Rules for the preparation, granting and maintenance of validity of Slovenian Technical Approvals (STS's) for construction products

Document for customers

1. Introduction

These rules provide a definition of the procedures involved in the preparation, granting, maintenance and withdrawal of Slovenian Technical Approvals (STS) for construction products. They include a definition of the tasks and responsibilities of both the Approval Body and the Applicant for the STS in the procedure for the preparation of the STS, and therefore serve as a reference document (a copy of the rules shall be supplied to the Applicant together with the acknowledgement of receipt of the application; the rules are also accessible on ZAG's web pages), at the applicant request, the document can be sent by regular mail or e-mail) In particular, these rules are for the use of manufacturers and suppliers of construction products who intend, in accordance with the provisions of the Construction Products Act – ZGPro-1 (Official Gazette of RS, No.82/2013) to apply to the Approval Body, ZAG, for a Slovenian Technical Approval (STS) for a construction product. More complete information about the procedure for acquiring an STS can be accessed at the Approval Body's website:https://www.zag.si/en/certificates-and-approvals/service-for-technical-assessment-and-approvals/.

The *informal meeting* is intended of interested producers with the process of obtained and content of the STS before submitting a formal application for of the STS. In the context of this informal meeting, either the Approval Body or its authorized representative will be able to provide more detailed information:

- about the application for a STS, and about which documents about the product and its intended use have to be submitted in the procedure;
- about a rough estimate of the costs involved, and about the anticipated time schedule for the preparation and granting of the STS; the actual costs and deadlines for the preparation of the STS will be defined later, on the basis of the work program for the preparation of the STS (see Section B);
- about the structure and content of the technical file for the product, which the manufacturer has to submit to the Approval Body at the latest by the start of the preliminary activities for the preparation of the STS (see Section B), in accordance with the **"Instructions for the Preparation of a Technical File"***(Service document)***.**

It is recommended that the manufacturer or supplier become acquainted with the legislation which is currently in force in Slovenia in connection with the placing of construction products on the market, and with the use of such products in works.

A. Receipt and handling of applications for STS's

A.1 Submitting applications

The application for granting (modification and/or extension) STS must be submitted by the manufacturer or supplier using a standard form, which will have been made available at the preliminary informal meeting, and can also be accessed at the Approval Body's website: https://www.zag.si/en/certificates-and-approvals/service-for-technical-assessment-and-approvals/

Application forms shall be considered valid only if all necessary data are supplied, and if the form has been signed by the authorized representative of the Applicant and is properly stamped with the

Applicant's stamp (if he uses it). If so, then the manufacturer becomes an Applicant for an STS. The Applicant is also requested to give details about any web-site where more information can be obtained about the product, as well as his VAT Registration Number, and contact details, i.e. fax and telephone numbers, and email address. If the Applicant has appointed an authorized agent to act on his behalf in the procedure for the STS, then he shall also supply **a copy of such an authorization** to the Approval Body, and also notify the latter about the agent's address for correspondence.

Submitted applications shall serve as a firm order for all the necessary preliminary activities (see clause B.1) up until the conclusion of a contract for the STS procedure. If, however, the procedure should be interrupted before such a contract is concluded, either at the request of the Applicant, or through the Applicant's fault, the Approval Body shall have the right to charge the Applicant for the costs of all work so far performed.

A.2 Verification of the adequacy of applications

A representative of the Service for Technical Assessment and Approvals (Service) of the Approval Body will assess the adequacy of submitted applications. In particular, this representative will verify the following:

- whether or not the content of the application is complete, and whether the documents which are needed for the initiation of the procedure have been submitted,
- whether or not the product has been described in a satisfactory manner, whether the intended use and, if necessary, the end use application of the product, has been defined, whether the predicted service life of the product has been stated, and whether the locations of all manufacturing plants have been announced,
- in the case of the issuance of duplicate STS's, if the permission on the STS holder's to issue duplicates is attached,
- whether or not, in the case of the product concerned, some other technical specification (TS), e.g. harmonized standards,
- whether or not a draft harmonized technical specification or guideline already exists for the product concerned, and if it does at what stage it is,
- whether or not the product can be the subject of a single STS, and whether the application needs to be suitably modified.

