#### Guidance from the Group of Notified Bodies for Construction Products Directive 89/106/EEC

NB-CPD/SG13-2008/001

Final version Issued : March 2008 Working document

TITLE: SG13 final draft position paper

SUBJECT: Final draft to be submitted to AG for formal

approval

Note of the secretariat: This document includes an amendment agreed by

CEN/TC 229 as well as some editorial comments raised during the SG 13 approval of the final draft

(December 2007)

Dear experts,

Please, find attached for information, the final version of the position paper which will be scrutinized for AG approval.

I will communicate the dates as soon as the enquiry is launched.

With best regards,

Claudine MUZET MICONNET SG 13 Secretary <a href="mailto:c.muzet-miconnet@cerib.com">c.muzet-miconnet@cerib.com</a>

### Guidance from the Group of Notified Bodies for Construction Products Directive 89/106/EEC

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Position paper for the certification of factory production control related to precast concrete products in compliance with Annex ZA of the EN series of CEN/TC 229 structural product standards (M 100 as amended) mentioned in the scope;

This document is consistent with EN 13369:2004 (after validation by CEN/TC229 it will be added "with the agreement of CEN/TC 229")

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## Precast Concrete Products Sector Group of Notified Bodies for the Construction Products Directive 89/106/EEC

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#### 1 FOREWORD

Article 13 clause 3 a) Directive 89/106/EEC of the Council of 21<sup>st</sup> of December, 1988 for approaching the legal and administrative regulations of the member states for construction products determines that the manufacturer may affix the CE conformity sign on his construction products only if he "has a system of factory production control to ensure that the production is in conformity with the relevant Technical Specifications".

This document was prepared by Sector Group 13 of the Notified Bodies working under Construction Products Directive 89/106/EEC) in liaison with CEN/TC 229 (Precast concrete products) (this paper has been approved by CEN/TC 229: to add when done). It is intended to give guidance to Notified Bodies in preparing equivalent procedures for the issue of a certificate of Factory Production Control (FPC) as required in Annex ZA of EN mentioned in parts 2 and 3, on request from a manufacturer of precast concrete products.

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), [including where applicable initial type calculation (ITC)], sampling and retesting do not fall under the tasks of the notified body but they have to be documented.

This document is for guidance only. In all cases the relevant product standards prevail.

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/SG13. The address of the secretary can be found on the CIRCA web site.

#### 2. SCOPE AND FIELD OF APPLICATION

This document defines and describes the sequence of the main position paper operations for granting and maintaining a certificate of factory production control under system 2+ for the precast concrete products under mandates 100, 126, 139 on the basis of the requirements of Annex ZA of ENs and of the documents mentioned in reference list.

#### 3 REFERENCE LIST

- All the harmonised standards prepared under mandates N° 100 (and its addendum January 2004), 126 and 139.
- EN 13369:2004 Common rules for precast concrete products
   NOTE: In addition, information from CEN/TC 229 on future amendments of EN 13369 (if need be)
   is available on CIRCA Website [SG 13 What's new].
- Guidance Paper B The definition of factory production Control in Technical Specifications for construction products.
- Guidance Paper K

   The attestation of conformity systems and the role and tasks of the Notified Body in the field of construction products directive
- Guidance Paper L Application and use of Eurocodes

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Guidance Paper M – Conformity assessment under the construction products directive.

#### 4. TERMINOLOGY

Terms used in this document are generally defined in the documents listed in clause 3. The following information is added:

#### 4.1 Non-compliance Deviations

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

#### Observation:

Non-compliance Deviation 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;

#### RemarkMinor non-conformity:

Non-compliance Deviation 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 Major non-conformity:

non-compliance Deviation that effects affects 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 deviation normally makes it necessary to repeat all or part of the inspection of the factory production control as soon as possible after that the manufacturer has reported that he had corrected the deviations.

#### 4.2 CE marking method

Method(s) chosen by the manufacturer to declare the performances or values accompanying the CE marking on the  $\frac{bases-basis}{}$  of:

• aAnnexes Y and ZA of the product standards concerned.

Paragraph to be added to explain roles and tasks of the notified body regarding the method(s) chosen by the manufacturer

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#### 5 APPLICATION

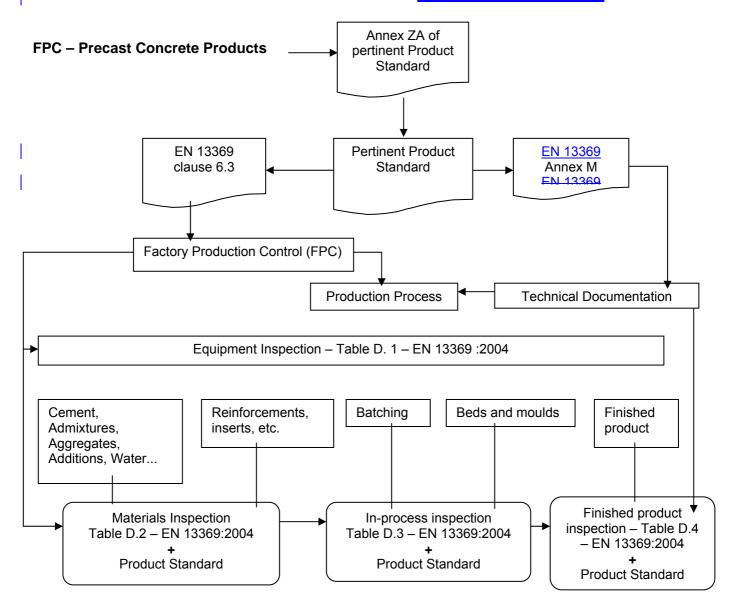
#### 5.1 Responsibility

The manufacturer is responsible for the performance of the factory production control (FPC) and shall-For for every factory (plant) or group of factories nominate a person shall be nominated, who is responsible for the FPC. This person shall have at his disposal suitable specialized staff, facilities, and equipment.

