

GNB-CPD SG02	Guidance from the Group of Notified Bodies for the Construction Products Directive 89/106/EEC	NB-CPD/SG02/03/002r1 Issued: 11 November 2004 APPROVED
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GNB-CPD position paper from SG02 - EN 934-2 AND EN 934-4

Procedures for certifying FPC for admixtures for **concrete**, grout and for prestressing tendons

A position paper from SG02 for the certificate of factory production control in compliance with annex ZA of EN 934-2 and EN 934-4 related to:

- concrete admixtures
- admixtures for grout for prestressing tendons

Revisions to NB-CPD/SG02/03/002 issued 20 April 2003 and incorporated in this document NB-CPD/SG02/03/002r1:

Rev1. *After discussions within SG02, minor and largely editorial changes have been made to the forward of NB-CPD/SG02/03/002 issued 20 April 2003.*

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1. FOREWORD

This document was prepared by Sector Group 02 of the Notified Bodies working under Construction Products Directive 89/106/EEC. It is intended to give guidance to notified bodies in preparing equivalent procedures in relation to the issue of a certificate of Factory Production Control (FPC) as required in Annex ZA of EN 934-2 and / or EN 934-4 on request from a manufacturer of admixtures.

The scope of this document is the initial assessment of the factory production control (FPC) and the continuous surveillance once the certificate has been issued. Initial type testing (ITT), sampling and retesting do not fall under the tasks of the notified certification body.

This document is guidance only. In all cases the relevant standard prevails.

To maintain equivalent use and interpretation of this document by the NBs it is important that any questions are communicated to the secretary of the NB-CPD/SG02. The address of the secretary can be founded on the CIRCA web site.

2. SCOPE AND FIELD OF APPLICATION

This document defines and describes the sequence of the main operating procedures to be followed by a notified certification body in granting and maintaining a certificate of factory production control for admixtures on the basis of the requirements of Annex ZA of EN 934-2 and/or EN 934-4.

1 3. REFERENCE LIST

EN 934-2:2001 Admixtures for concrete, mortar and grout – Part 2: Concrete admixtures – Definitions, requirements, conformity, marking and labelling

EN 934-4:2001 Admixtures for concrete, mortar and grout – Part 4: Admixtures for prestressing tendons – Definitions, requirements, conformity, marking and labelling

EN 934-6:2001 Admixtures for concrete, mortar and grout – Part 6: Sampling, conformity control and evaluation of conformity

Guidance paper K – The attestation of conformity system and the role and tasks of the notified bodies in the field of the Construction Products Directive.

Position paper NB-CPD 01/002-rev 04: Guidance on the participation of the notified bodies in the attestation of conformity under the Constructions Products Directive 89/106/EEC. (Annex 5 contains the relevant parts for the attestation of conformity for level 2+).

4. TERMINOLOGY

For terms used in this document that are not covered in the documents listed in clause 3, explanations are given below.

4.1 Producer / manufacturer

Company having full control and responsibility for the quality of the delivered admixtures and carrying out the factory production control. Typical activities are selection of raw material, diluting, mixing and filling of transport media.

4.2 Supplier / trader

A company buying a CE-marked admixture and selling it under its own (brand) name without changing the composition of the admixture. The admixture is sold with the CE marking of the producer.

4.3 Non-compliances

In the context of these operating procedures the following degrees of non-compliances are applied. These are criteria, recommendations based on a large experience in the certification activity.

Observation:

Non-compliance which affords no risk to the functioning of the factory production control but must be dealt with before the next inspection of the factory production control;

Remark:

Non-compliance which affords no risk to the effective functioning of the factory production control when dealt with within a limited period of time, for example 2 months;

Non-conformity:

non-compliance that effects the functioning and the effectiveness of the factory production control in such a way that products that do not comply with the relevant standard can be put on the market. This kind of non-compliance normally makes it necessary to repeat all or part of the inspection of the factory production control.

4.4 Notified certification body

In the context of these operating procedures the term "notified certification body" can also refer to a subcontracting inspection body carrying out inspection tasks under the responsibility of the notified certification body. All contacts with the manufacturer will go through the notified certification body.

5. CERTIFICATION PROCESS

The scheme to be followed by the Notified Certification Body to grant and maintain the Certificate of Factory production Control is divided into four main "operative phases":

- the application (see chapter 6),
- the initial inspection of the factory and the FPC (see chapter 7) and
- the issuing of the certificate (see chapter 8)
- the continuous surveillance of FPC (see chapter 10).

