

**GUIDANCE
FOR THE ACCREDITATION
OF PRODUCT CERTIFICATION BODIES,
FACTORY PRODUCTION CONTROL CERTIFICATION BODIES AND
TESTING LABORATORIES
INVOLVED IN THE ASSESSMENT AND VERIFICATION OF
CONSTANCY OF PERFORMANCE
AS DETERMINED BY THE CONSTRUCTION PRODUCTS REGULATION
(305/2011/EU)**

ESYD G-CPR

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Prepared by: Quality Manager of ESYD

Approved by: Chairman of ESYD

Quality Manager of ESYD

Chairman of ESYD

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Abbreviations

TT: Type Testing

FPC: Factory Production Control

DoP: Declaration of Performance

NB: Notified Body

hTS: harmonised Technical Specification

hEN: harmonised European Standard

EAD: European Assessment Document

ETA: European Technical Assessment

TAB: Technical Assessment Body

CPD: Construction Products Directive 89/106/EEC

CPR: Construction Products Regulation 305/2011/EU

Equivalent Terms	
Construction Products Directive 89/106/EEC	Construction Products Regulation 305/2011/EU
System of attestation of conformity	System of Assessment and Verification of Constancy of Performance
Declaration of Conformity	Declaration of Performance
Essential requirements	Basic requirements for construction works
Characteristics	Essential Characteristics
Initial Type Testing	Type Testing

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1. Scope

This guidance refers to:

1.1 Additional requirements for the conformity assessment of bodies, being in the process of accreditation by ESYD, as well as to the selection of appropriate European standards for the accreditation of bodies issuing certificates of constancy of product performance, bodies issuing certificates of conformity of the FPC and testing laboratories for the determination of product-type, as specified by the Regulation 305/2011/EU and the decisions and directives of the European Commission and

1.2 The requirements for the establishment of uniform certification regulations and manufacturers control procedures by bodies, being in the process of accreditation by ESYD.

2. References

- [1] Construction Products Regulation 305/2011/EU
- [2] Guidance Note on the Construction Product Regulation, Version I, April 2012
- [3] Guidance Papers A, B, D, K and M
- [4] Micro-enterprise as defined in the Commission Recommendation of 6 May 2003
- [5] Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes EA-2/17

3. Definitions and Responsibilities of CPR

3.1 Definitions [1]

'construction product' means any product or kit which is produced and placed on the market for incorporation in a permanent manner in construction works or parts thereof and the performance of which has an effect on the performance of the construction works with respect to the basic requirements for construction works;

'product-type' means the set of representative performance levels or classes of a construction product, in relation to its essential characteristics, produced using a given combination of raw materials or other elements in a specific production process;

'harmonised technical specifications' means harmonised standards and European Assessment Documents;

'European Assessment Document' means a document adopted by the organisation of TABs for the purposes of issuing European Technical Assessments;

'European Technical Assessment' means the documented assessment of the performance of a construction product, in relation to its essential characteristics, in accordance with the respective European Assessment Document;

'Specific Technical Documentation' means documentation demonstrating that methods within the applicable system for assessment and verification of constancy of performance have been replaced by other methods, provided that the results obtained by those other methods are

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equivalent to the results obtained by the test methods of the corresponding harmonised standard;

'**micro-enterprise**' means a micro-enterprise as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium- sized enterprises.

There are three categories of micro-small and medium enterprises (SMEs):

1. Within the SME category, a medium sized enterprise is made up of enterprises which employ fewer than 250 persons and whose annual turnover does not exceed EUR 50 million or whose annual balance-sheet total does not exceed EUR 43 million.

2. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million.

3. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million.

To gain a better understanding of the real economic position of SMEs and to remove from that category groups of enterprises whose economic power may exceed that of genuine SMEs, a distinction should be made between various types of enterprises, depending on whether they are autonomous, whether they have holdings which do not entail a controlling position (partner enterprises), or whether they are linked to other enterprises. The current limit shown in Recommendation 96/280/EC, of a 25 % holding below which an enterprise is considered autonomous, is maintained.

In order to avoid arbitrary distinctions between different public bodies of a Member State, and given the need for legal certainty, it is considered necessary to confirm that an enterprise with 25 % or more of its capital or voting rights controlled by a public body is not an SME (Exceptions exist as for example, universities or non-profit research centres).

3.2 Factory Production Control [3]

The term "Factory Production Control" (FPC) means the documented, permanent and internal control of production in a factory, in accordance with the relevant harmonised technical specifications (see also the definition in paragraph 2 – Guidance Paper B).

The FPC certification bodies should check if the manufacturer has and implements a FPC at the plant. The minimum requirements for the FPC are listed in Annex A of this guidance.

3.3 Type Testing [2]

All construction products should be subjected to type testing. Type Testing is equivalent to Initial Type Testing of CPD and is performed by a laboratory which must participate in inter-laboratory comparisons covering all the above tests, according to ESYD PDI, in the cases where accreditation and/or notification is required for the laboratory.

Additional guidance for type testing is provided in Annex D.

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3.4 Declaration of Performance

Extensive information on the declaration of performance is included in Chapter II of Regulation 305/2011/EU.

It is noted that ESYD assessors will evaluate in witnessed assessments if the certification bodies auditors examine the existence of the Declaration of Performance rather than its content.

An outline of the manufacturer's DoP and of the certificate of constancy of performance (if relevant), will be included in Annex ZA.3 of the hEN or in a section in the relevant EAD.