In all cases the manufacturer is solely responsible for the factory production control <u>by</u> which he ensures that the construction products comply with the appropriate Technical Specifications.

This scheme summarizes the relationship between the main relevant documents.

#### SCHEME OF THE PRODUCTION CONTROL ACTIVITIES BY THE MANUFACTURER



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#### 5.2 Non-conformities of finished products

EN 13369, § 6.3.7 applies.

#### 5.3 Notified Body

The Notified Body is in charge of the assessment of FPC concerning all the elements, requirements and provisions adopted by the <u>producer\_manufacturer</u> to fulfil his obligations under CPD.

See hereafter.

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The notified body can appoint subcontractors that perform <u>technical inspection</u> tasks on its behalf. Guidance papers A and K give more information on subcontracting matter.

#### 6 CERTIFICATION PROCESS

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

- the application (see chapter 7),
- the initial inspection of the factory and the FPC (see chapter  $\frac{78}{}$ ) and
- the issuing of the certificate (see chapter 9),
- the continuous surveillance of FPC (see chapter 4112).

#### 7 APPLICATION FOR CERTIFICATION

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.

A certification agreement between the producer and the Notified Body must be signed.

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

- reference to the general certification regulations of the Notified 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;
- list of relevant products and/or product families;
- CE marking method(s) for designed mechanical resistance and/or resistance to fireused to determine properties relative to essential requirements (1, 2, and/or 3a, and 3b) for each product or product family.

Note: when a manufacturer wants to use a new CE marking method, he has to inform the Notified Body in advance.

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#### 8 INITIAL INSPECTION OF THE FACTORY AND THE FACTORY PRODUCTION CONTROL

Before carrying out the initial inspection of the factory and the FPC, the Notified Body verifies whether all articles described in 6.3 "Evaluation of conformity" of all the reference standards are dealt with appropriately in the factory production control manual and related documents.

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

When the documentation is accepted by the Notified Body a date for the initial inspection of the factory and the FPC will be agreed upon (including sub-contractors when relevant). During this initial inspection the Notified Body will investigate whether the documented system is implemented in accordance with the requirements of products standards.

The documented factory production control of the manufacturer includes notably the following items:

- Description and checking of raw material and components.
- Checking of mechanical and/or fire resistance calculation for products or product families covered by CE marking methods 2 and 3b.

NOTE: where the relevant calculation is sub-contracted, evidence must be available that producer's Factory Production Control covers the supervision enof calculation.

- Controls and examinations that have to be performed during the production at fixed intervals.
- Proofs and examinations on the finished product that have to be performed at appropriate intervals.
- Relevant calibrations that shall be performed at regular intervals with precisely determined measurements and testing instruments and the recording of these.
- Records that shall be kept for a period in accordance with the legal requirements of the Member State and at least five years and shall be available to the Notified Body.
- Where applicable, relevant subcontracting (see guidance B 3.2) activities location and conditions- (a contract has to be established).

The notified body checks that the manufacturer observes the inspection schemes and regularly complete the documents of the Factory Production Control agreed with the Notified Body to enable the level of confidence obtained by the factory production control to be the same as that achieved as required by the product standard.

Tasks, responsibilities, authorities and skills within the organization of factory production control are to be documented and should be kept up to date.

A checklist, prepared by the Notified Body, should support the inspector in this task. Items found not to be in compliance are classified as observations, <u>remarksminor</u> or <u>major</u> non-conformities and reported at the end of the initial inspection. Examples of checklist are given in annex 4.

Routines and procedures for the initial type testing (ITT), including where applicable the initial type calculation (ITC), are part of the factory production control system and shall be documented. The procedures shall include, where relevant, the identification of the nationally determined parameters (method 2) or identification of the design specification (including the national application document) to be applied (method 3b). The notified body should check that these routines and procedures exist and assess that they are applied. The results of applying these routines and procedures are not part of the Notified Body's tasks.

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The initial type testing (ITT) [including, where applicable, and/or the initial type calculation (ITC)] are not part of the factory production control but must have been carried out by the producer in accordance with the methods and/or the test methods described in the standard and shall be documented.

Previous type tests performed before this the date of availability of the pertinent product standard, on the same product may be considered according to the conditions given in the pertinent product standard.

Shared ITT (excepted ITT on concrete) and/or ITC may be used provided their representativeness is documented.

ITT <u>and/or ITC areis under</u> the responsibility of the producer. The declared values chosen by the producer are based on ITT <u>and/or ITC</u>. So the notified body sees evidence of ITT <u>and/or ITC(including, where applicable, ITC)</u>.

Test results from FPC must comply with the requirements of the product specification and be consistent with ITT. 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 <u>during FPC</u> 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. Determination of the correlation of test results is carried out by the manufacturer on a regular basis using a procedure described in the factory production control manual (EN 13369 § 6.3.9). The Notified Body should examine that the correlation is documented and established regularly.

Results of production control tests of the products or family of products mentioned in the application form must be available for at least one product <u>or product family</u> at the time of the initial inspection.

A report containing the results of the assessment of the factory 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 should inform the Notified Body about the corrective actions taken by him within the delay time limit mentioned in the report and no longer than 3 months from receipt of the report of the initial inspection.

If the Notified Body classifies the corrective actions as not sufficient the Notified Body should cease the application procedure process and the applicant will be informed of this motivated decision.

