POSITION PAPER: Guidance on AVCP system 2+

1 Introduction

The tasks of notified bodies under AVCP system 2+ are defined in CPR Annex V, point 1.3, litra b:

> *The notified factory production control certification body shall decide on the issuing, restriction, suspension or withdrawal of the certificate of conformity of the factory production control on the basis of the outcome of the following assessments and verifications carried out by that body:*
>
> *(i) initial inspection of the manufacturing plant and of factory production control;*
>
> *(ii) continuing surveillance, assessment and evaluation of factory production control.*

The above description does not provide much detail on the intended content of the tasks, or on how notified bodies should undertake the issuance of certificates, initial inspection, continuing surveillance, assessment and evaluation. Therefore, to facilitate a harmonised approach among notified FPC certification bodies, this position paper has been developed.

Since the CPR gives preference to notified bodies accredited to harmonised accreditation standards within the meaning of the 'New Legal Framework', it seems appropriate to apply the principles of accredited certification to notified body tasks under AVCP system 2+.

Consequently, notified FPC certification bodies shall follow the same general practices irrespective of their accreditation status because CPR Article 55 requires the formation of a Group of Notified bodies (i.e. the GNB-CPR) and CPR Article 43(11) states that the notified body "*shall apply as general guidance the administrative decisions and documents produced as a work result of that group."*

This position paper supplements the normative and informative guidance given in NB-CPR/AG/03/002 '*Guidance to notified bodies on the assessment and verification of constancy of performance under the Construction Products Regulation 305/2011/EU'* and the informative guidance given in NB-CPR/13/567r4 '*What certification of an FPC system means for construction products at AVCP system 2+'*.

Although this position paper aims specifically at AVCP 2+, the principles it describes for the assessment of Factory Production Control would be generally applicable to systems 1 and 1+ as well. It should however be noted that section 4.3 of this document is not applicable to systems 1 and 1+.

2 Basic principles and objectives

In CPR, factory production control (FPC) is defined as *'the documented, permanent and internal control of production in a factory, in accordance with the relevant harmonised technical specifications'.*

It should be emphasised that FPC does not only consist of the documented system of the manufacturer but also the practical implementation including personnel, equipment and other resources used for the controlling of the production.

~~Some MS authorities and national accreditation bodies have considered EN ISO/IEC 17021 as the reference accreditation standard for accreditation of notified bodies operating under system 2+, whereas the majority of MS authorities and national accreditation bodies have preferred EN 45011.~~

For the purpose of GNB guidance under the CPR, certification of FPC under AVCP system 2+, should be seen as *process certification*.

EN ISO/IEC 17065 has been cited in Official Journal of the European Union (OJEU) which gives EN ISO/IEC 17065 the status of a harmonised standard[1] ~~with a transition period until 15 September 2015[2]. After this transition period, it should supersede EN 45011~~. Importantly, EN ISO/IEC 17065 defines the '*product'* as the result of a '*process'* and thereby allows for certification of the *process* itself without certifying the *product* as such. It is therefore recommended that EN ISO/IEC 17065 should be the preferred accreditation standard for notified FPC certification bodies under AVCP system 2+ ~~once EN 45011 is superseded~~[3].

~~It should be noted that the European co-operation for Accreditation (EA), which represents all European national accreditation bodies, has not developed specific guidance to assist its members in accrediting notified bodies to the different AVCP systems under the CPR. Should specific EA guidance be issued it may affect the accreditation requirements expected of notified bodies to the CPR.~~

2.1 Effectiveness of factory production control

On applying the concept of process certification, the objective of the certified processes should be seen as **achieving construction products meeting the defined requirements**, i.e. the manufacturer is effectively able to manage and demonstrate the actual performance of the construction products.[4]

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[1] *The term 'harmonised standard' refers in this case to EU Regulation 765/2008 on accreditation and market surveillance and to CPR Article 44 on presumption of conformity.*

[2] ~~*See NB-CPR/M07-015/Sep 2013 - List of Harmonised Accreditation Standards cited in the OJ 2013/C 258/05.*~~

[3] *Other accreditation standards, such as ISO 17020 (inspection) and EN ISO/IEC 17021 (management system certification) can be used as evidence of compliance with requirements of CPR Article 43 in order to be designated as a notified FPC certification body. Irrespective of which standard a notified FPC certification is accredited against, the notified FPC certification body shall also comply with the relevant parts of ~~EN 45011 /~~ ISO 17065.*

[4] *The actual performances may be higher than those given in the manufacturer's Declaration of Performance. The manufacturer may for example, wish to maintain a safety factor, or even make two declarations for what is essentially the same construction product; one with low declared values for a generic construction product and the other with higher values for a specialist construction product for more demanding applications.*

CPR Article 52(3) states:

> *Where, in the course of the initial inspection of the manufacturing plant and of factory production control, a notified body finds that the manufacturer has not ensured the constancy of performance of the manufactured product, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate.*

Hence, the effectiveness of FPC ~~should~~ shall be assessed with regard to its ability to ensure the constancy of the declared performance of the construction products.