3.5 Systems of Assessment and Verification of Constancy of Performance [2,3]

The system of Assessment and Verification of Constancy of Performance (AVCP) is the term applied to define the degree of involvement of third parties in assessing the conformity of the product according to the relevant technical specification(s). As AVCP systems are the 5 systems as listed in Annex V of CPR:

System	Responsibility	Type of Notified body	Tasks
1+	Notified Body	Product certification Body	Initial Inspection of the FPC System Continuous Surveillance of the FPC system Determination of the product-type Audit testing
	Manufacturer		Factory Production Control and further testing of samples
1	Notified Body	Product certification Body	Initial Inspection of the FPC system Continuous surveillance of the FPC system Determination of the product-type
	Manufacturer		Factory Production Control and further testing of samples
2+	Notified Body	Factory production control certification body	Initial Inspection of the FPC System Continuous Surveillance of the FPC system
	Manufacturer		Factory Production Control and further testing of samples Determination of the product-type
3	Notified Body	Testing laboratory	Determination of the product-type
	Manufacturer		Factory Production Control
4	Manufacturer	No independent involvement	Factory Production Control Determination of the product-type

The certification bodies for systems 1, 1 + and 2 + must have regulation and certification procedures for which indicative – minimum requirements are given in annexes B & C of this guidance.

The procedures for assessment and verification of constancy of a product performance are set out in the relevant technical specification. For hENs these usually appear in Annex ZA.2, whereas for ETAs in a section in the relevant EAD/ETA (for reasons of confidentiality only the basics are included, the details are provided only to the notified body involved in AVCP).

For all systems the manufacturer is required to have a fully documented FPC system. The criteria for this should be included in the hTS.

Once all the appropriate conformity assessment tasks have been carried out for the product, the manufacturer is required to draw-up a DoP, which is kept with the technical file concerning the product. This may be supported by a certificate of constancy of performance, certificate of conformity of the FPC, testing laboratory reports or certificates and/or the manufacturer's own test results, depending on the system of AVCP required.

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3.6 Affixing of CE marking

As from 1 July 2013, construction products placed on the market and covered by a hEN or an ETA will have to be accompanied by a DoP. CE marking must be affixed when the manufacturer has drawn up a Declaration of Performance for the product, otherwise not.

The CPR generally applies to three groups of products:

Group 1. Products covered by a hEN

Group 2. Products not fully covered by a hEN, i.e. where a hEN exists but for at least one essential product characteristic, the method of assessment is inappropriate or there is no assessment method.

Group 3. Products which do not fall within the scope of a hEN.

For group 1 products, a DoP, as set out in the relevant hEN, and consequent CE marking will be mandatory from 1 July 2013.

For groups 2 and group 3 products, a manufacturer has choices in the way of declaring and supporting claims of performance as follows:

- a. Declare performance against an EAD using an ETA issued by a relevant TAB. Performance declared by this route should bear the CE marking.
- b. Declare performance and have this supported by a National Approval. Those bodies who are part of EOTA generally seek to use methodology and a technical language in line with that used by CEN and EOTA, thus allowing progression to route A later.
- c. Declare performance with or without the support of other information (e.g. a test report) using assessment methods of their choice. However, as the technical language used in regulations and procurement progressively moves towards a common EU-wide system, the relevance of such data in the long-term should be considered.

4. Selection of the appropriate European Accreditation Standards for the Systems of Assessment and Verification of Constancy of Performance

Systems 1+ and 1 involve product certification, system 2+ involves factory production control certification, system 3 involves the realization of the required tests by a testing laboratory, while system 4 involves control of the correctness of the type testing and of the FPC, performed by the manufacturer himself.

For the assessment and accreditation by ESYD of product certification bodies, FPC certification bodies and laboratories, which are involved in the assessment and verification of constancy of performance, according to CPR, the selection of the accreditation standards is the following:

1. The European standard for the assessment of product certification bodies' competence (**systems 1+ and 1**) is **EN 45011** (will be replaced by the EN ISO/IEC 17065 till 15.09.2015). Additional requirements are those of each hEN or EAD, for which the body seeks accreditation. It should be noted that **the testing laboratories for type testing have to be accredited according to EN ISO/IEC 17025**.
2. The European standards for the assessment of FPC certification bodies' competence (system 2+) is **EN 45011** (will be replaced by the EN ISO/IEC 17065 till 15.09.2015) or

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EN ISO/IEC 17021, Additional requirements are those of each hEN or EAD, for which the body seeks accreditation. It should be noted that **the testing laboratories for type testing have to conform to the requirements of EN ISO/IEC 17025 (also see annex B, § 2.5).**

3. The Standard for the assessment of testing laboratories' competence (system 3) is **EN ISO/IEC 17025**. Additional requirements are imposed by the test methods of the each hEN or EAD, for which the laboratory seeks accreditation.

Moreover, for the above cases 1, 2 & 3, the assessment includes the verification of conformity of the body to the requirements of the guidance document EA-2/17.

5. Obligations of Notified Bodies (certification bodies, laboratories)

Notified product certification bodies, FPC certification bodies and testing laboratories must:

- 5.1 Monitor developments in relevant standards and legislation requirements.
- 5.2 Conform to the uniform certification regulations per product family {prepared by the Advisory Committee of NB EU (Advisory Group of Notified Bodies),} this ESYD guidance and, additionally, apply the administrative decisions and documents of the Coordination Group of Notified Bodies as general guidance.
- 5.3 Participate in, or ensure that their assessment personnel is informed of, the relevant standardization activities and the activities of the Coordination Group of Notified Bodies and apply the administrative decisions and documents produced as a result of the work of that group as general guidance.
- 5.4 Participate in the work of the Coordination Group of Notified Bodies, directly or by means of designated representatives, or ensure that the representatives of notified bodies are informed thereof.
- 5.5 Furthermore, have the necessary procedures to perform activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
- 5.6 Assign (applies only to NBs of systems 1 and 1+) laboratory testing to accredited laboratories, when they do not dispose accredited test facilities. Where justified by technical, economic or logistic reasons or on the request of the manufacturer, the tests (only for systems 1, 1+, 3) can be carried out under the supervision of NBs either in the manufacturing plants or in an external laboratory.

Notified bodies carrying out such tests shall be specifically designated as competent to work away from their own accredited test facilities, and before carrying out those tests, they shall verify whether the requirements of the test method are satisfied and shall evaluate whether:

- (a) test equipment has an appropriate calibration system and the traceability of the measurements is guaranteed;
- (b) the quality of the test results is ensured (see annex D – permissible alternatives).