#### 9 ISSUE OF THE CERTIFICATE

The Notified Body issues 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-compliance<u>deviations</u> were detected during the initial inspection, all <u>minor and major</u> non-conformities <u>and remarks</u> must be dealt with to the satisfaction of the Notified Body. The Notified Body will acknowledge this in writing and a certificate of factory production control will be issued by the Notified Body to the applicant.

A certificate is issued covering one product, a list of products or one or more family of products from the product standard(s) in chapter 3 as long as the products are produced under the same system of factory production control. The certificate shall identify for each product, list of products or family, the declaration

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method(s) [1, 2, 3a, 3b] used by the manufacturer (see Guidance Paper L and Annex ZA of the standard).

Annex 3 gives reference for the certificate. Translations in other languages of the Formats exemplified in the Position Paper of GNB-CPD can be found on CIRCA.

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

- 1. the notification number of the Notified Body;
- 2. the acronym CPD;
- 3. a unique reference number allocated by the Notified 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 Body.

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#### 10 EXTENSION OF A CERTIFICATE

A producer can use the application form to ask the Notified Body for an extension to an issued certificate to include additional types <u>or families</u> of precast concrete products complying with different technical specifications, but manufactured under the same system of FPC in the same factory. It could require a further inspection of the FPC.

For each factory a single certificate is issued, regardless from the number of the produced types of relevant precast concrete products under M100, 126, 139, as amended. The issuing of the extended certificate is made according to clause 9.

#### 11 PERIOD OF VALIDITY OF A CERTIFICATE

See Annex 3

The certificate may remain valid as long as the following are not modified significantly:

- The conditions laid down in the harmonised Technical Specification being referenced,
- The manufacturing conditions in the factory,
- The factory production control itself.

#### 12 CONTINUOUS SURVEILLANCE OF FPC

The notified body exercises the surveillance of the FPC on the basis of the requirements of the relevant harmonised standard(s) and <u>— when relevant — on further ITT results</u>, on the basis of the initial inspection of the factory and FPC.

At least each year all relevant aspects of the FPC is assessed. Each inspection is announced.

The manufacturer is required to have informed the Notified Body of any changes in the factory production control, including modifications to the factory and extension of products type/families or extension of the range of a family [or equivalent concept depending on the product standard(s)]. Failure to so do may result in a non-compliancedeviation being raised by the notified body.

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

The Notified Body examines evidence of testing and respect of the corresponding frequency, and actions following non-conformities major non-conformities.

Appropriate further type testing (see 6.2.3 of EN 13369) is the responsibility of the producer.

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 guidance for the frequencies of testing required by the manufacturer according to the factory production control for the product, is contained in each product standard. A guidance for the control of concrete strength is given in annex 2.

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The Notified Body informs the manufacturer in a written report about the results of all continuous surveillance visits and of any non-compliance deviations (observations, remarks or minor or major non-conformities) it has detected.

The Notified Body may decide to carry out further visits if serious deficiencies in the factory production control are identified.

Where a non-compliancedeviation is identified, it is the responsibility of the manufacturer to investigate the cause of the problem and report to the Notified Body effective corrective action measures appropriate to the nature of the non-compliancedeviation raised.

In the case of confirmed non-implementation of suitable corrective action or continuing non-compliance (non-conformities) deviation, the Notified Body advises the producer of the action it-he intends to take.

The Notified Body can decide to withdraw the certificate of factory production control and, in such cases, the manufacturer will be informed as soon as this is practicable.

If the FPC has to be reassessed to regain a certificate that has been withdrawn, or ceased to be valid, the assessment of the NB is relevant to the cause of withdrawal or cessation of validity.

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

#### 13 NON-COMPLIANCEMANAGEMENT OF DEVIATIONS

Non-compliance Deviations apply only to the FPC and its implementation.

A non-compliancedeviation occurs when a manufacturer fails to follow the requirements detailed in the relevant part of his production control manual documents or fails to take action following a failure in the specified systems, equipment calibration or a product with test results outside the limit values (consistent with ITT) stated in his FPC system. The Notified Body has to determine whether the non-compliancedeviation can be seen as "observation", "remark" or minor or major 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 deviation of FPC-. However, the absence of rectifying the shortcoming on non conforming product(s) and of corrective actions in the production control manual documents to cover such deviations or the absence of corrective actions as such do qualify as a non-compliance.major non-conformity.

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#### 14 MARKING AND TRACEABILITY

It is the responsibility of the manufacturer or its representative to provide complete records about individual products or product batches including their relevant production details and characteristics. The notified body checks that the manufacturers keep records.

Individual products or batches and the relevant details of the production shall be identifiable and traceable in order to allow the manufacturer to implement the corrective actions possibly needed according to § 6.3.7 of EN 13369. The Notified Body shall check it.

Reminder: the manufacturer marks the construction product itself, the delivery note, the packaging or the delivery documents with the CE marking as well as with a reference to the certification provided that the technical specifications do not prescribe something else. (See table).

#### 15 LIST OF CERTIFICATES OF FACTORY PRODUCTION CONTROL

The notified body should, as a minimum, keep an up-to-date list of the certificates of FPC it has issued. This list and the content of certificates should be made available on <u>substantiated</u> request <u>(e.g. national authorities responsible for market surveillance)</u>.

as required.