The representative of the Service shall, together with the corresponding Leading Expert, verify whether or not the conditions for the issuing of an STS are fulfilled, as well as whether or not the product described in the application is a construction product, and whether or not it is regulated by any other technical regulation.

If the available data are sufficient and complete, and if no corresponding technical specification already exists for the product, the representative of the Service shall notify the Applicant about the receipt of the application and request that the latter settle the **costs of processing the application**. If the available data are insufficient and/or incomplete the Applicant will be requested to make the necessary alterations and additions. Together with such a notification the representative of the Service shall provide copies of the following documents:

- **"Rules for the preparation, granting and maintenance of validity of Slovenian Technical Approvals (STS's) for construction products",**
- **"Instructions to the applicant for the Preparation of a Technical File",**

and will at the same time inform the Applicant about which Leading Expert will process the application for the issuing of the STS.

In the case that the Applicant does not provide the additional requested data or does not pay the costs of the processing of the application, as a rule within a period of 1 month from the date of the issuing by the Approval Body of the corresponding proforma invoice, the representative of the Service shall notify the Applicant about the cancellation of the procedure.

B. Preliminary activities, and work programs for the preparation of STS's

B.1 Activities before the preparation of the STS

During his/her contacts with the Applicant, the Leading Expert will try to obtain from the latter as much useful data and as many relevant documents as possible, so that the product is described in a satisfactory manner. On the basis of the delivered technical documentation the Leading Expert shall, together with the staff of the Approval Body, prepare and send to the Applicant a **draft work program** and an **estimate of the costs involved**, in the form of an offer, for the inspection of the delivered documentation, any (if necessary) identification and proving tests (preparation of the Technical File), and an estimate of the costs of the procedure for the preparation and granting of the STS.
In the case of more complex work programs, which require a larger amount of preliminary studies (in particular, in the case of unique and innovative products) the representative of the Approval Body may require payment in advance from the Applicant, corresponding to the estimated costs of the preliminary analyses which are necessary for the preparation, as well as the scheduling and financial evaluation, of the work program.
In the case that the Leading Expert does not receive the documents needed for the preparation of such an offer, the Approval Body will, at his or her recommendation, cancel the procedure for the preparation of the STS by means of a corresponding notification of cancellation.

B.2 Analysis of the technical file

Analysis of the Technical File will be performed by a Leading Expert of the Approval Body in the field of the construction product concerned. He/she will check particularly the following:

- whether or not the technical file has been prepared in accordance with the given instructions, and whether it is in conformity with the information given at the time when the application was submitted,
- whether or not it contains sufficient information about the product and its intended use,
- whether or not it contains **information which the Applicant explicitly does not wish to be stated in the STS** (such information must be suitably indicated),
- whether or not the existing results of tests and/or calculations of individual characteristics of the product, and the results of conformity control submitted by the manufacturer, can be used for evaluation of the required characteristics, and for the assessment of the fitness for use of the product (see subclause C.4.1).

After analysing the technical file, the appointed Leading Expert of the Approval Body will decide:

- about whether or not the information given in the technical file is sufficient for the preparation of the work program, or else that additional information needs to be supplied by the Applicant; in the latter case, a deadline - of usually up to 30 days - will be defined, by which time the Applicant shall supply the additional information required,
- about whether or not a visit to the Applicant's manufacturing plant(s), including inspection of the production process, needs to be made before starting the preparation of the work program.