6. APPLICATION

See 2.2 of annex 5 for general information.

The application for certification of factory production control is submitted by the producer or his legal representative to the notified body. A model for an application form is given in annex 1.

Before a certificate can be issued a certification agreement between the producer and the notified certification body must be signed. This can take place immediately after the application form has been submitted or before the issuing of a first certificate, depending on the certification regulations of the notified certification body.

The agreement will be dealing with (among others) the following items:

- reference to the general certification regulations of the notified certification body;
- financial obligations;
- starting date, duration of the agreement and terms for discontinuation of the contract;
- specific regulations about liability as far as they are not mentioned in the general regulations;
- declaration of confidentiality.

7. INITIAL INSPECTION OF THE FACTORY AND THE FACTORY PRODUCTION CONTROL

See 2.3 of annex 5 for general information.

Before carrying out the initial inspection of the factory and the FPC the notified certification body shall verify whether all articles described in 5.4 (specifically 5.4.3) of EN 934-6 are dealt with appropriately in the production control manual and related documents.

If this is not the case the Notified Certification Body will inform the producer about the non-compliances found and request corrective actions and an updated version of the documents.

When the documentation is accepted by the notified certification body a date for the initial inspection of the factory and the FPC will be agreed upon. During this initial inspection the notified certification body will investigate whether the documented system is implemented in accordance with the requirements of EN 934. A checklist, prepared by the notified certification body, should support the inspector in this task. Items found not to be in compliance are classified as observations, remarks and non-conformities and reported at the end of the initial inspection.

The initial type testing (ITT) (see 5.3 of EN 934-6) is not part of the factory production control but must have been carried out by the producer in accordance with the test methods described in the standard.

ITT is the responsibility of the producer, but the certification body may wish to see evidence of ITT to check the results from the factory production control for similarity and credibility.

Test results from FPC must comply with the requirements of the appropriate part of EN 934 and the product specification (manufacturers stated values as referred to in table 1 of the

appropriate part of EN 934). The manufacturer stated values and a procedure for the evaluation of the test results must therefore be part of the production control manual of the producer.

Test methods used by the producer must be the methods prescribed in the relevant standards. Alternative methods can be used if the results of those methods have a reliable correlation with the results of the reference method. See also the explanation under "Table 13" in Annex 2. Determination of the correlation of test results should be carried out on a regular basis using a procedure described in the production control manual. In case of doubt the method prescribed in the standard prevails.

Checks on proper functioning and reliability should be carried out on equipment used in the relevant test methods. Guidance is given in annex 3.

Results of production control tests (see 5.4.5.e of EN 934-6) of the admixtures mentioned in the application form must be available for at least one produced batch at the time of the initial inspection.

A report containing the results of the assessment of the works production control manual and related documents and the initial inspection of the factory will be sent to the producer within an agreed time after the initial inspection, normally not longer than 6 weeks.

The producer shall inform the notified certification body about the corrective actions taken by him within 3 months from receipt of the report of the initial inspection.

If the notified certification body classifies the corrective actions as not sufficient the notified certification body may cease the certification process and the applicant will be informed of this decision.

8. ISSUE OF THE CERTIFICATE

See 2.4 of annex 5 for general information.

The notified certification body shall issue a "certificate of factory production control" when the initial inspection was conducted with a positive result. The applicant will be informed about this as soon as possible.

In the case non-compliances were detected during the initial inspection, all non-conformities and remarks must be dealt with to the satisfaction of the notified certification body. The notified certification body will acknowledge this in writing and a certificate of factory production control will be issued by the notified certification body to the factory concerned.

A certificate is issued covering those types of admixture requested by the manufacturer as defined in 4.2 of the appropriate part of EN 934 as long as the products are produced under the same system of factory production control.

Annex 4 gives an example of a certificate. Translations in other languages of the Formats exemplified in the Position Paper of GNB-CPD could be found on CIRCA.

The certificate of factory production control shall have a unique number, which shall be allocated by the notified certification body. The number is divided in three parts, separated by hyphens as follows:

1. the notification number of the notified certification body;
2. the acronym CPD;
3. a unique reference number allocated by the notified certification body for each individual certificate. This unique reference number shall be composed of a number or an alpha-numeric combination consistent with the procedures of the notified certification body.