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#### 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 of precast concrete products
I the undersigned $^{\rm B}$ , in my capacity as representative of $^{\rm C}$ , with its registered office in $^{\rm D}$
as a manufacturer, <sup>E</sup> as authorised representative established in the EEA <sup>F</sup> , of the manufacturer located in <sup>G</sup> ;
in compliance with Annex ZA of the relevant standard (s)
Part of,
Additional information: L, Additional identification: M,
<ul> <li>It is further declared that:         <ul> <li>initial type testing<sup>N</sup> of the product(s) has been / is being* performed under the responsibility of the above manufacturer</li> </ul> </li> <li>the factory in question has/ has not* received any other valid EC certificate of factory production control.</li> <li>(*delete as appropriate).</li> </ul>
In addition I declare I have read the current rules and conditions of this Notified Body for this service under this directive and fully accept all the provisions.
I authorise the access of the inspectors appointed by the Notified Body to carry out the required initial inspection of the factory and of the factory production control, and continuous surveillance of the same

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The following documents are attached in support of this application:

- production control manual describing the FPC system,
- identification of the type/families of products covered by the FPC system,
- identification of declaration method (s) used in relation to the product (s),
- list of related quality documents,
- others <sup>NO</sup>

I authorise the Notified Body to use the above data in order to manage the relevant procedures.

A The Application should be drawn up by the manufacturer or by his authorised representative established in the EEA.

The application should be presented in one original, written in a language previously accepted by the receiving Notified Body.

<sup>&</sup>lt;sup>B</sup> 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.

<sup>&</sup>lt;sup>G</sup> Name of the extra country.

H Name of the factory, full address, phone and fax numbers and e-mail address of the factory.

If applicable.

<sup>&</sup>lt;sup>K</sup> Products or family products according to the relevant part of EN. 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.

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 Including, for declaration methods 2 and 3b, mechanical and/or fire resistance calculation

NO Any other needed or applicable document.

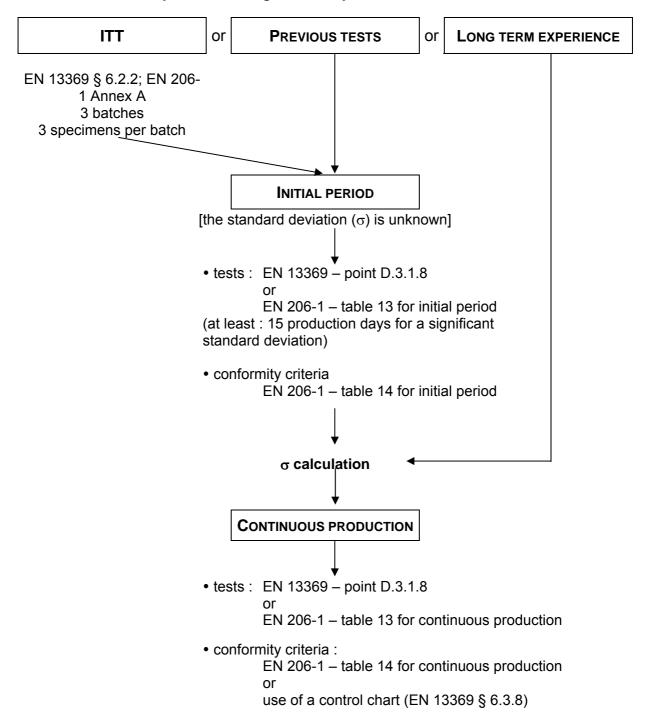
<sup>&</sup>lt;sup>OP</sup> Name of person and job title.

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ANNEX 2 – Concrete compressive strength – Principle of control



- For initial period and continuous production Ttypes of concrete may be grouped into documented families (EN 13369 § 6.2.1 and EN 206-1 § 8.2);
- Previous type tests performed on the same product before the date of availability of the pertinent product standard may be considered if they comply with the requirements of the product standard (EN 13369 § 6.2.2 and EN 206-1 Annex A);
- The manufacturer may perform test before 28 days to evaluate the potential compressive strength (EN 13369 § 4.2.2.2.2);

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- The manufacturer may use direct structural strength or indirect structural strength to confirm potential strength (EN 13369 § 4.2.2.2.1);
- The manufacturer is responsible for concrete he uses. Requirements for FPC should be the same whether he uses concrete from a supplier or made by himself.

To delete: no more information than in papers K and L

### ANNEX 3: Example of a certificate of FPC based on the EN "structural products" series of standards

This example is based on the one given in annex 3 of the Advisory Group approved guidance document NFNB-CPD/AG/04/002r1 Eng (on CIRCA: library\approved GNB Position Papers – Guidance and Information\AG Guidance – horizontal guidance and information \NB-CPD/AG/03/003r1 – REVISED example certificates of NBs and translations.

#### Logo, name and address of the notified 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

#### STRUCTURAL PRODUCTS

characterised as

precast concrete products types/families

Declaration method(s) used for each of them

List of rReference standard(s) (one product or a family of products)

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 notified body **Name of the 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** List of reference standards (one product or a family of products) 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 ......

Originally issued in (Llanguage of issue):

City, Date Authorised signature

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Title, Position

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ANNEX 4: Examples of Check lists for initial inspection of FPC

A Example 1 : checklist for precast concrete products – <u>|L|</u>inear structural elements (proposal from CERIB)

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Factory Production Control (FPC) evaluation report – 2+ CE Marking EN 13225 Precast concrete products – Linear structural elements

D: documented in FPC A: application C: conform - O: observation - R: remark MNC: minor non-conformity - NC: major non-conformity - NA: non applicable

N°	Examined points	YES	NO	_		arking ration	_	Comments
				1	<u>2</u>	<u>3a</u>	<u>3b</u>	
Définiti	on des produits concernés par le marquage CEList of pro	oducts	/prod	uct fa	milie	<u>s</u>		
1	Types of products manufactured in the factory:  ✓ Reinforced columns;  ✓ Prestressed columns;  ✓ Reinforced structural beam;  ✓ Prestressed structural beam;  ✓ Reinforced floor beam;  ✓ Prestressed floor beam;  ✓ Prestressed secondary beam;  ✓ Prestressed secondary beam;  ✓ Prestressed foundation beam;  ✓ Prestressed foundation beam;							

<sup>1</sup> for memory: (to be updated – if necessary – when the final frame for ZA annex is available);

method 1: declaration of geometrical data and material properties;

<sup>-</sup> method 2: declaration of geometry, material properties and product properties according to the product standard and to EN Eurocodes;

<sup>-</sup> method 3a: declaration of product compliance with a given design specification provided by the client;

method 3b: declaration of product compliance with a given design specification provided by the manufacturer according to the client's order.