B.3 The acceptability of already existing data about tests and/or calculations

The acceptability of already existing data about tests and/or calculations will be assessed by the Leading Expert according to the following criteria:

- the evidence of any tests or calculations shall refer to the same type of product, which has to be confirmed by means of a declaration of identity of the product and, if necessary and applicable, by means of identification tests or measurements,
- data given in evidence shall be reliable and properly documented, and as a rule may not be older than one year, and as a rule may not be older than 5 years for complex products (in such a case there shall be sufficient proof that the product has not changed since the date of the test),
- the sampling procedure shall be equivalent to the procedure which is specified in the corresponding table mentioned in clause C.3, and the samples shall be representative of the product and of its method of production,
- the test method or the method of calculation shall be equivalent to the method prescribed in the corresponding table mentioned in clause C.3, and in the case of any transpositions of existing results, correlation between the results shall be defined,
- the quality and competence of the testing laboratory which has performed the tests must be verified and proved (e.g. by means of an accreditation document, or by witness testing, i.e. by repeating the test in the presence of a representative of the Approval Body), especially if the laboratory is not accredited for the particular or a similar method.

Decisions regarding the acceptability of submitted existing data for the verification of required characteristics will be taken by the appointed Leading Expert, together with other experts, of the Approval Body.

In special cases the Applicant may refer to existing data, which are owned by a third party. In such cases the Applicant shall provide the Approval Body with **permission to use such data**, as well as a declaration by the Applicant that he/she is in complete agreement with the data stated in the technical file of the third party. In such cases it is important to take into account the fact that the Applicant is **not the owner** of the data, and may not, without the permission of the third party, change or add to the data. In the case of any such changes or additions (without the permission of the third party) the Approval Body will not be able to take such data into account in the procedure for the preparation, granting and maintenance of validity of the STS.

B.4 Defining of identification procedures

During the period of validity of the STS, the identity of a product, when placed on the market, will be periodically checked by means of identification procedures against the product for which the STS has been granted. Verification of the identity of products during continuous production is particularly important in the case when the STS has been granted on the basis of the verification and assessment of the prototype.

Some examples of identification procedures are:

- testing of the identification characteristics of components (using direct or indirect methods),
- testing of the identification characteristics of the product,
- checking of the composition (formulation) of the product,
- checking of the parameters of the manufacturing process.

If the appointed Leading Expert considers that identification procedures need to be carried out, he/she will define the identification characteristics as well as the identification procedures for the product and/or for individual components of the product. Initial identification is always obligatory on the sample of the

product which was used in the procedure for the granting of the STS. Identification procedures should not be confused with the performance of in-process or auto-control tests within the framework of factory production control.

B.5 Development of the work program for preparation of an STS

B.5.1 General

The work program for the preparation of an STS will be developed by the appointed Leading Expert. The work program for the item "verification tests and/or calculations" will be split up into programs for the tests/calculations of the characteristics of the assembled system, of the components of the product, and of the product itself. The work program will show clearly which of the contracting parties (i.e. the Approval Body or the Applicant) is responsible for carrying out individual tests or calculations, as well as whether acceptable evidence already exists about the satisfying of individual required characteristics.
The work program will include all tests and/or calculations which will be performed by the Approval Body, evaluated in financial terms and in terms of agreed deadlines, as well as all other activities of the Approval Body's experts in the preparation of the STS, but it will not include those tests and/or calculations for which acceptable evidence already exists, nor those which are to be performed by the Applicant. The basis for the defining of prices will be the Approval Body's schedule of fees (ZAG Official Price List) for tests and calculations, as well as for the work of experts, based on the amount of time which they need to use.

The work program will also include a time schedule for the performance of tests and/or calculations, and of other key tasks which need to be performed within the scope of the preparation of the STS.

The work program will have the status of an internal document of the Service, and as a rule it will not be supplied to the Applicant in its entirety. A summary of the work program, with a recapitulation of the estimated costs, shall be a constituent part of the Contract between the Applicant and the Approval Body.

