity assessment shall be enforced pursuant to provisions of relevant New/Global/Old Approach Regulations and other relevant legislations.

ARTICLE 15 - (1) In addition to the article 28 of Certification Directive;

(2) As a result of the interim audit or follow-up processes, WARNING notification is made to the owner of conformity certificate with the justified decision of Conformity Assessment Committee in order to correct the non-conformities which do not directly violate the conformity with the basic requirements of the technical regulations. The certificate owner is responsible for notifying TSE in writing of the corrective activities he/she realized to conform to the requirements of warning within the given time.

(3) The certificate is suspended with the decision of Conformity Assessment Committee in the cases that:

a) Certificate owner does not follow the contractual requirements;

b) Non-conformities notified for correction are not corrected;

c) Determination of non-conformities violating at least one of the basic requirements of technical regulations as a result of the interim audit or follow-up processes;

d) The certificate owner requests suspension due to force majeure such as strike, lock-out, transfer of company if it is a legal person, acts of God, limited raw materials, limited orders etc.;

e) Certificate owner does not follow the conformity marking rules of use.

(4) Suspension period of certificate is determined by Conformity Assessment Committee up to 6 (six) months at maximum.

(5) Certificate owner is responsible for stopping the use of conformity marking by the declaration of suspension decision and for not declaring that the product is certified during the suspension period.

(6) When it is proven that the cause for suspension of certificate has been eliminated Certificate is validated again with the decision of Conformity Assessment Committee.

(7) Notifications relevant to suspension of certificate shall be made.

(8) As a result of the assessment at the end of the suspension period and with the request of certificate owner in writing, decision to maintain the suspension of certificate for a certain period may be taken for once period by Conformity Assessment Committee.

Withdrawal of certificate and termination of agreement

ARTICLE 16 - (1) In addition to the article 29 of Certification Directive;

(2) Certificate utilization agreement and certificate of the certificate owner may be withdrawn by the decision of Conformity Assessment Committee.

Causes for withdrawing the agreement and certificate are given below; if:

- a) Non-conformity is not corrected at the end of suspension period;
- b) A change is made on a product with conformity certificate and this change is not notified to TSE;
- c) Validity period of conformity certificate has expired;
- d) Certificate owner does not fulfill the obligations undertaken in the agreement signed during the grant of certificate;
- e) Certificate owner goes bankruptcy or stops the activity under the scope of certificate;
- f) Conformity certificate is used unfairly and misleadingly;
- g) Certificate owner himself/herself requests;
- h) Some changes are made on the relevant Technical Regulations regarding the Conformity Assessment of the product;
- i) Notified Body status of TSE for the relevant Technical Regulation or product is removed.

Processes following the withdrawal of conformity certificate

Article 17 - (1) Withdrawal of the conformity certificate is notified to the authorized body and other organizations stated under the relevant legislations and the agreement is terminated. Owner of conformity certificate is liable to pay the current debt and termination expenses, and stop using the conformity marking and the certificate.

Unfair use of notified body number or conformity assessment certificate

Article 18 - (1) All relevant documents are submitted to Legal Consultancy Department for imposing necessary legal and criminal actions against those who use the conformity assessment certificate-notified body number without any agreement signed or who use the conformity assessment certificate-notified body number although their agreement has been terminated for any reason.

Mutual recognition, and recognition and use of foreign country conformity certificates

Article 19 - (1) For recognition by TSE of conformity certificates and test reports given by other conformity assessment bodies, Turkey's national legislation, AEA legislation and principle on conformity with the internationally accepted criteria and mutual recognition are based respectively.

Product responsibility

Article 20 - (1) It is the responsibility of certificate owner, who places the product in the market, to ensure that a product conforms to relevant Regulations and to sustain this conformity. Any damage arising from the product awarded with a conformity certificate upon completion of conformity assessment processes shall belong to the conformity certificate owner.

CHAPTER FIVE

Validity, Change in Certification Procedures and Principles and Execution

Validity

ARTICLE 21 - (1) This Certification Procedures and Principles has been accepted with the Board Decision of TSE dated 29/04/2014 and numbered 50-236 and shall be effective as an attachment to Certification Directive by the date of 05/05/2014.

Change in Certification Procedures and Principles

ARTICLE 22 - (1) Board of Directors is authorized to change this Certification Procedures and Principles.

Execution

ARTICLE 23 - (1) The provisions of this Certification Procedures and Principles shall be executed by General Secretary of TSE.