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Note:

According to the working document CPR 003/14 of the European Commission, which interprets article 46 of Regulation 305/2011/EU, NBs can, in the exceptional cases described in Article 46.1 of the Regulation, use either the manufacturer's laboratory facilities or an external laboratory (i.e. facilities other than those referred to in their notification scope). In order to be designated as competent for the aforementioned activity, they are required to have either their own accredited testing laboratory or use an accredited testing laboratory as subcontractor.

- 5.7 Issue, if notified, certificates of constancy of product performance (systems 1 and 1+) or certificates of conformity of the FPC (system 2+), in accordance with this ESYD guidance.
- 5.8 Demonstrate that all personnel involved in audits has been informed and trained on the latest edition of European technical specifications and legislation provisions, relevant to the NB's scope of accreditation, as well as the documents referred to in § 5.2.
- 5.9 Identify training needs of the above personnel and follow relevant continuous training programs.
- 5.10 Maintain training records to document the fulfillment of the above needs.
- 5.11 There should be CVs and job descriptions for NB auditors, to document technical competence in a particular product category, through specialization and experience in a specific product or product type design and manufacture or in the testing and statistical control of production or in the auditing of a specific product or product type.
- 5.12 There should be a methodology for the evaluation of auditors and experts and the relevant evaluation reports.
- 5.13 The NBs shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the assessment and/or the verification performed.

Further information on the obligations of the NBs is included in article 43 of Regulation 305/2011/EU.

6. ESYD Requirements and procedures

6.1 The granted scope of accreditation refers to European standards and/or the European Assessment Documents, even in cases of organizations involved in system 2+ certification.

6.2 The ESYD assessment team, apart from fulfilling the requirements of ESYD Assessors Criteria, is expected to have:

- 6.2.1 Documented knowledge and training on the requirements of each hEN or EAD, included in the scope the body seeks accreditation for, as well as in the systems of

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assessment and verification of constancy of performance, of the requirements of Regulation 305/2011/EU and of this ESYD guidance.

6.2.2 ESYD assessors are expected, among others, to examine:

- The completeness and adequacy of systems of assessment and verification of constancy of performance
- issues relating to the qualifications of the certification body auditors
- the existence and implementation of a requirement to review the technical documentation for its completeness
- third party tasks in accordance with the systems of assessment and verification of constancy of performance carried out within the scope of the NB's notification and any other activity performed, including cross-border activities and subcontracting (article 53.1d of CPR and additional requirement of guidance document EA-2/17).

7. Scope of Accreditation

7.1 The scope of accreditation for notification purposes contains all the information necessary to notify the body in NANDO database and, for systems 1, 1+, 2+, regardless of the accreditation standard, consists of three columns:

- ✓ The first column gives the description of the product group, as in the applicable standard
- ✓ The second column lists the activities of assessment and verification of constancy of performance the organization performs and the system applied. Particularly, in the second column it is indicated:
 - ✓ For System 1 and 1+
 - Product certification body
 - ✓ For System 2+
 - FPC certification body
- ✓ In the third column, the technical specification and the Commission Decision on the type of assessment of constancy of performance of this product group is indicated.

7.2 For testing laboratories in System 3, the scope of accreditation is a typical scope of EN ISO/IEC 17025, with the clarification that, in the third column, in addition to the technical specification, the specific test methods the laboratory performs are listed.

7.3 For systems 1, 1+, 2+, in order to indicate a technical specification in the third column, the NB must have at least one client in the corresponding family of technical specifications falling into the same Commission Decision.

8. Transition issues

8.1 CE marking on the basis of a hEN: A manufacturer may draw up a DoP on the basis of a Certificate of Conformity or a Declaration of Conformity, which has been issued before 1 July 2013, according to CPD 89/106/EEC.

The specific construction products covered by hENs, which were placed on the shelves before 1 July 2013 without the CE marking, will not need to be withdrawn. However, the respective construction products manufactured after that date will be subject to the CE marking requirements of the CPR.

8.2 CE marking on the basis of a European Technical Approval: Guidelines for European Technical Approval (ETAGs) published before 1 July 2013 in accordance with article 11 of the CPD may be used as EADs. Manufacturers and importers may use European Technical Approvals issued in accordance with article 9 of the CPD before 1 July 2013 as European Technical Assessments throughout the period of validity (usually five years from the date of issue) of those approvals.

9. Simplified Procedures

The simplified procedures of articles 36-38 of CPR determine two different cases, the replacement of the a) type-testing and b) assessment of performance.

9.1 Replacement of type-testing by Appropriate Technical Documentation

In determining the product-type, a manufacturer may replace type-testing or type-calculation by Appropriate Technical Documentation demonstrating that:

a) for one or several essential characteristics of the construction product, which the manufacturer places on the market, that product is deemed to achieve a certain level or class of performance without testing or calculation, or without further testing or calculation, in accordance with the conditions set out in the relevant harmonised technical specification or a Commission decision;

b) the construction product, covered by a **harmonised standard**, which the manufacturer places on the market corresponds to the product-type of another construction product, manufactured by another manufacturer and already tested in accordance with the relevant harmonised standard.

When these conditions are fulfilled, the manufacturer is entitled to declare performance corresponding to all or part of the test results of this other product.

c) the construction product, covered by a harmonised technical specification, which the manufacturer places on the market is a system made of components, which the manufacturer assembles duly following precise instructions given by the provider of such a system or of a component thereof, who has already tested that system or that component for one or several of its essential characteristics in accordance with the relevant harmonised technical specification.

When these conditions are fulfilled, the manufacturer is entitled to declare performance corresponding to all or part of the test results for the system or the component provided to him.

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The manufacturer may use the test results obtained by another manufacturer or system provider only after having obtained an authorisation of that manufacturer or system provider, who remains responsible for the accuracy, reliability and stability of those test results.

If the construction product referred above belongs to a family of construction products for which the applicable system for assessment and verification of constancy of performance is **system 1 + or 1**, the **Appropriate Technical Documentation shall be verified by a notified product certification body and the product is CE marked.**

In Annex D, see detailed examples under the paragraph "Possibilities of TT test costs reduction".