According to the CPR, the manufacturer always holds full responsibility for the construction product.

The involvement of a notified FPC certification body does not in any way reduce the responsibilities of the manufacturer (however, in cases of proven misconduct, the notified FPC certification body could be liable for consequences of their misconduct).

It should be emphasised that the notified FPC certification body is neither responsible for the construction product itself, the control of production activities, the declaration of performance, nor marking of the products.

Therefore, manufacturers should be made aware that they have sole responsibility – even if a notified FPC certification body should fail to meet its obligations and fail to detect nonconformities.

~~2.1~~2.2 Reference list

- Accreditation standards:
  - ~~EN 45011;~~
  - EN ISO/IEC 17065;
- ~~IAF / EA guidance:~~
  - ~~IAF GD5:2006 applies when EN 45011 is used as reference;~~
  - ~~When EN ISO/IEC 17065 is applied, no IAF guidance is expected.~~
- EC / SCC guidance:
  - However, as the guidance papers have not been updated to reflect the changes from CPD to CPR, and as the papers do not have (and never had) any legally binding status, the guidance papers should primarily be seen as ‘background information’. In particular, they should not be used when in direct conflict with the CPR;
  - The understandings expressed in Commission Guidance Papers ‘A’ through to ‘M’ can be of use in guiding notified bodies in some circumstances;
  - Guidance Paper ‘K’ gives background information on the Attestation of Conformity (AVCP) systems and the role and tasks of the notified bodies.
- Notified bodies shall observe:
  - CPR, in particular Article 52;

- Accreditation requirements derived from standards and legislation that are applicable to accredited bodies;

- ~~Member state requirements for the designation of bodies to the CPR.~~

3 Obligations of the manufacturer with regard to (FPC ~~systems)~~

A manufacturer is obliged to comply with the CPR and the harmonised technical specification(s) applicable to their construction product(s).

Additionally, the manufacturer is obliged to meet obligations derived from the accreditation standards, as the accreditation standards require the certification body to specify certain requirements to their client; e.g. to maintain records of complaints. This should be defined by the contract[5] between the manufacturer and the notified FPC certification body.

In principal, the FPC requirements defined in harmonised technical specifications should be sufficiently detailed to serve as a comprehensive basis for assessment of the manufacturers' FPC.

However, it is well-known that some harmonised technical specifications do not go into sufficient detail with regard to FPC requirements.

In such cases, Commission Guidance Paper 'B' may serve as a useful interpretative tool; as may CEN guidance for drafting AVCP clauses in harmonised standards.

Irrespective of how detailed the FPC clauses are in the harmonised technical specification, the notified FPC certification body shall satisfy itself ~~satisfy itself~~ that the FPC as implemented by the manufacturer is effective, i.e. the manufacturer is effectively able to manage and demonstrate the actual performance of the construction products.

4 Obligations of the notified FPC certification body

The work of the notified FPC certification body should follow the general principles for (accredited) product certification bodies.

Inspections (terminology of the CPR) should follow the general principles for auditing as described by EN ISO 19011. The effective functioning of the FPC should be assessed by on-site auditing of the systems followed by the personnel operating and taking responsibility for the individual activities.

Following the general principles of product certification it is also implied that priority is given to the technical competence of the auditors. As a minimum, auditors should have thorough knowledge of the construction product(s), the production process(es), and the relevant harmonised technical specification(s). The notified FPC certification body shall define its requirements regarding competence of auditors and ensure that the requirements are complied with. On request, compliance shall be demonstrated to the notifying authority and/or national accreditation body.