9. EXTENSION OF A CERTIFICATE

See 2.4.1 of annex 5 for general information.

A producer can use the application form to ask the notified certification body for an extension to an issued certificate to include additional types of admixtures complying to different technical specifications, but manufactured under the same system of FPC in the same factory and it could require a further inspection to the FPC.

For each factory a single certificate is issued, independently from the number of the produced admixtures.

10. CONTINUOUS SURVEILLANCE OF FPC

See 2.5 of annex 5 for general information.

The notified certification body exercises the surveillance of the FPC on the basis of the requirements of the relevant harmonised standard and on the basis of the initial inspection of the factory and FPC.

At least once per year an announced inspection of the factory production control will take place.

The manufacturer is required to have informed the notified certification body of any changes in the factory production control, including modifications to the factory. Failure to do so may result in a non-compliance being raised by the notified certification body.

It will be the decision of the notified certification body whether or not a further inspection visit is necessary at the time of the announcement of any such changes.

The notified certification body may wish to examine the frequencies and results of testing within the scope of the inspection of factory production control.

Repetition of the initial type testing and the necessity to do so (see 5.3.b/c of EN 934-6), is the responsibility of the producer. See Annex 2.

The test equipment and test methods used also fall under the scope of factory production control and may be assessed as part of the initial inspection of FPC and during each continuing assessment visit.

The product technical specification includes minimum frequencies of testing required by the manufacturer under the factory production control of the admixtures, e.g. EN 934-2 table 13.

The notified certification body may examine the observance of the required testing frequencies.

Where the notified certification body determines that the manufacturer is not implementing the defined frequencies of continuous audit/batch testing, a non-compliance should be raised.

The notified certification body shall inform the manufacturer about the results of all continuous surveillance visits and shall also inform the manufacturer of any non-compliances (observations, remarks or non-conformities) it has raised.

The notified certification body may decide to carry out further visits if serious deficiencies in the factory production control are identified.

Where a non-compliance is identified, it is the responsibility of the manufacturer to investigate the cause of the problem and report to the notified certification body effective corrective action measures appropriate to the nature of the non-compliance raised.

In the case of non-implementation of suitable corrective action or continuing non-compliance (non-conformities), the notified certification body should advise the producer of the action it intends to take.

The notified certification body may decide to withdraw the certificate of factory production control and, in such cases, the manufacturer will be informed as soon as this is practicable.

Only in the case when the certificate of factory production control is withdrawn as a result of continuing non-conformities, the notified certification body shall inform the competent authority in its Member State.

11. NON – COMPLIANCES

Non-compliances apply only to the FPC and its implementation.

A non-compliance occurs when a manufacturer fails to follow the requirements detailed in his production control manual or fails to take action following a failure in the specified systems, equipment calibration or a product with test results outside the limit values stated in his FPC system. The notified certification body has to determine whether the non-compliance can be seen as “observation”, “remark” or “non-conformity” as defined in 4.3.

The presence of one or more results outside the limit values should not be considered as a non-compliance. However, the absence of corrective actions in the production control manual to cover such deviations or the absence of corrective actions as such do qualify as a non-compliance.

12. LIST OF CERTIFICATES OF FACTORY PRODUCTION CONTROL

The notified certification body should, as a minimum, keep an up-to-date list of the certificates of FPC it has issued. This list shall be made available on request.

**ANNEX 1
MODEL FOR AN APPLICATION FORM**

**APPLICATION FORM ^A FOR SERVICES TO PROVIDE A CERTIFICATE OF
FACTORY PRODUCTION CONTROL**

REQUIRED AS PART OF THE EVALUATION OF CONFORMITY FOR ADMIXTURES
TO EN 934 PART 2 AND/OR PART 4 (CONCRETE, MORTAR AND GROUTS)

I the undersigned ^B, in my capacity as representative of ^C
.....,
with its registered office in
^D,
as a manufacturer, ^E
as authorised representative established in the EEA^F, of the manufacturer located in
^G

in compliance with Annex ZA of the relevant part of EN 934-2 and/or EN 934-4 given below,
apply, for the first time and only to this notified certification body, for the issue of a EC
certificate of factory production control for the admixture type(s) mentioned below, produced
at the factory of ^H.....,
with its registered office at
^I

Admixture type/ Part of EN 934-2 and/or EN 934-4: ^K

Additional information: ^L

Additional identification: ^M

It is further declared that:

- type testing of the product(s) has been / is being* performed under the responsibility of the above manufacturer
- the factory in question has/ has not* received any other valid EC certificate of factory production control.