9.2 Replacement of type testing by Specific Technical documentation (SME)

Small enterprises manufacturing construction products covered by a **harmonised standard** may replace the determination of the product-type on the basis of type-testing for the applicable systems 3 and 4 by using methods differing from those contained in the applicable hEN.

Those manufacturers may also treat construction products to which system 3 applies in accordance with provisions for system 4.

When a manufacturer uses these simplified procedures, the manufacturer shall demonstrate compliance of the construction product with the applicable requirements by means of a **Specific Technical Documentation and shall demonstrate the equivalence of the procedures used to the procedures laid down in the hENs.**

9.3 Replacement of the assessment of performance by Specific Technical Documentation

Construction products covered by a **harmonised standard** and which **are individually manufactured or custom-made in a non-series process in response to a specific order**, and which are installed in a single identified construction work, the performance assessment part of the applicable system, may be replaced by the manufacturer by **Specific Technical Documentation demonstrating compliance of that product with the applicable requirements and equivalence of the procedures used to the procedures laid down in the harmonised standards.**

If the construction product belongs to a family of construction products for which the applicable system for assessment and verification of constancy of performance is system 1 + or 1, the **Specific Technical Documentation shall be verified by a notified product certification body and the product is CE marked.**

All the simplified procedures are summarized in the following table:

Applicable System	All manufactures	SME
System 3 and 4	Type testing may be replaced by use of Appropriate technical documentation described in Article 36, CPR	(only micro enterprises) Products to which System 3 applies may be treated like System 4 by means of Specific Technical Documentation.
System 2+		
System 1+ and 1	The Appropriate and/or Specific Technical Documentation must be verified by a notified certification body	

Annex A

Factory Production Control

1. Introduction

The FPC system should always adapt to the requirements of the applicable harmonized standard, as specified by the guidance issued by the Group of Notified Bodies.

The FPC should meet the following minimum-indicative requirements.

2. Management

2.1 Duties and responsibilities

The responsibilities, the duties and the relationship between personnel who perform and verify work affecting the quality of products should be defined, including personnel who need to have the duty to:

- A) take action to prevent non-compliant products,
- B) identify, record and deal with any deviation in the quality of products.

2.2 Management Representative for the FPC

The manufacturer shall appoint a competent person to ensure that the requirements of the relevant harmonized standards are met, in the particular production site.

2.3 Management Review

In order to ensure continued suitability and effectiveness of the FPC system, the management should audit and review it at appropriate time intervals and also maintain the relevant records.

2.4 Personnel training

The manufacturer shall establish and maintain procedures for the training of the personnel involved in the FPC system and maintain appropriate records.

3. Control Procedures

3.1 Document and data control

Document and data control, related to the requirements of applicable standards, covers the markets, the processes, materials control and the documentation of the FPC system.

The FPC manual should contain documented management procedure of documents and data, which will cover the procedures and responsibilities for approving, issuing, distributing and

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managing internal documents and data, as well as the preparation, issue and recording of the written documentation changes.

3.2 Sub-contracting

When the manufacturer has subcontracted part of his work, he must have appropriate control procedures of the subcontractor and, in any case, he shall maintain the overall responsibility for the tasks.

3.3 Knowledge of the raw materials

There must be documentation that provides details about the nature of the source and the suitability of the raw materials.

4. Production Management

The FPC system should meet the following requirements:

I. There should be procedures for the production process.

NOTE: These procedures may refer to the maintenance and adjustment of the processes equipment, to the control or testing of samples taken during the manufacturing processes, to the adaptation of production processes where necessary etc.

II. There must be procedures for the identification and control of hazardous materials, where appropriate, in accordance with the applicable standard or National Legislation.

III. There should be procedures to ensure that materials are stored under controlled conditions and to determine their location as well as the products in storage locations.

IV. There should be procedures to ensure that materials obtained from stocks have not been altered to a degree that threatens their compliance.

V. Traceability of products should be ensured, during the first time they are available in the market.

5. Verifications and tests

5.1 General comments

The manufacturer must have the premises, equipment and personnel necessary to carry out the required verifications and tests.

5.2 Equipment

The manufacturer shall be responsible for the verification, calibration and maintenance of inspection, measurement and testing equipment.

The accuracy and frequency of calibration should be in accordance with the relevant applicable standards and also the manufacturer should maintain relevant records.

The equipment must be used in accordance with documented procedures and be uniquely identified.

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5.3 Inspections, sampling and testing frequency and site

The production control document should describe the frequency and nature of inspections.

The frequency of sampling and the testing, if required, should be performed for the corresponding characteristics specified in the applicable harmonized standard.

NOTE 1 Testing frequency is usually associated with periods of production or is defined according to the production quantity (e.g. per tonnes). A production period is defined as a full week, month or year of production working days.

NOTE 2 The FPC requirements can introduce visual inspections. Any deviations resulting from these inspections may involve increased testing frequency.

NOTE 3 When the measured value is close to a predetermined limit, it is possible to increase the frequency.

NOTE 4 Under special circumstances, it is possible to reduce the frequency of tests, compared to those provided by the harmonized standards. These conditions are:

- I. Highly automated production equipment.
- II. Long consistent experience in specific properties.
- III. Sources with high compliance.
- IV. Implementation of quality management system with excellent surveillance and monitoring of the production process.
- V. Low value dispersion of the measured characteristics.

The reasons for the reduction in testing frequency must be set out in the FPC document.

6. Records

The results of the FPC must be recorded in files, including sampling locations, sampling date and time, sampled and tested products and any other relevant information, e.g. ambient conditions.

When the product to be checked or tested does not meet the requirement of the specification or when there is an indication that it will not meet the specified requirement, this should be noted in the records, as far as the actions taken to handle the situation are concerned (e.g. test being repeated and/or measures taken to correct the production process).

Records must be maintained in the production area for at least the period required by the existing legislation (10 years).