B.5.2 Participation of the Applicant in the performance of the work program

The appointed Leading Expert and the Applicant may agree that part of the verification tests and/or calculations for the product, which are defined in the work program for the preparation of the STS, be carried out by the Applicant, on the latter's own responsibility and account. In this case, however, the Leading Expert will evaluate the competence of the laboratories which are proposed by the Applicant for the performance of individual tests, as well as defining the conditions under which such testing may be carried out (e.g. that it should be performed in the presence of the Leading Expert or another expert of the Approval Body). A similar limitation will apply in the case of persons who may be proposed by the Applicant for the performance of verification calculations. Any decision about the possibility of splitting up the performance of tests is the exclusive responsibility of the Approval Body.

The verification tests and calculations which will be performed by the Applicant will not be included in the total contract price, but will only be shown in the work program.

B.6 Carrying out of verification tests and/or calculations

B.6.1 General

Within the scope of preliminary activities for the preparation of an STS, the Leading Expert, shall, together with other experts, determine the method of obtaining or sources of necessary data for the verification of all required characteristics. The necessary tests and/or calculations of the required characteristics are as a rule performed within the framework of such preliminary activities, The existing results of tests of the product may also be used if adequately documented, as well as the results of tests from the previous

factory production control, if corresponding proof for such tests is available in the submitted technical file (see clause B.3). In this way it is possible to reduce costs and the scope of the work program for the preparation of the STS, and at the same time useful existing data of satisfactory quality are not wasted. Results obtained over a longer period of time, which are important for the assessment of the durability and service life of the product, are particularly useful.

The planned tests of the product will be performed:

- on samples of the product taken from continuous production, if the product has already been placed on the market, and if a system of factory production control has been established at the manufacturing plant,
- on representative samples of the prototype of the product, if continuous production of the product has not yet begun; in this case it will be necessary to perform the prescribed identification tests and measurements on the sample of the prototype as well as on a sample of the product which will actually be placed on the market.

Tests and calculations must be performed using the methods which have been defined in the work program, as a rule in ZAG's organizational units. The results of such tests or calculations will be documented in the form of records and/or reports in accordance with the quality management system valid in the particular organizational unit(s). If ZAG's organizational units are not competent for the performance of certain tests or calculations then the Leading Expert may order their performance in another organization, taking into account the conditions defined in clause B.3.

B.6.2 Procedures in the case of non-compliance of the testing/calculation results

In the case when, based on the results of tests or calculations, one or more of the characteristics of the product does not satisfy the performance requirements, the appointed Leading Expert will notify the Applicant about this in writing. The Leading Expert shall also notify the staff of the Service about this, and the latter shall file such notification(s) together with the other documents corresponding to the procedure. In this case the Service may propose one of the following solutions:

- that, if it is possible that the sample taken was, by chance, a poor one, the tests be immediately repeated on additional samples under conditions to be defined by the Leading Expert and other experts of the Service for Technical Approvals,
- that the tests or calculations be repeated after the Applicant has arranged for adequate modifications to be made to the design of the product and/or to the manufacturing process, this work to be performed by a deadline to be agreed upon between the Leading Expert and the Applicant,
- that preparations for the granting of the STS be temporarily suspended until the necessary modifications have been made to the product,
- that the procedure for the preparation of the STS be terminated, as well as the Contract about the preparation and granting of the STS, if the latter has been previously concluded.

C. Preparation and issuing of STS'S

C.1 Conclusion of a contract about the preparation and granting of the STS

When the technical file has been substantially prepared so far that the STS can be prepared, a representative of the Service shall, on the basis of the work program and the paid proforma invoice for the costs of processing the application, prepare a Contract and shall send two unsigned copies together with a corresponding letter to the Applicant. The subject of the Contract can be the preparation and granting of an STS for several products, for which the application has been made.

After any necessary coordination with the Applicant, the Contract will be signed by the Director of ZAG.

If the Applicant does not return the signed contract to ZAG within a period of 15 (SLO) / 30 (abroad) days, the Service will notify the Applicant that it will terminate the procedure for the preparation and granting of the STS, and that it is the duty of the Applicant to settle all costs which have so far arisen during the preparation of the work program and of the contract.