(*delete as appropriate).

In addition I declare I have read the current rules and conditions of this notified certification body for this service under this directive and fully accept all the provisions.

I authorise the access of the inspectors appointed by the notified certification body to carry out the required initial inspection of the factory and of the factory production control, and continuous surveillance of the same as required.

The following documents are attached in support of this application:

- production control manual describing the FPC system
- list of related quality documents
- others ^N

I authorise the notified certification body to use the above data in order to manage the relevant procedures.

I further authorise that all correspondence of the notified certification body concerning this matter is to be addressed to the named contact person.....^O

Place, Date

Signature

-
- ^A The Application shall be drawn up by the manufacturer or by his authorised representative established in the EEA.
The application shall be presented in one original, written in a language previously accepted by the receiving notified certification body.
- ^B Name and surname of applicant appointed by the manufacturer.
- ^C Acronym and full name of the applicant and relevant business name.
- ^D Full address.
- ^E If applicable.
- ^F If applicable.
- ^G Name of the extra country.
- ^H Name of the factory, full address, phone and fax numbers and e-mail address of the factory.
- ^I If applicable.
- ^K Type of admixture according to the relevant part of EN 934. It may be permissible to attach a separate list combining information required for items K,L and M in the case of submitting a large range of product types.
- ^L If applicable. It may be permissible to attach a separate list in the case of a large range of product type, see K.
- ^M If applicable. It may be permissible to attach a separate list in the case of a large range of product types, see K.
- ^N Any other needed or applicable document.
- ^O Name of person and job title.

ANNEX 2

GUIDANCE ON THE EN 934 SERIES OF STANDARDS

The following comments are intended to be helpful to both the manufacturer and the notified certification body when implementing or assessing the implementation of clauses of EN 934 with respect to Factory Production Control

EN 934-2

Clause 3.1.2 Compliance dosage

There is no requirement in EN934 or in EN480-1 for the compliance dosage to be stated or for the dosage used during ITT to be recorded. However, good laboratory practice includes recording of the actual amount of admixture added to the test mix

For FPC testing to EN 934-2 Table 13, the compliance dosage may change with time, depending on the cement and aggregate sources but should always be within the manufacturers recommended range.

Table 13

The test methods used for FPC of relative density and dry material content do not have to be those stipulated in EN 934-2 Table 1. However, the manufacturer should be able to demonstrate that his test method controls the product such that it will fall within the tolerance limits of table 1 when tested by the appropriate EN 480 method.

EN 934-4

Table 2 Range of Volume change

There is no requirement in EN934-4 to distinguish between expanding and non-expanding grout admixtures. However, the notified certification body should be aware that if a product is being sold as an expanding grout admixture, it should meet the $0 \leq S \leq 5\%$ requirement.

EN 934-6

Clause 4.2 and 5.4.5d Sampling

Sampling for FPC purposes may not be the same as sampling from manufacturers stock and alternatives to the method detailed in Clause 4.2 should be accepted by the NB for FPC purposes, provided they achieve the necessary level of control on product uniformity.

Clause 5.3 Formulation Changes requiring new ITT:

It is not the task of the notified certification body to deal with items concerning ITT. However, the notified certification body should ask the manufacturer:

- Has any product been changed as defined by EN934-6 clause 5.3, such that it requires a new ITT.
- Has there been a change in the FPC procedures as result of the ITT?
and act accordingly.

Clause 5.4.2 Factory Production Control Supervisor

Depending on the size of the production unit, most manufacturers will split this function into a Production Supervisor and a Quality Control Supervisor and may additionally have a Quality Manager.

If practical to do so, it is preferable to have this split in responsibilities and this should be acceptable provided the overall chain of responsibility for these positions to one manager with sufficient authority is shown within the production control manual.

ANNEX 3

OVERVIEW OF CHECKS ON PROPER FUNCTIONING AND RELIABILITY OF EQUIPMENT DESCRIBED IN THE EN 480 AND EN 934 SERIES OF STANDARDS

This annex gives information concerning the checks on proper functioning and reliability of equipment (in this annex referred to as "equipment checks") to be carried out as required by 5.4.5.a of EN 934-6. The equipment checks are not mentioned in the EN 934 series. It is the responsibility of the producer and should be based on the test method involved.