7. Treatment of non-compliant products

If the control or test results show that the product does not meet the requirements, then the product must be isolated in order to:

- a) be retreated, or
- b) be used for a different application, which is appropriate, or
- c) be rejected and marked as non-compliant

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The manufacturer must record all cases of non-compliance, investigate them and, if necessary, proceed with appropriate corrective action.

NOTE - The corrective action should include:

- a) Investigation of the cause of non-compliance, including examining the testing procedure and performing necessary modifications.
- b) Analysis of processes, operations, quality records, service reports and customer complaints to detect and eliminate potential causes of non-compliance.
- c) Implementation of preventive measures for handling problems at a corresponding level with the risk identified.
- d) Application of controls to ensure that corrective actions have been taken.
- e) Implementing and recording changes in procedures resulting from corrective actions.

8. Handling, storage and conditions at production areas

The manufacturer must carry out the necessary arrangements to maintain the quality of the product during handling and storage.

NOTE: These arrangements should take into account the following:

- a) Pollution caused by the product
- b) Separation
- c) Cleaning handling equipment and storage areas.

9. Packaging, marking and transportation

The manufacturer FPC system must determine the extent of liability in relation to packaging, marking, storage and delivery.

Annex B

Requirements for the certification of system 2+

1. General Requirements

a) Manufacturer's duties

(1) determination of the product-type on the basis of type testing (including sampling), type calculation, tabulated values or descriptive documentation of the product;

(2) factory production control;

(3) testing of samples taken at the factory in accordance with the prescribed test plan

(b) the notified production control certification body shall issue the certificate of conformity of the factory production control on the basis of:

(4) initial inspection of the manufacturing plant and of factory production control;

(5) continuous surveillance, assessment and evaluation of factory production control.

2. Certification procedure

2.1 Application

The manufacturer shall submit to the Notified Body - NB formal application (application template in Appendix 1).

The application will identify the specific product or group of products, as defined in the relevant decision of the European Commission and, where applicable, in the additional guidelines.

The application normally covers a single factory.

The NB confirms receipt of the application and informs the applicant, as required, for further actions to deal with it.

Before the certification process, an agreement must be signed between the manufacturer and the NB, to agree on the following:

- The general certification rules of the NB.
- The financial obligations.
- The starting date and duration of the contract, as well as the conditions for its discontinuation.
- The special arrangements to cover liability insurance, in cases that it is not covered by the general rules of certification.
- The privacy statements.
- The appeal procedures.

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2.2 Initial inspection of the manufacturing plant and of FPC

2.2.1 The NB reviews the submitted documentation to verify that it meets the provisions of the applicable harmonized standards, and, if deficiencies exist, the NB informs the manufacturer.

2.2.2 When the documentation is found complete, the inspection date is agreed.

2.2.3 During inspection, the NB examines whether the documented FPC is implemented in accordance with the requirements of the hENs.

2.2.4 To support the inspection, the NB should prepare a checklist, taking into account the requirements of Annex A of this guidance, the applicable hTS and, where appropriate, the checklist provided by the Guidance Group of NBs. In the aforementioned checklist, the items identified as non-compliant are recorded and notified to the manufacturer after the initial inspection.

2.2.5 The type testing (TT) is not part of the FPC, but shall be conducted by the manufacturer, according to the testing methods specified in the hEN, comply with appropriate provisions and be available for at least one lot, before the initial inspection.

It is noted that in systems 1 and 1+, the TT is conducted by the NB.

2.2.6 The content of TT is the responsibility of the manufacturer and the NB should seek evidence of TT, in order to check the results obtained by the FPC for similarity and reliability. The requirements for the manufacturer's type testing laboratory are given in the following §2.5.

2.2.7 The test results of the FPC must comply with the requirements of the hEN. The FPC Manual must include the values declared by the manufacturer, as well as a process for evaluating the test results. The manufacturer must be aware of and comply with any local regulations, relating to the values of the examined properties.

It is noted that in systems 1 and 1+, the TT is conducted by the NB.

2.2.8 The testing methods used by the manufacturer shall be as specified by the hEN. Alternative methods may be used, if the results obtained are reliable, compared with those obtained with the reference method. The relevant evidence must be submitted and approved by the NB. The determination of the relation between the test results should take place on a regular basis, through a process described in the FPC Manual. In case of doubt, the hEN method is the dominant.

2.2.9 The NB should check the proper functioning and reliability of the equipment, which is used in accordance with the testing methods, as indicated in the applicable hEN.

2.2.10 After the completion of the initial inspection and no later than within 6 weeks, the NB is preparing a report on the inspection results, which is being notified to the manufacturer.

2.2.11 Within three (3) months from receiving the report, the manufacturer must inform the NB on the implemented corrective actions.

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2.2.12 If the NB finds the corrective actions as inadequate, the NB may stop the assessment and inform the manufacturer.

2.2.13 In any case, the time to implement adequate corrective actions cannot exceed the 6 months period from the initial inspection.

2.2.14 When an ETA is implemented, the NB should seek from the corresponding TAB the corresponding technical documentation, which is required for confirmation of compliance. In case of significant non-compliance, the NB should inform the TAB, so that the ETA file is kept informed.

Additional guidance concerning sample marking and test reports is given in Annex E.

2.3 Certification

2.3.1 Upon completion of the initial inspection and if appropriate actions, with the approval of the NB, have been taken for any non-conformities or observations, provided that the requirements of Annex ZA of the applicable hEN or relevant ETA have been fully satisfied, NB grants Certificate of the FPC as soon as possible (certificate template in Appendix 2).

It is noted that in systems 1 and 1+ the above certificate is not issued.

2.3.2 Normally the certificate covers one plant and one hEN or a group of related hENs.

2.4 Continuous surveillance of FPC

2.4.1 The NB conducts the surveillance of the FPC based on the requirements of the relevant harmonized technical specification, the additional scheme guidance and the results of the initial evaluation of the FPC.

2.4.2 The NB should examine the frequency and results of the tests performed as part of the FPC, in order to verify their effective implementation.