The procedures of the notified FPC certification body should include the 'four eyes principle' or 'two-man rule' to make sure that all decisions regarding issuance of certificates are undertaken by a

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[5] *Requirements derived from the accreditation standards are only binding for manufacturers if defined by the contract between the manufacturer and the FPC certification body.*

person who has not been involved in the certification process (See EN ISO IEC 17065 clauses 7.5.1 and 7.5.2)

4.1 Extent of assessment

The notified FPC certification body shall assess the FPC-system (as implemented) in its entirety for the initial inspection with regard to its effectiveness as described above.[6]

This implies that all parts of the documented system and the operational practices of the manufacturer with relevance to the conformity/performance of the essential characteristics being assessed shall be subject to assessment.

In some harmonised technical specifications, the 'FPC-clauses to apply' referenced by the annex ZA may not be particularly detailed. This should not be seen as a limitation or restriction of the notified FPC certification body responsibility.

The notified FPC certification body shall still assess the effectiveness of the FPC and may use appropriate tools and references for the interpretation of the harmonised technical specifications.

4.2 Manufacturer's declarations and product markings

~~It is a widely held opinion that~~ The tasks of notified FPC certification bodies do not include assessment of the manufacturer's Declaration of Performance (DoP), CE marking or other declarations/markings of construction products.

Nevertheless, the Declaration of Performance is one of the starting points for understanding the scope of the FPC and knowledge of the content of the DoP is necessary when assessing the effectiveness of the FPC.

~~Moreover, Notified FPC certification bodies should be aware that CPR Articles 44, 47 and 48 suggest that accreditation is the preferred route for notification, and that accreditation standards require the certification body to exercise control of the client's way of indicating that construction products (processes) are certified and also requires the certification body to have a contractual agreement in place covering that aspect.~~

~~Most notified FPC certification bodies consider assessment of construction product declarations and markings an essential element of the certification, and abstaining from assessing declarations or markings may even present a risk of noncompliance with accreditation standards.~~

~~As it is a common opinion that n~~Notified bodies ~~should~~ are not expected to assess neither the~~declaration s~~ DoP nor the CE marking for which the manufacturer is solely responsible. Nonetheless, the~~s, the notified~~ FPC certification body should inform the manufacturer if it becomes aware of any error or omission in the DoP or the CE marking. ~~may therefore choose not to report these assessments as part of its AVCP tasks but instead inform the manufacturer of the findings by other means.~~

The correction or such errors or omissions in the DoP or CE marking would be the sole responsibility of the manufacturer and their correction should not be a prerequisite for the issuance or the maintenance of the FPC certificate. However, if a notified Body becomes aware of any

[6] *At subsequent inspections (audits) the notified FPC certification body shall carry out surveillance ~~on selected parts~~ of the FPC-system as part of the notified body's audit programme.*

misleading references to the certification, e.g. if the manufacturer is using the ID number of the notified body in connection with products not covered by the scope of the certificate the notified body shall require the manufacturer to remove the misleading references. Accreditation standards do ~~however~~ also require the certification body to take appropriate action in case of misleading references to certification.~~.~~

~~Whether or not findings related to the declarations or markings of construction products are formally reported, i~~It should be clear to the manufacturer that the notified FPC certification body neither has authority to officially approve nor validate the declarations or markings.

4.3 The manufacturer's Assessment of the performance of the construction product[7]

In AVCP system 2+, all activities related to the assessment of the performance of the construction product are left to the manufacturer who is responsible for ensuring that everything is conducted in compliance with the rules, including the documentation on sampling and testing.

The role of the notified FPC certification body is to assess that the manufacturer is conducting the assessment of the performance of the construction product correctly, adequately and credibly. The fact that the manufacturer is responsible does not remove the notified FPC certification body's responsibility to verify compliance.

Assessment of the manufacturer's assessment of the performance of the construction product should ensure that:

- Sampling is documented, and that it is justified that the samples taken are representative of continuous production;
- The correct methods, as specified in the harmonised technical specification, are used to perform the assessment of the performance of the construction product;
- The assessment of performance is documented in accordance with the requirements of the harmonised technical specification~~.~~;
- That all mandatory threshold levels are being met;
- The relevant personnel appear suitably qualified and competent to perform the assessment of the performance of the construction product;
- Suitable practices are in place for calibrating and maintaining equipment, including evidence of correct calibration of the equipment used to perform the assessment of the performance of the construction product;
- Where the assessment of the performance of the construction product is (was) subcontracted, the manufacturer provides a justification of the competence of the testers/calculators/assessors;
- The manufacturer has the competence to assess the field of application of the test report.