C.2 Inspection of the manufacturing plant and of the production process

The purpose of visits to manufacturing plants is that the Leading Expert may become acquainted in more detail with the production process, and also, if the product is produced continuously, with the implemented system of factory production control. The information obtained by the Leading Expert about the production process will help in the determining of the required characteristics of the product, whereas information about the system of factory production control will help in deciding about appropriate methods for the evaluation and assessment and verification of constancy of performance (AVCP).

Such an inspection can be taken into account as a basis for the initial inspection of factory and of factory production control, if a designated certification body is involved in the AVCP of the product with the requirements of the granted STS. Designated certification body need agree to this.

C.3 Determination of the required characteristics of the product for its intended use

The required characteristics of the product for its intended use, as well as the associated performance requirements, will be determined by the Leading Expert and other experts on the basis of:

- the Slovenian technical regulations, currently in force, which regulate the use of the product in works (list of the currently valid legislation is published on the website of the Ministry responsible for the economy,
- Article 10. of ZGPro-1 or Annexes to Regulation (EU) No.305/2011, which, for each basic requirement for works, define the products and their characteristics which have an effect on the fulfilling of the relevant basic requirement.

Particularly in the case of products which are already being continuously manufactured, the Leading Expert may, when determining the required characteristics, make use of appropriate existing technical specifications for the product concerned, e.g. the national standards of Member States of the EU, draft European Standards (prEN), or any already published but not yet legally valid standards for the product.

When assessing the fitness of a product for its intended use, the following will be taken into account:

- the characteristics of the product which is to be installed in works or in an assembled system such as a kit,
- the characteristics which are related to the assembled system, but are also relevant for the intended use of the product (including the "characteristics of the installed product"),
- the characteristics of the components of the product, if they are relevant for the intended use of the product (these are usually related to dangerous goods or important constituent parts).

The so determined required characteristics of the product, as well as the corresponding verification method and the associated performance requirements, will be tabulated in the Evaluation Report.

C.4 Preparation of reports about the evaluation of the required characteristics, and the assessment of the fitness of products for their intended use

C.4.1 General

In the Evaluation Report, the verified performance level of each determined characteristic of the product will be judged and assessed by the Leading Expert against the established performance requirement. The verified performance level of each characteristic will be based on the results of the tests and/or calculations as they are related to the required characteristics of the product. Evaluation of each and every required characteristic of the product is the basis for the assessment of the fitness of the product for its intended use. The product is presumed to be fit for its intended use when the performance requirements are fulfilled for all the determined characteristics.

The Evaluation Report shall include a conclusion as to whether the product, with respect to the results of the verification of the required characteristics, is fit for its intended use, and for its end use application, respectively. If the product is declared fit for its intended use, then the Leading Expert will start to prepare an STS for it, in accordance with the provisions of clause C.5.

The Evaluation Report is not a constituent part of the STS. However, the Applicant will receive the Evaluation Report of it even in the case when an STS will not be granted because the product has been found not to be fit for its intended use.

C.4.2 Procedure in the case when the product is found not to be fit for its intended use

If during evaluation the Leading Expert finds that the product is not fit for its intended use, then he/she will notify the Applicant in writing, and provide an explanation of the reasons for such a conclusion. If the detected non-conformity/non-conformities can be relatively easily eliminated, the Applicant may do so by a deadline to be agreed upon with the Leading Expert. All modifications which are made at this time to the product shall be documented in a corresponding appendix to the technical file. The Leading Expert and other experts of the Service will then determine and perform all necessary additional verification tests and/or calculations, or else will repeat them on new samples. These additions to the work program shall be confirmed in writing by the Applicant.
In the case of an unsatisfactory product the Applicant may change the intended use of the product so that it corresponds to the actual characteristics of the product.