2.4.3 If serious problems are identified during surveillance, the NB may conduct additional inspections.

2.4.4 In cases of failure to take appropriate corrective actions or continuous non-compliance, the NB should inform the manufacturer of the action it intends to take, including the withdrawal of the Certificate, with simultaneous notification of the state authority.

2.4.5 The manufacturer is informed of the surveillance results.

2.4.6 The manufacturer must inform the NB for any intended changes in the manufacturing process or in the FPC, if these changes are likely to influence the declared product properties. It is the NB's responsibility to determine whether the reported changes require another audit or need to be further investigated. In these cases, the manufacturer is not allowed to release products with CE Marking, produced after the changes have taken place, until is informed by the NB.

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2.4.7 In the case of an ETA, when non-conformities or modifications of the FPC appear, the NB informs the TAB which granted the ETA, to update the product ETA file or renew the ETA, whatever is applicable.

2.4.8 The manufacturer shall maintain records of all non-conformities and complaints related to the product covered by the FPC Certificate and make them available to the NB, when asked.

2.5 Requirements for the manufacturer's / external testing laboratory

The manufacturer's (or external) testing laboratory, which conducts the TT, must comply with the requirements of EN ISO/IEC 17025, at least as regards the following:

- Sampling instructions (§ 5.7.1)
- Instructions for laboratory testing (§ 5.4.1)
- Competence to conduct a test (confirmation by witnessing the test) (§ 5.2.1)
- Calibrated equipment that meets the requirements of the testing methods (§ 5.5.1, 5.5.2)
- Records / test reports (§ 4.13.2, 5.10.1)
- Quality assurance of test results (§ 5.9.1)

Appendix 1

Application template for the certification of the FPC

I, the undersigned [name and surname],
as legal representative of [company name]
whose head office is at [address]
as manufacturing company [if applicable] (or as authorized representative established in the
EEA of the manufacturer) which is based in [complete address of the manufacturer]
.....
in compliance with Annex ZA of the EN [the numbers of the applicable hENs are provided]
.....,
apply for the first time and only to this notified certification body, for the granting of the factory
production control certificate,
of the products described below: [description of products according to the EN Standards]
.....,
produced in the factory which is at [full factory address].....

Also it is stated that:

- The product type testing has been conducted/is in the process of being conducted *, under the responsibility of the manufacturer.
- The above factory has received/not received * another valid factory production control certificate.

(* deleted accordingly)

Also I state that I know the certification rules of this notified certification body, in the framework of Regulation 305/2011/EU, including free access of the NB's auditors in this factory for performance assessment purposes, which I fully accept.

The following documents are attached:

- FPC Manual
- List of FPC system related documents

The contact person is [name and surname].....

Signature Place Date

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Appendix 2

Certificate of the FPC for the system 2+

[Number of Notified Body]/CPR/[Unique number given by the NB]

In accordance with the provisions of Regulation 305/2011/EU it is certified that the product

**[product]
[final product parameters (product performance) and classes, description of the product (type, identity, use ...), field of direct application, special conditions applicable to the use of the product in accordance with the technical specification]**

which is produced by the manufacturer:

**[Name of the Manufacturer]
[Complete address of the manufacturer]**

in the plant

[plant]

has been submitted by the manufacturer to type testing and factory production control and that the notified body [Name of the NB] has performed the initial inspection of the manufacturing plant and of factory production control and conducted continuous surveillance, assessment and evaluation of factory production control.

This certificate states that all the planned actions for the confirmation of factory production control were applied, which are described in annex ZA of the standard

[EN XXX:YYYY] or [ETA XYZ]

This certificate is issued on [date] and shall remain in effect as long as the conditions of factory production or the FPC do not change significantly, as laid down in the harmonised technical specification and no later than [date] (as indicated in the applicable standard).

[City, Date]

[Authorised signature, title]

Annex C

Requirements for the certification of system 1+

1. General Requirements

a) Manufacturer's duties

1. Factory Production Control- FPC,
2. Further testing of samples taken at the factory in accordance with the prescribed test plan;

b) Notified body's duties.

3. Determination of the product-type on the basis of type testing (including sampling), type calculation, tabulated values or descriptive documentation of the product
4. initial inspection of the manufacturing plant and of FPC,
5. Continuous surveillance, assessment and evaluation of factory production control.
6. audit-testing of samples taken before placing the product on the market.

2. Certification procedure

The procedure in Annex B is applied, adapted to the manufacturer's and NB's duties, as defined above, while the corresponding templates of certificate and application are set out in Appendices 3 and 4 below.

In addition, the following shall apply:

2.1 Performing type testing and granting certification

2.1.1 The manufacturer must implement an internal quality control system for testing each certified product. This system should be used to demonstrate compliance with the requirements of the section entitled "Compliance Criteria" in the relevant product specification.

The properties that are to be tested, the testing methods, the minimum internal quality control testing frequency during routine tests and initial period tests, as well as the compliance criteria must follow the basic requirements of the section entitled "Compliance Criteria" in the relevant product specification.

All test results must be documented.

2.1.2 The NB implements appropriate procedures for type testing and audit-testing of samples taken on the open market, at the factory or on site.

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The audit-testing requires that:

- The testing of the product is in accordance with the testing methods defined in the technical specification and the TT.
- Test results are compared with the declared product performance, derived from TT.
- A test report is issued and delivered to the manufacturer, which confirms that the conclusions are in conformity with the technical specifications, the TT and the requirements of FPC.

2.1.3 After successful completion of type testing, of the initial inspection of the factory and the FPC, as well as the audit-testing of samples, the NB issues the certificate of constancy of performance of the product.

2.2 The NB should have an appropriate sampling scheme and acceptance criteria for the following:

- ✓ the manufacturer's internal quality control
- ✓ used by the certification body to check the correctness of the sampling carried out by the manufacturer (applicable only for systems 1, 1+)
- ✓ used by the certification body to check the correctness of the testing performed by the manufacturer (applicable only for systems 1, 1+)

Moreover, the NB should have clear decision-making rules and related measures, for the cases when one or more of the above acceptance criteria are not met.