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N°	Examined points	YES	NO	Comments
	•			
2	List of the products concerned by the CE Marking [Cf. annex ZA and Linear structural elements application rules];			
3	Product specifications :			
	✓ Definition of the concrete(s) compressive stregnth_strength_at 28 days (potential strength);			
	✓ Definition of ultimate tensile and tensile yield strength of steel (prestressing and reinforcing steel);			
	✓ declaration method* for mechanical strength and resistance to fire chosen by the factory (method 1, 2, 3):			
	✓ durability against corrosion (concrete cover and concrete composition);			
	<ul> <li>definition of the applicable ambient condition(s);</li> </ul>			
	<ul> <li>corresponding exposition class(es);</li> </ul>			
	✓ composition of concrete specifications			
	✓ NDP option (Non Determined Performance);			
	* <del>for memory :</del>			
	-method 1: declaration of geometrical data and material properties, and/or reference to the technical information;			
	-method 2: declaration of product properties, obtained by calculation;			
	- method 3: declaration of compliance with a given design specification.			

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N°	Examined points	YES	NO	Comments
4	Initial Type Test (ITT) :			
	<ul> <li>✓ of finished products (detailing);</li> <li>✓ of mechanical and/or fire resistance calculation (methods 2 and 3b only)</li> <li>✓ of concrete (determination of the declared compressive strength at 28 days);</li> <li>✓ of steel (supplier certificate of conformity)</li> </ul>			
5	ITT results ≥ values declared in FPC ;			
6	Definition of criteria to decide whether a new ITT is necessary in case of modification of the product or process;			
7	Content of the accompanying documents related to CE Marking; Content of the technical information;			
8	Content and application of the FPC			
	Management responsibility			
8.1	Management commitment ;			
8.2	Scope of the FPC (products concerned);			
8.3	Definition of the responsibilities and substitutions for the personnel concerned with the FPC (substitutions for the key positions);			
8.4	Designation of a management representative for the FPC (substitution);			
8.5	Internal communication and finality of FPC ;			
8.6	Management review ;			

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N°	Examined points	YES	NO	Comments
	FPC documentation system			
8.7	Description of the composition of the <u>FCP</u> documentary system ( <del>QM, PQP, Procedures, Instructions, records)</del> ;			
8.8	Document control ;			
8.9	Record control;			
	Management of resources	<u> </u>		
8.10	Competence - forming(training) of the staff concerned by the CPU (identification - recording);			
8.11	Description of the means of production means;			
8.12	Means of production control;			

(<u>EAdd e</u>quipment inspection table as appropriate)

N°	Examined points	D	Α	Comments
	Production			
8.13	Definition of the specifications of the product described in the FPC or in the referenced product files			

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N°	Examined points	D	Α	Comments
8.14	Purchases and supplies (including subcontracting):			
	✓ Definition of the requirements;			
	✓ Possible subcontracting (contracts);			
	✓ Control and testing on reception;			

#### (Materials Add materials inspection table as appropriate)

N°	Examined points	D	Α	Comments
8.15	Production management: existence of documents of production (plans, instructions);			
<u>8.16</u>	For declaration methods 2 and 3b: mechanical and/or fire resistance calculation			
	Consistency of FPC results with ITT and declared values			
8.1 <u>7</u> 6	Concrete composition;  ✓ number of concrete types used  (1 concrete type = 1 composition/heat treatment couple;  ✓ methode of protection against drying out:  - without addition of water;  - keep the concrete moist by addition of water;  - use of curing compounds (in this case initial testing showing that the strength reached with curing compounds is of the same order as the strength obtained by one of the means above).			

(PAdd process inspection/concrete table as appropriate)

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N°	Examined points	D	Α	Comments
8.1 <u>8</u> 7	Process			

(Process Add process inspection/other process subjects table as appropriate)

N°	Examined points	D	Α
8. <del>1</del> 8 <u>19</u>	Marking – labelling - traceability :		
	✓ labelling procedure (where, when, how, what);		
	<ul><li>✓ only authorized products or models are CE marked;</li><li>✓ conformity of the marking;</li></ul>		
	✓ traceability from materials to product delivery (including subcontracting)		
8. <del>19</del> 20	$\begin{array}{lll} \mbox{Handling} & -\mbox{ storing (in particular stability of the products) and} \\ \mbox{segregation of non conforming products ;} \end{array}$		
8. <del>20</del> <u>21</u>	Delivery - transportation  ✓ documents provided to the customer to ensure handling and storage;		
8. <del>21</del> 22	Testing and measuring equipment management :  ✓ availability of the equipment necessary to carry out the tests specified in the FPC;		

(<u>EAdd finished product inspection table as appropriate</u>)

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N°	Examined points	D	Α	Comments
	Testing – analysis - improvement			
8. <del>22</del> 23	Inspection and testing:			
	✓ subcontracting of some tests, if yes:			
	<ul><li>testing laborateory;</li><li>existence of a contract;</li><li>conformity of the test reports.</li></ul>			
	✓ Use of a control chart ;			
8. <del>23</del> 24	Non conforming products :			
	✓ Non conforming product are clearly identified, segregated and dealt with;			
	$\checkmark$ If the products are repaired, control after fixing (recording of the results) ;			
8. <del>2425</del>	Management of the customers complaints :			
_	✓ the complaints on the products are recorded, treated and corrective actions are carried out when justified;			
	✓ number of complaints on CE marked products (and in connection with the range of CE marking) since last audit. Specify their nature.			
8. <del>25</del> 26	Analysis of the test results			
8. <del>26</del> 27	Corrective actions			

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### B. Example 2: <u>General checklist</u> for precast concrete products under Mandate M100, 126, 139 as amended.