If the Applicant does not eliminate the non-conformity or non-conformities by the agreed deadline, the Head of the Service shall, at the instigation of the Leading Expert, suspend the procedure for the preparation of the STS, and notify the Applicant in writing about such a decision in accordance with the provisions of subclause C.7.1.

If the Approval Body and the Applicant agree that the detected non-conformities cannot be eliminated within a realistic period, and if at the same time a change in the intended use of the product is not justified, they may agree to suspend the procedure for the preparation of the STS. The Approval Body will in this case, too, proceed according to the provisions of subclause C.7.1.

C.5 Content and documents of the STS

C.5.1 Content of the STS

Each STS has a prescribed form and content, with the following main parts and sections:

- Legal basis and general conditions.

- Special conditions of the STS.
  - Description of the product and definition of its intended use.
  - Characteristics of the product and verification methods.

    This section defines the required characteristics and the associated performance requirements, in accordance with clause C.3, as well as the corresponding verification methods for each characteristic.

  - Evaluation and assessment and verification of constancy of performance

    This section defines the system of assessment and verification of constancy of performance (AoC system) according to Regulation (EU) No.305/2011 ZGPro-1, and describes the tasks of the manufacturer as well as those of any approved body which may be involved in such assessment and verification of constancy of performance.

    Regulation (EU) and ZGPro-1 i defines the obligations of the holder of the STS before the product is placed on the market with a granted STS. These are, in particular, the obtaining of a certificate of constancy of performance for the product or certificate of conformity of the factory production control (if required by the AoC system), the issuing of a declaration of performance, and marking of the product.

    A constituent part of the STS is the control plan (see clause C.6),which provides detailed definitions of the inspections and tests which need to be performed within the scope of initial type testing, factory production control, identification of the product, and surveillance of assessment and verification of constancy of performance.
  - The assumptions according to which the fitness of the product for its intended use has been evaluated.

    Descriptions are provided regarding the manufacturing conditions, as well as the conditions for storage, installation and maintenance, upon which the characteristics of the product may depend.
  - Identification of the product.
  - Recommendations to the manufacturer.
  - Reference documents and other sources.
- Annexes

  Annexes to the STS usually contain detailed data, including sketches/photographs, about the product and its intended use (i.e. about its design and manufacture), as well as the obligatory control plan.

C.6 Control plans

The control plan is a document which specifies the types and frequency of the inspections and tests which need to be performed on a product by the manufacturer and by the designated certification body (if involved in the AVCP), as well as the required value levels of the control parameters in order to maintain the specified characteristics of the product, and to prove the continuing conformity of the product with the STS.

The control plan will consist of a number of tables, which will deal with:

- the manufacturer's control plan for the final product (in particular, initial type testing of the final product and factory production control),
- the manufacturer's control plan for the receiving inspection of components and raw materials,
- the control plan for the designated certification body, if involved (in particular, the initial inspection of factory, and regular surveillance of conformity).

The control plan does not have to include all of the product's required characteristics, but only those which must be tested during continuous production, since such data are needed for the evaluation of conformity and for identification of the product. Indirect test methods can only be used if adequate correlation has been established between the reference method and the applied method.

As a rule, the control plan will contain the requirement that the manufacturer's system of quality assurance and factory production control must be documented in a manual of factory production control, which must include the requirements of the relevant STS about factory production control. An implemented system of quality management according to the standard SIST ISO 9001 may be sufficient to fulfil the requirements for the management and performance of factory production control so long as the relevant provisions of the STS about factory production control are also taken into full consideration.

Before finalizing the requirements for factory production control, the Approval Body may find it necessary to revisit the manufacturing plant.

The control plan is a confidential annex to the STS, which, however, the manufacturer must supply to the designated certification body if is included in the assessment and verification of constancy of performance, as well as to market surveillance inspectors, if requested by them.