2.3 Corrective actions

The factory quality manual should document the procedures for the review and proper modification of the factory production control in the case of non-compliance.

The actions taken in the case of non-compliance should be recorded in a report, which will be checked during management review.

2.4 Maintenance of the certificate of constancy of product performance

To maintain the validity of the certificate, the NB applies the schedule below:

- 2.4.1 Annual factory, FPC inspection and testing laboratory audit, if it is not determined in the relevant specifications, otherwise the requirements of the relevant specifications should be followed.
- 2.4.2 Management of the non conformities / corrective actions arising from the aforementioned annual inspection.
- 2.4.3 Evaluation of audit-testing conducted by the manufacturer.
- 2.4.4 Management of the non conformities / corrective actions arising from the aforementioned evaluation.

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2.4.5 NB's audit-testing.

2.4.6 Management of the non conformities / corrective actions arising from the
aforementioned audit-testing.

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Appendix 3

Application template for the certification of the constancy of product performance

I, the undersigned [name and surname],
as legal representative of [company name]
whose head office is at [address]
as manufacturing company [if applicable] (or as authorized representative established in the
EEA of the manufacturer) which is based in [complete address of the manufacturer]
.....
in compliance with Annex ZA of the EN [the numbers of the applicable hENs are provided]
.....,
apply for the first time and only to this notified certification body, for the granting of the
certificate of the constancy of performance of the products described below: [description of
products according to the EN Standards],
produced at the factory which is at [full factory address].....

It is also stated that:

- The above-mentioned factory and the Production control system comply with the requirements of the EN [the numbers of the applicable EN standards are provided]
- The above-mentioned products comply with all the requirements specified in annex ZA of the above EN standards.
- This product has not yet received another valid certificate of the constancy of performance.

Also I state that I know the certification rules of this notified certification body, in the framework of Regulation 305/2011/EU, including free access of the NB's auditors in this factory for performance assessment purposes, which I fully accept.

The following documents are attached:

- System Manual
- List of system's related documents

The contact person is [name and surname].....

Signature Place Date

Note: the above application can adapt accordingly to the specific requirements of applicable documents that may exist for the particular product/product group.

Appendix 4

Certificate of the constancy of product performance

[Number of Notified Body]/CPR/[Unique number given by the NB]

In accordance with the provisions of Regulation 305/2011/EU it is certified that the product

**[product]
[final product parameters (product performance) and classes, description of the product (type, identity, use ...), field of direct application, special conditions applicable to the use of the product in accordance with the technical specification]**

which is produced by the manufacturer:

**[Name of the Manufacturer]
[Complete address of the manufacturer]**

In the plant

[plant]

has been submitted by the manufacturer to factory production control and to further testing of samples taken at the factory in accordance with the prescribed test plan and that the notified body [Name of the NB] has performed the determination of the product-type, the initial inspection of the manufacturing plant and of factory production control and conducts continuous surveillance, assessment and evaluation of factory production control and the audit-testing of samples taken from the plant.

This certificate states that the predictions for the Declaration of Performance were applied, which are described in annex ZA of the standard **[EN XXX:YYYY] or [ETA XYZ]** and that the product meets all the minimum prescribed requirements by this standard or ETA.

This certificate is issued on [date] and shall remain in effect as long as the conditions of factory production or the FPC do not change significantly, as laid down in the harmonised technical specification and no later than [date] (as indicated in the applicable standard).

[City, Date]

[Authorised signature, title]

Note: the above certificate can adapt accordingly to the specific requirements of applicable documents that may exist for the particular product/product group.

Annex D

Type Testing [GP M]

Type Testing (TT)

Construction products, which are subjected to a system of declaration of performance on the basis of harmonised technical specifications, must be submitted to type testing. In practical terms this means that the producer must indicate certain characteristics of the product in accordance with the harmonised standard by conducting the type testing, even for products that are already on the market.

For the TT the following principles are applied:

1. TT is the complete set of tests or other procedures, which are described in the harmonised technical specification and which determine the performance of samples of the product, representative of the product type.
2. TT verifies that the product complies with the harmonised technical specification and defines the performance of all harmonised characteristics that must be declared.
3. Depending on the purported uses and markets of the product, it is possible to limit the extent of TT.
4. TT can cover product group, provided that the various types of products do not affect the level of safety and the other requirements, connected to the performance of the product.

The term type testing is not only used to cover physical tests but also other ways of demonstrating conformity of a product, such as calculations, conventionally acceptable performance or table made reference data.

However, even in the case of use of product categorization without the need for further testing, the producer may need to conduct some controls (e.g. measurement of density) in order to demonstrate that his product meets the definition (product definition).

The test and assessment methods according to a hEN or EAD may require one of the following approaches:

1. pass/fail,
2. test results that are used to establish levels or classes that are declared (e.g. fire behavior classes),
3. that the manufacturer states the test result itself, a mean value, or a mean value plus a declared tolerance, according to what is required by the technical specification.
4. a 'manufacturer's limiting value' (the value which all products have to meet or exceed in tests)
5. other, statistical means of declaration (e.g. characteristic/design value, acceptable or limiting quality levels).

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Possibilities of TT test costs reduction

Where a manufacturer produces the same product on more than one production line or unit, or in more than one factory, there may be no need to repeat TT for these different production lines or units (the manufacturer takes responsibility for ensuring that the products are indeed the same).

The need to repeat TT depends on whether the production equipment used in the factory, and/or the production line or unit, might influence the performance declarations forming part of the CE marking. Where an influence exists, technical specifications may need to specify that TT needs to be performed for each factory, production line or unit separately. Otherwise, the individual manufacturer can decide on this issue, being the ultimate responsible for the declarations accompanying the CE Marking. Manufacturers must be conscious that if TT is performed on samples from various production units, lines or even factories, they will have to ensure that the declarations are valid for all products that rely on that TT.