This Check-list can be used as a basis to establish operational check-lists adapted to the relevant product standard(s) to carry out inspections on site.

It takes into account the requirements of CPD, of Guidance Papers B and K, and the indications given by the Sector Group of Notified Bodies SG-13.

It has been developed having as reference, for the general part, the European document NB-CPD/AG/03/004 (adapted to 2+ AoC level).

It is not a legally binding document, but for information only.

It is divided in two parts:

- 1.- CHECK LISTQUESTIONNAIRE FOR INITIAL INSPECTION and
- 2.- CHECK LISTQUESTIONNAIRE FOR THE SURVEILLANCE
- 3.- EXAMPLE OF CHECK LIST TO BE FILLED OUT IN EVALUATION AND SURVEILLANCE

The NB's Auditor, according to the type of visit, uses the relevant part.

Company		
Type of product		
Reference Standard		
Production Unit		
Auditor		
Type of visit	☐ Initial Inspection	☐ Surveillance
Date		
Auditor's Signature		

**N.B:** auditor shall attach copy of the FPC Manual assessment and copy of the audit plan.

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### **CHECK LIST 1. QUESTIONNAIRE** FOR INITIAL INSPECTION

#### 1.I. General Questions

N°	Questions	Answers and Comments
1.a	For which product/product family and Standard(s) is a factory production control established and has an initial type test (ITT) —possibly including initial type calculation ITC-[including initial type calculation (ITC) for mechanical and/or fire resistance for declaration methods 2 and 3b] been carried out?	Annex 1
1.b	Which is (are) the declaration method (s) used for each product/product family and Standard(s)?	
2	Does the producer have a certified ISO 9001 quality management system?  If Yes,  ils the certificate valid? By whom is it issued?  Is the Factory production Control for the products subjected to CE marking integrated in the certificate?	
3	Has a factory production control manual been established that includes or recalls the procedures by which the requirements of the FPC are fulfilled?  Indicate the edition and the date of the manual	
4	Did the documental review give a positive result?  Indicate the date of the documental test:	
5	If any remarks have been formulated in the documental review have these been solved? (If not the problem must be formalized by the inspector)	
6	Are the methods and the equipment used to carry out the ITT documented	
7	Have some of the activities of manufacturing, testing and verification of the producer been given in sub-contract? If Yes, which of them? If Yes, was a control of these activities established in order to retain overall responsibility for all the sub-contracted activities?	
8	Is there a formalized contract between the producer and the sub-contractor?	
9	Is the organization chart of the responsibilities of the production personnel defined and effective?	
10	Has a person responsible for the FPC been appointed for each production unit?  Does such person have the authority to ensure the carrying out and the respect of all the requirements of the FPC?	

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N°	Questions	Answers and Comments
11	Is it foreseen that the FPC system is reviewed at least once a year in order to ensure its continuous suitability and that such review is recorded?	
12	Is there a document and data management procedure, described or recalled in the Production Control Manual regarding the procedures and the responsibilities for the approval, issue, distribution, change and the management of documents and of internal and external data?	
13	Do the documents subject to control procedures include also documents concerning checking activities on materials and on supplied products, on manufacturing, on calculation of mechanical and/or fire resistance for declaration methods 2 and 3b and on finished products inspection?	
14	Did the producer prepare a checking programme that includes the type and the frequency of the tests and respects the minimum requirements of the standard?	
15	Did the producer include in the documents of the factory production control the criteria for the increasing or decreasing of test frequencies?	
16	Does the FPC define the responsibility of the producer in relation to the delivery and storage?	
17	For the products in question, does the producer have an adequate documented system concerning product complaints received, and is it integrated in the FPC?	

### 1. II. Specific questions according to the referred European harmonized Standards

N°	Questions	Answers and Comments
18	Are the values declared by the manufacturer for the harmonized characteristics covered by ITT (possibly including ITC) and is the consistency between ITT results and declared values documented?	
<u>19</u>	Is the consistency between ITT results and declared values documented?	
<del>19</del>	Does the verification of finished products take place using	
<u>20</u>	the test methods given by the relevant standards?	
2 <u>1</u> 0	If alternative methods are used, is the existing correlation between the results obtained with the standard methods and the alternative methods demonstrated and available?	