The production control manual of the producer should contain an overview of all equipment checks to be carried out, mentioning the equipment, frequency and methods to be used.

The remaining part of this annex gives additional information to the notified bodies concerning equipment checks in the relevant standards.

EN 480 SERIES ADMIXTURES FOR CONCRETE, MORTAR AND GROUT – TEST METHODS

EN 480-1 Reference concrete and reference mortar for testing

No references to equipment checks are given in this standard.

References are made in the relevant standards of the normative references.

EN 196-1

Clause 4.2: Regular measurements of the equipment in figure 1 to 3 has to be performed. In case of non-compliance the equipment has to be replaced.

Clause 4.4: The gap between the blade and the mixing-bowl has to be determined once a month.

EN 413-2

The weights, dimensions and proper functioning of the reference equipment should be checked.

Clause 4.3.2: The test results of alternative equipment are compared with the test results of the reference equipment at least once per month.

All other cited standards of the normative references do not refer to equipment checks .

EN 480-2 Determination of setting time

No references to equipment checks are given in this standard.

References are made in the relevant standards of the normative references as follows:

EN 413-2

The weights, dimensions and proper functioning of the reference equipment should be checked.

Clause 4.3.2: The test results of the alternative equipment are compared with the test results of the reference equipment at least once per month.

All other cited normative references do not refer to equipment checks.

EN 480-4 Determination of bleeding of concrete

No references to equipment checks are given in this standard.

No references are made in the relevant standards of the normative references.

EN 480-5 Determination of capillary absorption

No references to equipment checks are given in this standard.

References are made in the relevant standards of the normative references

EN 196-1

Clause 4.2: Regular measurements of the equipment in figure 1 to 3 have to be performed. In case of non-compliance the equipment has to be replaced.

Clause 4.4: The gap between the blade and the mixing-bowl has to be determined once a month.

EN 413-2

The weights, dimensions and proper functioning of the reference apparatus should be checked.

Clause 4.3.2: The test results of the alternative equipment are compared with the test results of the reference equipment at least once per month.

All other cited standards of the normative references do not refer to equipment checks .

EN 480-6 Infrared analysis

No references to equipment checks are given in this standard.

No references are made in the relevant standards of the normative references.

EN 480-8 Determination of the conventional dry material content

No references to equipment checks are given in this standard.

No references are made in the relevant standards of the normative references.

EN 480-10 Determination of water soluble chloride content

No references to equipment checks are given in this standard.

No references are made in the relevant standards of the normative references.

EN 480-11 Determination of air void characteristics in hardened concrete

No references to equipment checks are given in this standard.

The relevant standard ISO 2736/2 of the normative references gives only the requirement that the moulds should be capable of providing test specimens, and the dimensions and tolerances of which should conform to ISO 1920.

EN 480-12 Determination of the alkali content of the admixtures

Clause 7.2: Reference is made to equipment checks of the equipment (AAS). Each measurement begins with the confirmation of the calibration graph using standard solutions.

Reference is made to ISO 1042 regarding the use of volumetric flasks of class A and to ISO 648 regarding the use of calibrated pipettes.

EN 934 SERIES ADMIXTURES FOR CONCRETE, MORTAR AND GROUT

EN 934-2 Concrete admixtures – Definitions and requirements

No references to equipment checks are given in this standard.

Regarding equipment checks the following relevant standards of the normative references have to be checked:

ISO 758	Determination of density at 20°C No information on equipment checks is given in this standard
ISO 4316	Determination of pH of aqueous solutions A method but not a frequency is given in clause 7.2.
ISO 1158	Determination of chlorine No information on equipment checks is given in this standard
EN 12350-2 (prEN 12382)	Slump test Dimensions, including tolerances are given in the standard. No information is given on frequency of the repetition of the equipment checks.
EN 12350-5 (prEN 12358)	Flow table test Dimensions, including tolerance is given in the standard. No information is given on frequency of repetition of the equipment checks
EN 12350-7 (prEN 12395)	Air content – Pressure methods Annex C and D give details of the method for equipment checks and recommendations on initial and subsequent checks.
EN 12390-1	Moulds Dimensions, including tolerance is given in the standard. No information is given on frequency of repetition of the checks.
EN 12390-4	Compression testing machines Information is given on calibration in clause 5. with an annual re-calibration

EN 934-4 Admixtures for grouts for prestressing tendons – Definitions, requirements, conformity, marking and labelling

No references to equipment checks in this standard.