To avoid the repetition of testing, two different possibilities are presented below:

A. Shared TT results (in principle applicable to all AoC systems)

A manufacturer may use TT results obtained by someone else (e.g. by another manufacturer, as a common service to manufacturers, or by a product developer), to justify his own declaration of performance regarding a product that is manufactured according to the same design (e.g. dimensions) and with raw materials constituents and manufacturing methods of the same kind. This procedure is applicable under certain requirements (see Guidance Paper M, § 4.13.1).

B. Cascading TT (to be applied under systems 1, 1+ and 3 only)

For some construction products, there are companies (system houses) which supply or ensure the supply of, some or all of the components to an assembler who then manufactures the finished product in his factory.

The system house may take the responsibility for the TT regarding one or several mandated characteristics of an end product which is subsequently manufactured and/or assembled by other firms in their own factory. When doing so, the system house must submit an “assembled product” using components manufactured by it or by others, to type testing and then make the TT report available to the assemblers, i.e. the actual manufacturer of the product placed on the market.

The assembler can use the TT report that the system house has obtained with regard to tests carried out by a Notified Body for CE marking purposes, without the assembler having to involve again a Notified Body to undertake TT of the product's characteristic(s) that were already tested. In this case, it must be verified that the assembler manufactures a product which uses the same combination of components (components with the same characteristics), and in the same way, as that for which the system house has obtained a TT report. If this report is based on a combination of components not representing the final product as to be placed on the market, and/or is not assembled in accordance with the system house's instruction for assembling the components, the assembler needs to subject his finished product to TT. The assembler remains responsible for the product being in compliance with all the provisions of the CPR, including both the design and the manufacture of the product.

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Permitted alternatives

In principle, testing laboratories approved for type tests for systems 1, 1+ and 3 and audit testing (1+) should perform their testing using their own testing apparatus and personnel. However, such tests may also be performed using the manufacturer's testing facilities (for instance, if it is excessively complex [e.g. large samples difficult to be transported] or economically disproportionate to perform the tests in the Notified Body's premises), provided that:

- the manufacturer's equipment for testing are calibrated with documented traceability,
- the Notified Body agrees to the use of the manufacturer's testing facilities knowing that he retains the responsibility for the test performed and its results,
- the Notified Body conducts the test, and assists to them also in the case they are carried out by the manufacturer's staff,
- the tests at the manufacturer's test facilities are performed in strict conformity with the testing procedure of the relevant test technical specification, including sampling and the preparation of samples, and
- the Notified Body decides whether to take into consideration the test results or not.

Insofar testing laboratories use manufacturer's testing facilities, it must be assured that they are and must remain third parties independent of their clients and other interested parties.

The use of the manufacturer's testing facilities does not mean any subcontracting (Guidance Paper A clause 3.4). It does not give to the manufacturer the status of a notified body.

When facilities of the manufacturer are used by a Notified Body to perform all or part of testing this shall be noted in the test report.

Under AoC systems 2+ and 4, for which TT is a task for the manufacturer, the latter may entrust this task or parts of it to any party equipped and qualified to undertake correct TT for the product concerned, provided that all rules relevant for the AoC system in question will be properly applied. So therefore the testing laboratory should implement the requirements of EN ISO/IEC 17025 without the need for accreditation.

Type testing in system 3

Each product type, which is subjected to Declaration of Performance, must be tested by a notified body in accordance with the relevant technical product specification. The tasks for the notified body involved in the type testing are limited to the characteristics mentioned in Annex ZA of the standard.

The sampling of products which will undergo type testing is the responsibility of the producer. The sample should be taken from finished products, ready for marketing. Also, the sample must be taken in random order and be representative of normal production and also be recognized purely to ensure that the sample is intended to control. The producer must record the following:

1. producer name and address
2. description of the product
3. the way in which the product is marked,
4. marking of the product by the manufacturer
5. production batch control,
6. sample size,
7. place and date the sample was taken,
8. other necessary product information useful for testing.

Sampling and characteristics of the product must be in accordance with the relevant harmonised standard.

Annex E

Part A

Sample Marking

1. All samples to be used for testing purposes need to be suitably marked to allow a subsequent verification that the producer has fulfilled his obligations. This demonstrates that the manufacturer has followed the rules in the harmonised EN or EAD, that all tests have been carried out on the same batch of samples, if this is specified, and that the samples are representative for the product to be placed on the market.

2. Sample-marking on the product will at least include production line, date and time of the taking of the sample. The sample identity needs to be recorded in all test reports to enhance traceability.

3. Products declared by the manufacturer to be defective may only be excluded from sampling if they have been set aside and marked accordingly.

4. In the case of sampling by a Notified Body, the sampler needs to prepare and sign a record on sampling that needs to be countersigned by the manufacturer or his representative (when relevant). The record should at least include the following information:

- Manufacturer and manufacturing plant
- Place of sampling
- If necessary, stock or batch quantity (from which the samples have been taken)
- Number or quantity of samples
- Identification of the construction product in accordance with the technical specification
- Marking of the product by the manufacturer
- Marking of the samples by the sampler (when relevant)
- Where necessary, properties to be tested
- Place and date
- Signatures
- Registration number of the Notified Body

Part B

Test Reports

The results of each test, independent of whether this test is part of the type test or audit testing by the manufacturer or a third party, need to be recorded in a "test report". The test report should at least include the following information:

- Manufacturer and manufacturing plant
- Identification of the construction product in accordance with the relevant technical specification
- Information about
 - sampling
 - date of testing
 - involved personnel
 - applied testing methods according the relevant technical specification
- Identification of the organization and personnel executing the test
- Place and date
- The results of the test, including analysis of these when relevant.
- Place and date of the delivery of the test report.
- Registration number of the Notified Body (when relevant)
- Signature of the head of the testing laboratory and stamp (when relevant).

The test report must comply with the relevant clauses of the technical specifications. The complete set of test reports will be kept by the manufacturer and the certification body (when relevant) and will be made available to the market surveillance authorities on demand.

Test laboratories will keep the test reports that they have issued.