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### **2.CHECK LISTQUESTIONNAIRE** FOR THE SURVEILLANCE INSPECTION

### 2.I. General Questions

N°	Questions	Answers and Comments
101	Have some products been added and/or eliminated as regards to the previous audit? If affirmative, which?	Annex 1
102	Has the production system and/or the technical specifications changed from the last visit carried out on the products/product family?	
103	In case if significant changes of the raw materials, or of the production process or in the case of introduction on the market of new products, have the appropriate initial type tests and/or initial type calculation been carried out?	
104	Are the methods and the equipment used to carry out the new ITT those requested by the referred standards?	
105	Has the factory production control manual changed as regards to the last audit?	
	Indicate the edition and the date of the manual	
106	Did the review of possible documental changes give positive result?	
107	Have some activities of manufacturing, testing and verification of the producer been given in sub contract? If Yes, which of them? If Yes, was a of control of these activities established in order to retain the overall responsibility for all the subcontracted activities?	
108	Is there a formalized contract between the producer and subcontractor?	
109	Has the organization chart of the responsibilities of the production personnel been modified?	
110	Does a person responsible have the authority to ensure the carrying out and respect of all the FPC requirements?	
111	Has the FPC been reviewed in order to assure its continuous suitability?	
112	Is the document and data management procedure, inserted or recalled in the Production Control Manual regarding the procedures and the responsibilities for the approval, issue, distribution, change and the management of documents and of internal and external data and documents applied?  Has the procedure been modified from the last audit?	
113	If Yes, do the documents subject to procedure still include the documents concerning checking activities on materials and on supplied products, on manufacturing and on finished products inspections?	

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N°	Questions	Answers and Comments
114	Did the producer change the control programme?  If Yes, does the new control programme include the type and frequency of the tests and does it respect the minimum requirements of the standard?	
115	Did the producer include in the documents of the factory production control the criteria for the increasing and decreasing test frequencies?	
116	Does the FPC define the responsibility of the producer in relation to storage and delivery?	
117	For the products in question, does the producer apply an adequate documented system concerning to the complaints received, and is it integrated in the FPC?	

### II. Specific questions according to the referred European harmonized Standards

N°	Questions	Answers and Comments
118	Do the initial type tests cover the essential characteristics given in Annex ZA of the relevant standard? (see annex 2)	
119	Does the audit of the finished products take place using tests methods given by the relevant product standards?	
120	Do the initial type <u>calculationtest</u> cover <u>calculation of mechanical and/or fire resistance</u> where <u>declared under methods 2 and 3b ?</u> relevant the essentials characteristics given in Annex ZA of the relevant product standard and declared under Method 2?	
121	If alternative methods are used, is the existing correlation between the results obtained with the standard methods and the alternative methods demonstrated and available?	
122	Are the products CE marked according to annex ZA of the relevant product standard ?Are the CE marking of products and the accompanying documents in accordance with EN YYY standard for the declaration method(s) adapted?	

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#### 3. EXAMPLE OF CHECK LIST TO BE FILLED OUT IN EVALUATION AND IN SURVEILLANCE

For structural concrete elements the technical or design documentation shall include:

- Design calculations (only for Method 2 and 3b)
- Production specification

	(1) organizational (2) technical	YES	NO (1)	NO (2)	NA
	The production instructions detail the operative procedures referring to the phases of:				
	Cleaning and treatment of the moulds/beds				
	- Laying of the reinforcement and of the inserts				
	Detailing of reinforcement				
	- Preparation and closing of the moulds				
	Tensioning of prestressing steel				
	- Concreting				
	<ul> <li>Vibration, constipation compaction and finishing</li> </ul>				
	– Curing				
	Detensioning of prestressing steel				
	<ul> <li>Demoulding and lifting</li> </ul>				
	- Handling and Movement				
	– Further operations and finishing				

• Instructions on handling, storage and transport

			YES	NO (1)	NO (2)	NA
	-	Such documents detail the operative procedures related to the phases of:				
		<ul> <li>Loading on trucks</li> </ul>				

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Production specification consists in:

- Complete production drawings
- Production data with material properties, tolerances and weights

		YES	NO (1)	NO (2)	NA
	Are all the necessary measures and the complete description of the detailing of reinforcement /prestressing in the production drawings?				
	— Are production and assembly tolerances indicated on the production drawings or on the attached documents?				
	Is the characteristic strength of concrete given in the production drawings?				
		YES	NO		NA
	— Is the compressive strength of concrete specified at demoulding, at detention of prestressed elements, at post tensioning time for post tensioned elements given in the production drawings?				
	Are the used steel characteristics given in the production drawings?				
		YES	NO (1)	NO (2)	NA
	<ul> <li>Does the technical information contain a description of each product and country destination? (Method 2 or 3)</li> </ul>				
	<ul> <li>Does the technical information contain sketches with the principal dimensions and indications about relevant performances of each product according to its use?</li> </ul>				

#### **MATERIALS INSPECTION**

#### Inspection on supplied products (only where EN 13369 D.2.2 applies)

	Y	ES	NO (1)	NO (2)	NA
	Is there an inspection programme to carry out on materials/products at their arrival in the factory according to what foreseen in Table D2?	3			
	<ul> <li>Does the producer carry out tests and the necessary inspections before using the supplied products (according to Table D2)?</li> </ul>	]			
	<ul> <li>Are the necessary test/inspections carried out to ascertain that the total content of chloride in concrete does not exceed the limits foreseen by EN 206?</li> </ul>	J			
	Are tests foreseen carried out on other materials for concrete mix?	3			
	Lightening materials /isolations – Fibres – Finishing aggregates - Other				
	<ul> <li>Are tests foreseen carried out on materials and finishing products applied in the factory?</li> </ul>	3			
	Are tests foreseen carried out on outsourcing product components?	<b>3</b>			
	- Are the tests carried out registered?	3			

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#### Laboratory Equipment List

		YES	NO	NA
	<ul> <li>Does the laboratory has a testing programme of the equipment that he uses for tests and measurements?</li> </ul>			
	<ul> <li>Is the equipment used in a way to assure that their measuring uncertainty is with adequate to measurements to be carried out?</li> </ul>			
	<ul> <li>Is all the equipment for testing and measuring clearly identified?</li> </ul>			
	Are calibrations and/or tests of all equipment carried out with foreseen frequency?			
	<ul> <li>Does the laboratory evaluate the validity of the measurements made previously if the equipment results out of calibration?</li> </ul>			