Regarding equipment checks the following relevant standards of the normative references have to be checked:

ISO 758	Determination of density at 20°C No information on equipment checks is given in this standard
ISO 4316	Determination of pH of aqueous solutions A method but no frequency is given in clause 7.2.2
ISO 1158	Determination of chlorine No information on equipment checks is given in this standard
EN 445	Grout for pre-stressing tendons – Test methods A method but not the frequency is given for the immersion method only, in clause 3.2.1.3

EN 934-6 Sampling, conformity control and evaluation of conformity

No references to equipment checks are given in this standard.

No references are made in the relevant standards regarding the normative references.

ANNEX 4
EXAMPLE OF A CERTIFICATE OF FPC BASED ON THE EN 934 SERIES OF STANDARDS

Logo, name and address of the notified certification body

Certificate of Factory Production Control
XXX - CPD - YYY

In compliance with the Directive 89/106/EEC of the council of European Communities of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to the construction products (Construction Products Directive - CPD), amended by the Directive 93/68/EEC of the Council of European Communities of 22 July 1993, it has been stated that the construction products

ADMIXTURES

characterised as

List of EN 934 parts 2 and/or 4 and admixture types

intended for use in the preparation of

- concrete
- grout for prestressing tendons

and produced by the manufacturer

Name,
address

in the factory located at
town / city

is submitted by the manufacturer to initial type testing of the products and factory production control and that the approved body **Name of the certification body** has performed the initial inspection of the factory and of the factory production control and performs the continuous surveillance, assessment and approval of the factory production control.

This certificate attests that all provisions concerning the attestation of factory production control described in Annex ZA of the standard **EN 934 Part(s) 2 and/or 4** and in accordance with the procedures given in **EN 934-6**, were applied.

This certificate was first issued on and remains valid as long as the conditions laid down in the harmonised technical specification in reference or the manufacturing conditions in the factory or the factory production control itself are not modified significantly or at the latest until

City, Date

Title, Position

Authorised signature

ANNEX 5
GUIDANCE ON THE PARTICIPATION OF THE NOTIFIED BODIES IN THE
ATTESTATION OF CONFORMITY UNDER THE CONSTRUCTION PRODUCTS
DIRECTIVE 89/106/EEC.

The information in this annex is a copy of relevant parts of the position paper NB-CPD - 01/002 rev 04 Issued: 07 April 2001

1. The certification of the factory production control under systems 2+ and 2

Under systems 2+ and 2, the task assigned to the notified bodies is the certification of the factory production control based on the Initial inspection of the factory and of the factory production control;

Under system 2+, continuous surveillance, assessment and approval of the factory production control;

2.1 Basic conditions

The basic conditions for issuing a certificate of factory production control are that the applicant follows the general rules as laid down in the harmonised technical specification and, when relevant, the additional guidelines commonly agreed by the relevant sector group of notified bodies.

These additional guidelines may be included in specific documents of the Group of Notified Bodies (GNB), which should also be taken into account. These documents should serve as guidelines to ensure that the attestation of conformity is consistent and equivalent for all manufacturers. They have to be approved by the Advisory Group NB-CPD after having consulted the relevant CEN committee according to the procedure laid down in the CEN Reykjavik Resolutions (October 2000). As far as EOTA-Guidelines are concerned the respective Working Group of EOTA should have been involved.

2.2 Application for a certificate of factory production control

The application shall be made on a special form obtainable from a notified FPC-certification body.

The manufacturer or his authorised representative established within the European Economic Area (further called "the applicant") shall, in his application, refer to the specific product or group of products determined in the relevant Decision of the European Commission and, when relevant, in the additional guidelines. It should normally cover one factory only.

A notified FPC-certification body on acceptance of a completed application form will confirm this to the applicant and provide him with any further information necessary for the processing of his application.

2.3 Initial inspection of the factory and production control

2.3.1 General

After confirmation of the acceptance of the application, the certification body shall make the necessary arrangements with the applicant for the initial inspection, in accordance with the rules of the scheme.

The notified FPC-certification body is responsible for all actions of certification of the factory production control including inspection of the factory and of the factory production control, but should pay particular attention to those characteristics identified as being relevant for FPC in Annex 3 of the mandate. Under system 2+, the notified FPC-certification body is also responsible for surveillance, assessment and approval of the factory production control.