C.7 Granting of an STS

C.7.1 Decisions about the granting of an STS, and about the cancellation of an application for an STS

The Head of the Service will decide in favour of the final preparation and granting of an STS in the case when the assumption about the fitness of the product for its intended use is confirmed in the conclusion of the Evaluation Report (see subclause C.4.1). An STS will be granted on the basis of such a decision after the Applicant has settled in full the costs for the preparation of the STS.
A complete list of all granted STS's is accessible on ZAG's web pages.

As a rule, the STS will be granted for a period of 5 years.

On the other hand, the Head of the Service will decide to cancel the application for the STS if the assumption about the fitness of the product for its intended use is not confirmed in the evaluation report, as well as in the case when the Applicant has not eliminated the non-conformities listed in the evaluation report by the agreed deadline and/or has not fulfilled one or more of its contractual obligations.

In the case when the application is cancelled for one of the above-stated reasons, the Approval Body shall have the right, in accordance with the provisions of the contract about the preparation of the STS, to charge the Applicant the costs for all work carried out up until that time.

The Applicant may submit a complaint about the decision of the Approval Body to cancel the application for the STS. In accordance with the procedure: Complaints-Appeals (general document), the complaint is resolved in three two stages. The complaint is first considered by the head of the Service as a matter of priority. If the client is not satisfied with his solution, he can complain again to the head of the ZAG Quality Management Service. He will convene a commission to resolve the appeal at the second level.

C.7.2 Responsibilities of the Holder of the STS

After an STS has been granted, the Applicant will become the Holder of the STS, and shall have the following responsibilities:

- that, during the period of validity of the STS, he will ensure the continuous conformity of the product with the granted STS,
- that, before placing the product with the granted STS on the market for the first time, he will, by means of a declaration of performance, ensure the conformity of the product with the requirements of the STS. If so required by the system of AVCP which is prescribed in section 3 of the granted STS, such a declaration of performance shall be based on a certificate of constancy of performance for the product or certificate of conformity of the factory production control,
- that he will notify the Approval Body, in a timely manner, about any planned changes/modifications to the product and/or to the intended use of the product and/or to the general data about the holder of the STS, marked on the product,
- that he will notify users about any changes/modifications that may be made to the product.

C.8 Maintenance of the validity of the STS

Firstly the manufacturer of a product, and secondly the Approval Body, shall be responsible for the maintenance of the validity of the STS. The validity of a granted STS will cease in the case that the assumption about the fitness for use of a product is no longer fulfilled. The reason for this could be non-conformity of continuous production with the requirements of the STS, or non-fulfilment of the considered basic requirements, or changes in the sense of subclause C.9.3.
It is the responsibility of the manufacturer to notify the Approval Body about each and every non-conformity of the product with the granted STS, whereupon the Approval Body will decide about necessary measures.
The Approval Body shall have the right to monitor the validity of a granted STS in its own way. In the case of detected non-conformities, it shall also be the duty:

- of the involved designated (inspection or certification) body in the case that the system of attestation assessment and verification of constancy of performance in the granted STS requires continuous surveillance by an approved body (AVCP systems 1+, 1 and 2+), and
- market and building inspection.

C.9 Extension of the validity of STS's, modifications and issue of a duplicate of STS's

C.9.1 General

During the period of validity of the granted STS, the holder of the STS may ask the Approval Body:

- to extend the period of validity of the STS beyond the date upon which it would otherwise expire,
- to agree to a modification of the STS in the case when the holder intends to modify the product, to change its constituents, the manufacturing process or the product's intended use,
- to extend the period of validity of the STS and at the same time to accept a modification of the STS.

The Approval Body may also issue a duplicate of an already issued STS.