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[7] *The term "Assessment of the performance of the construction product" is taken from the 2nd edition of CPR Annex V. In the 1st edition of Annex V, the term was "determination of product type". Under CPD, the terminology was "Initial Type Testing".*

- That the manufacturer has processes defined to ensure that assessment of the performance of the construction product shall be repeated in case of changes to the construction product, FPC or harmonised technical specification which are likely to affect the declared performance.

4.4 Complaints

In most types of certification, complaints are generally considered a very important source of information.

The CPR does not however address how a manufacturer should respond to complaints, or whether a notified FPC certification body shall assess the manufacturer's processes for complaints from its clients.

It should however be noted that accreditation standards require the certification body to require the manufacturer to record complaints and make these records available to the certification body. Hence, the contract between the accredited notified FPC certification body and the manufacturer shall allow the accredited notified FPC certification body to investigate complaints. Notified FPC certification bodies should use complaints as a source of information on the effectiveness of the FPC[8].

4.5 Interpretation of harmonised technical specifications

Harmonised technical specifications that give inadequate, unclear or incorrect guidance need to be corrected by the relevant Technical Committee of CEN or EOTA. To assist in their amendment and correction there should be regular communication between the relevant Technical Committee and the relevant GNB-CPR Sector Group regarding problems with harmonised technical specifications. As an interim measure, the GNB-CPR sector group can draft a position paper for approval by Advisory Group, clarifying how NBs should implement the harmonised technical specification until it is improved by CEN or EOTA. A position paper should not contradict a harmonised technical specification unless serious errors have been found in the technical specification, and the relevant technical committee has agreed that the position paper conforms to an anticipated revision of the technical specification.

It should be noted that harmonised standards developed under CPD are in general not aligned with CPR. In case of any discrepancy between a harmonised standard and CPR, CPR overrules the harmonised standard.

4.6 Multiple site sampling[9]

CPR Annex V, clause 1.3. b (i) requires the notified FPC certification body to decide on the issuing of the certificate on the basis of the outcome of

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[8] *Complaints regarding product costs, late delivery etc. would normally be irrelevant to the effectiveness of the FPC.*

[9] *Multisite sampling is a method of reducing the number of audits when an organisation has a number of similar sites conducting identical production of similar product (i.e. same harmonised technical specifications) under the same unique management system. For certification of management systems, rules are described by International Accreditation Forum in the document IAF MD 1:2007.*

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

Hence, for the initial inspection multisite sampling is not an option.

For the continuing surveillance, notified bodies should be aware of the extensive risks related to multisite sampling, as failing to audit each of the manufacturing plants could reduce the credibility of the certification.

Multisite sampling ~~should~~ shall not be applied without a properly documented justification specific to the individual manufacturer

4.7 Duration and frequency of audits

Notified Bodies shall have a documented process for the determination of audits/inspections.

No typical/general audit durations can be defined because the time required for the audit depends upon the construction product(s), process(es) and manufacturing location(s) assessed.

However, Sector Group may develop guidance related to harmonised specifications in their field of work.

For the frequency of audits, reference is made to the position paper NB-CPR 16/684

4.8 Importers and distributors - "Article 15 manufacturers"

When an importer or distributor places a construction product on the market under his own name or trademark or modifies a construction product already placed on the market, according to CPR article 15 he is considered a manufacturer for the purposes of CPR and has all the obligations of CPR gives to a manufacturer.

Accordingly, when the client is an importer or distributor acting as an "article 15 manufacturer" the tasks for the notified FPC certification body is basically the same as when the client is any other manufacturer.

In particular, it should be emphasised that the notified FPC certification body[10] shall always conduct an initial inspection at the 'manufacturing plant' as basis for the decision on issuing the certificate. This means that the notified FPC certification body shall visit the site where the manufacture physically takes place. To visit the premises of the importer/distributor would not be sufficient.

If storage or other processes that could affect conformity with the declared performance(s) are conducted by the importer/distributor, those processes shall be covered by factory production control carried out by the importer/distributor. Accordingly, the premises where the processes take place shall be subjected to initial inspection and the factory production control at those premises shall be subjected to continuing surveillance, assessment and evaluation conducted by the notified FPC certification body.

[10] *CPR Annex V 1.3 b requires the notified FPC certification body to conduct the tasks described. That does not exclude the possibility of subcontracting tasks in accordance with CPR article 45.*

4.9 Simplified procedures

This position paper does not provide any guidance related to ‘simplified procedures’ according to CPR article 38.