When the inspection of the factory and of the factory production control, as well as the surveillance and assessment of the factory production control are conducted by an inspection body different from the notified FPC-certification body, a report on the performed inspections and assessments is communicated to the notified FPC-certification body.

The inspection body involved in the attestation of conformity is responsible for carrying out its tasks. The certification body is responsible for assembling all the relevant information, verifying that the tasks have been carried out according to the technical specifications and assessing and certifying the factory production control.

The notified FPC-certification body shall inform the applicant of the results of the initial inspection. If the notified FPC-certification body is not satisfied that all the requirements for the certification of FPC are being met, it will inform the applicant of those aspects in which his application has failed. If the applicant can show that remedial action has been taken by him to meet all requirements within a specified time limit, the notified body concerned will repeat only the necessary parts of the initial inspection procedure. Otherwise the application shall be cancelled.

Re-inspection may not be needed for subsequent applications for the same product.

2.3.2 Assessment of factory production control

Assessment of the applicant's system of factory production control forms part of the initial inspection. This may be done according to the specific guidance agreed by the group of notified bodies for the product.

Ideally, guidance for these elements should be included in the harmonised standard or in the ETAG/CUAP/ETA.

All records produced for the implementation of the factory production control related to certification shall be readily available for attestation body inspection.

The applicant shall ensure that the question of responsibility to the notified FPC-certification body for the factory production control is clearly defined, e.g. by appointing a designated person who is independent from production management ¹ as far as the technical performance of his function is concerned and who is qualified to maintain the contact with the notified FPC-certification body, to ensure that the above provisions have been observed.

In case of ETA's it should in particular be recalled that the notified FPC-certification body shall seek to obtain from the Approval Body the relevant technical documentation which is essential for the fulfilment of its tasks of attestation of conformity (i.e. the relevant elements contained in the possible confidential part of the ETA).

The notified certification body should also inform the Approval Body of its investigation results, in particular in cases of significant non-conformity to allow it to keep the ETA-file updated.

2.4 Certificate of factory production control

The notified FPC-certification body, when complete fulfilment of the requirements laid down in Annex ZA of the harmonised standard or in the relevant ETA has been established, informs the applicant accordingly and issues a certificate of factory production control.

The certificate should normally be issued for one factory in respect of one harmonised specification. In any case, the factory(ies) covered have to be clearly identified on the certificate of factory production control.

2.4.1 Certificate of factory production control for other products from the same factory

A manufacturer wishing to obtain certificate(s) of factory production control for additional type(s) or model(s) of product(s) made in the same factory to the same harmonised standard or another ETA as the product for which a certificate of factory production control is already held, shall apply to the certification body, using the usual application form. The certification body can decide in such case not to carry out or to only carry out partial factory inspection and to grant the corresponding certificate.

If the manufacturer wishes to apply the certification of the factory production control to additional types of products made at the same factory, but to different harmonised technical

¹ In the case of SME's with reduced staff, this condition is not of application

specifications, or if the manufacturer wishes to apply for certification of factory production control to be applied in an additional factory that is not covered by an earlier EC-certificate or certificate of factory production control, the elements that have already be assessed during the previous assessment(s) could be used again when relevant, in accordance with sector group practices. In case of doubt, the notified body shall consult the sector group concerned.

2.5 Surveillance (system 2+ only)

The certification body exercises the surveillance of the factory production control on the basis of the requirements of the relevant harmonised technical specification and of the additional guidance of the scheme and on the basis of the original assessment of the factory production control.

The certification body may appoint an inspection body to carry out the surveillance under its authority and responsibility, exercised under agreed conditions.

The manufacturer shall be informed about the results of the surveillance.

The manufacturer shall inform the notified certification body about any intended modification of the production process or factory production control, where this is likely to have an effect on the stated properties of the product. It is up to the certification body to determine whether the announced changes require another inspection or other further investigations. In such cases the manufacturer is not allowed to release CE-marked products resulting from such changes until the certification body has notified the manufacturer accordingly.

In the case of ETA, the notified body shall inform the Approval Body that issued the ETA in the case of non-conformity and by any modification of the FPC to allow him either to update the ETA file of the product or to renew the ETA when relevant.

The manufacturer shall keep a record of all non-conformities and complaints relative to the product covered by the certificate of factory production control and make this available to the certification body on request.