C.9.2 Extension of the period of validity of an STS

The period of validity of an STS may be extended for a further period of five years in the case when the conditions which were the basis upon which the original STS was granted have not changed. In this case the Approval Body will issue a new edition of the original STS, with the same designation, but a new date of issue.
Applications for an extension of the validity of an STS shall be submitted by the holder of the STS as a rule at least six months before the expiry date. Such an application shall be made on the standard form, and be accompanied by the technical documents required by the Leading Expert. From the application it must be evident:

- that the conditions under which the original STS was granted have not changed, in particular the characteristics of the product and its intended use (statement),
- that the product has performed satisfactorily in use,
- that, in the previous period, there have been no serious complaints about the fitness of the product for its intended use,
- that no significant changes have occurred in the state-of-the-art of products of the same kind, which could affect the product's fitness for its intended use.

In the case of the extension of the validity of an already granted STS, the Leading Expert will perform all the tasks as for a new STS. However, the required tests, calculations and evaluations may be reduced in scope or substituted by a simple checking process, provided that it is possible to demonstrate reliably that

the conditions under which the original STS was granted have not changed significantly. In the case that a system of AVCP 1+, 1 or 2+ has been prescribed for the attestation of conformity, the Approval Body will take into account information obtained from the approved body involved.

C.9.3 Modification of an STS

An already granted STS needs to be modified in the following cases:

- if there is a change in the product due to the manufacturing process, or if there are changes in the components of the product,
- if there is a change in an important characteristic of the product,
- if there is a change in the intended use of the product.

Before implementing any planned change, the Holder of the STS shall obtain the opinion of the Leading Expert about the effect of the proposed change on the fitness for intended use of the product, as defined in the granted STS. If the Leading Expert considers that the change is a significant one, he/she will propose to the Holder of the STS that the latter submits an application for a modification of the granted STS.

The Leading Expert will then, in accordance with the provisions of these rules and to the extent dictated by the proposed change(s), perform the necessary procedures for a new assessment of the fitness of the product for its intended use. On this basis the Approval Body will then replace the previous STS with a new STS, the period of validity remaining unchanged unless the Holder of the STS has simultaneously applied for an extension of the period of validity of the STS. In this case the rules for the extension of the validity of STS's shall apply.

C.9.4 Modification of an STS, with a simultaneous extension of its period of validity

In the case where a modification of an STS is to be made, with a simultaneous extension of the period of the latter's validity, the provisions of subclauses C.9.2 and C.9.3 shall be taken into account. This means that, in accordance with subclause C.9.2, verification of the whole product will be performed, and that additionally a detailed verification will be carried out regarding the effect of the change or changes, in accordance with subclause C.9.3.

C.9.5 Granting of duplicate STS’s

The granting of a duplicate STS is possible only on the basis of the written permission of the basic STS’s holder for the issuance of a duplicate, which the applicant of duplicate attaches to the application for granting of a STS. The obligations of the holder of the STS duplicate are the same as the obligations of the holder of basic STS. The duplicate STS is valid from the day of issue until the expiration of the basic STS, duplicate STS obtains its own STS number.

C.10 Withdrawal of STS's

The Approval Body has the right to withdraw a previously granted STS if, in any way, it finds:

- that the conditions under which the STS was originally granted have significantly changed, in particular the characteristics of the product and its intended use, and that these changes cannot be dealt with by means of a modification of the STS in accordance with the provisions of subclause C.9.3,
- that the product, which is in continuous production, is no longer in conformity with the requirements of the granted STS,
- that the holder of the STS has ceased to fulfil the provisions of the contract.
- that a significant change has occurred in the state-of-the-art of products of the same kind, which could affect the product's fitness for its intended use
- at the request of the holder of the STS.

Withdrawal of permission to use an STS can be a temporary or permanent measure, which may come into force immediately or with a delay. Decisions about such withdrawals will be taken by the Head of the Service, who will acquaint the holder of the STS in writing with the reasons for such a decision.

C.11 Harmonized standards

Whenever a harmonized standard with obligatory use is published, in the case of any particular product, the Service shall notify the holder of the STS about the cessation of use of the STS.

In the case that a corresponding harmonized standard has come into force during the procedure for the preparation of an STS, the procedure for the granting of the STS shall be terminated.