#### **Production process**

		YES	NO	NA
	Is there an exhaustive scheme that illustrates the significant processes and the monitored parameters?			
	— Is there and operative programme of all checks to be carried out during the production?			
	Is the correspondence of produced concrete mixture with the expected one verified?			
	— Is the water content of concrete verified ? Does the value verified by the inspector respect the given tolerances?			
	<ul> <li>In case of doubt, is the chloride content in concrete calculated again when the components change?</li> </ul>			
	Is the water/cement ratio verified through calculation?			
	- When requested, is the air content in concrete verified?			
	Is the correctness of mixture operations verified periodically?			
	Is there a necessary number of specimen for each produced mix?			
	— Is the packaging date and composition number shown on the specimen?			
	Is there a composition register with the conservation of historical data?			
	<ul> <li>Is there a register of the daily inspections carried out on specimen with numbered pages, authentication and certain date?</li> </ul>			
	Are structural strength tests on specimen carried out before demoulding?			
	Did the acceptance inspection of the previous month, for each mix, result valid?			
	If not, have measures been taken?			
	Are the results of the resistance tests carried out, during Inspectors visit,, congruent with those pertinent to the previous period?			
	— Is the density of concrete verified (especially for light and heavy weight concrete)?			
	<ul> <li>Is there a correspondence between the actual reinforcement (normal and/or prestressed) and production drawings?</li> </ul>			
	Are welding operations opportunely verified?			
	Are possible straightening operations of steel rolls verified?			

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	YES	NO	NA
<ul> <li>Are moulds and beds adequately verified? Does the positioning and closure of the take place according to the foreseen prescriptions?</li> </ul>	moulds		
<ul> <li>Does the tightening of the tendons and its inspection take place according to the for prescriptions (tension, straightening)?</li> </ul>	oreseen		
Before the casting, have all the foreseen inspections been carried out with positive resi	ults?		
Is the authorization of the casting released by the responsible?			
<ul> <li>Does the concrete casting take place with foreseen procedures in order to guarar compactness?</li> </ul>	ntee the		
If necessary, are efficient procedures applied to avoid the fast drying of concrete?			
Are the procedures of accelerating maturity inspectioned adequately?			
Is the prescribed maturation cycle respected?			
Does the demoulding of manufactures take place according to the foreseen procedure:	s?		
<ul> <li>For prestressed elements, does the release of tendons take place at the reaching prescribed resistance?</li> </ul>	g of the		
Does the clearing of elements take place according to the foreseen procedures?			
Is the shortening of ropes verified after the transfer of the prestressing?			
Are there registrations on carried out inspections?			
<ul> <li>During the tests and inspections carried out, did the responsible show the necessary for carrying out the requested tests and inspections?</li> </ul>	practice		
When the products are provided FOB at erection site, are the operations of load unloading checked?	ing and		

#### Calculation process (mechanical and/or fire resistance) where method(s) 2 and/or 3b are applied

		<u>YES</u>	<u>NO</u>	<u>NA</u>
	Does ITT include calculation?			
	Does FPC cover calculation?			
	Are calculation data (e.g. concrete characteristic strength) confirmed by FPC results?			

# Precast Concrete Products Sector Group of Notified Bodies for the Construction Products Directive 89/106/EEC

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#### **Precast elements preservation**

		YES	NO	NA
	<ul> <li>Are there operative rules that allow maintaining unaltered the conformity of the products in the different phases: identification, movement, packaging, storage and protection?</li> </ul>			
	<ul> <li>In particular, are there depositions concerning the movement and storage procedures in the factory?</li> </ul>			
	<ul> <li>Do such dispositions also include instructions to prevent excessive deformations at short or long terms?</li> </ul>			
	<ul> <li>Are there any written dispositions regarding to possible instructions in relation to the maturity of products (in a way, for example, that products yet not suitable for transport/assembling are not delivered)?</li> </ul>			
	Do machinery (included those of third party) and areas on disposal result adequate?			
	Does the personnel responsible know the procedures and operative dispositions?			
	Are procedures and dispositions applied?			
	<ul> <li>Are there written dispositions for the inspection on the deterioration of stored elements with prearranged frequency and procedures?</li> </ul>			
	<ul> <li>Do the procedures carried out (labels, ink, and other) consent the continuing of identification for a necessary time or anyhow, for the components, until delivered?</li> </ul>			
	<ul> <li>Do procedures of loading (maximum leap, positioning on truck, tripods etc.) and devices for the maintenance of the position of the components during transportation (ropes, blocking devices, supporting devices and other) guarantee that these will not be damaged?</li> </ul>			
	Is there correspondence between the written dispositions and the operations checked at sampling by the Inspector?			
	<ul> <li>Does the producer protect adequately the deteriorating parts of his products until his responsibility finishes?</li> </ul>			

#### **Surveillance on non-conforming products**

		YES	NO	NA
	Does the producer predispose and keep active written procedures for the non-conformed product management?			
	Are there any exhausted application comparisons of such procedure and consequent actions?			
	In particular, does the producer describe also the treatment and/or the re-manufacturing carried out on products resulted non-conformed to the inspection?			
	Does the producer verify again the products corrected in a way to demonstrate their conformity to the given characteristics?			
	Does the producer adopt appropriate actions as regards to real or potential effects deriving by such non-conformed products when the product has been found non-conformed after its consignment or after its using?			