

<b>GNB-CPD</b>  <b>AG</b>	<b>Guidance from the Group of Notified Bodies for the Construction Products Directive 89/106/EEC</b>	<b>NB-CPD/AG/03/004r2</b> Issued: 16 February 2011  <b>APPROVED – INFORMATIVE</b>
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## GNB-CPD position paper

### ***Checklists for initial inspection of factory and factory production control and continuous surveillance of factory production control***

#### **General scope, limitations and aim of this guidance for notified bodies**

This position paper contains guidance for certification/inspection bodies involved in inspecting factories and factory production control systems (AoC systems 1+, 1, 2+ and 2) towards the attestation of conformity of construction products or their FPC to harmonized technical specifications. The purpose is to help bodies work equivalently and come to common judgments. This guidance contains only informative material (which bodies should or may follow).

This guidance is thought necessary to provide clarity and completeness for NBs so that they can work equivalently. It **supplements and makes practical for NBs** the relevant harmonized technical specifications, and Standing Committee guidance in the form of GPs, which also apply - unless otherwise explicitly stated in this guidance. This position paper should **not** contradict nor extend the scope of the work and role of a NB, nor impose additional burdens on the manufacturer, beyond those laid down in the CPD and the relevant technical specifications.

This guidance should be considered valid until guidance from the Commission or SCC has changed on relevant matters. Whereupon, the paper should be considered for withdrawal/revision and be replaced by new guidance as necessary.

This position paper was considered approved in its original form by Advisory Group on 17-18 December 2001, with substantial changes in its revision 1 form on 6 October 2009, and in its revision 2 form on 12 February 2011.

This position paper was first revised following a review of the original version and in particular to facilitate its use as a basis for inspection reports. Its 2<sup>nd</sup> revision extended the note below the table of general questions in the check list for continuous surveillance.

## **Use of these checklists**

### **Use of checklists by certification/inspection bodies for inspections**

Within the context of Commission Guidance Paper 'B' and the CPD, certification/inspection bodies undertaking inspections should seek evidence of fulfilment of all the requirements of the harmonized technical specification for the product or FPC. Checklists can assist an inspector in his task by helping to ensure that no aspects of the manufacturing process are overlooked. However, for each

aspect, the inspector should apply his knowledge and experience to the situation rather than relying on options proposed by checklists.

For best results, checklists should be developed and tailored by the body for particular applications. As a starting point for creating individual checklists:

- The certification/inspection body should first check whether the relevant harmonized technical specification includes or references appropriate checklists and whether any GNB-CPD Sector Group (SG) position papers have been developed for the products that include relevant checklists to act as a basis for the body's own checklists.
- If more specific checklists are not available, bodies may adapt the general checklists in this paper for their needs.

The enclosed checklists:

- are recommendations provided for information only - their use is not obligatory;
- refer to the initial inspection and the continuous surveillance only;
- agree with the provisions of the CPD and of Guidance Papers 'B', 'K' and 'M'.

Where specific checklists do not already exist, the lists below are intended to form a basis for bodies to structure their inspections when assessing factory production control (FPC) under attestation of conformity systems 1+, 1, 2+ and 2 (continuous surveillance is not required under AoC system 2).

The questions forming these checklists should be regarded only as points to consider. Users will need to decide whether they expect a manufacturer to comply with a particular question, or whether the question is only for background information for the body, and also what action is appropriate when questions are not answered by a "YES". Users should adapt and extend these lists to suit the particular products and manufacturing system they are inspecting, taking account of any key steps indicated in the harmonized technical specification.

These checklists may also be used as a basis from which to structure reports of the inspections.

## **Use of these checklists for developing other documents**

These checklists:

- may be adapted by SGs to generate checklists for particular products or groups of products;
- may be taken by CEN/EOTA for consideration when specifying the respective methods of control of conformity.

SGs are invited, where they think appropriate, to review these checklists, and elaborate, amend or otherwise adapt them to produce checklists for the initial inspection of the factory and the FPC, and for continuous surveillance of the FPC, of particular products or groups of products.

## **Initial inspection of the factory and FPC**

The initial inspection of the factory provides for the identification and documentation of the kind and manner of the manufacturing process and FPC of the products. This is to enable the body to assess the compliance with the provisions of the technical specification on the one hand and to provide a baseline to identify possible changes that may occur during surveillance.

## **Surveillance of FPC**

The surveillance of the manufacturing process includes:

- checking the documentation of the FPC to ensure continuing compliance with the provisions of the technical specification, and;
- the identification of changes by comparing data obtained during the initial inspection or during the latest inspection.

# Check List for Initial Inspection of Factory and of FPC

In the course of the initial inspection the following criteria should be considered:

## I. General questions

	Questions to be considered	Comments
1	For which product/product family has a FPC been established and an initial type testing of the product been carried out?	
2	<p>Does the manufacturer already apply a quality management system related to the technical specification?</p> <p>If YES, is that proved by a valid certificate and by whom?</p> <p>Does the FPC for the products to be certified form part of the quality management system?</p> <p><i>NOTE: In all cases the NB shall assess the FPC in accordance with the relevant harmonized technical specification. The FPC system may be part of an existing quality management system (e.g. in accordance with EN ISO 9001), the scope of which covers the manufacture of the products. In this case if a notified certification body, or a body sub-contracted to the NB (see Commission Guidance Paper 'A' §3.4), has issued an EN ISO 9001 certificate for the quality management system of the manufacturer, information from that certification may be used in support of the FPC.</i></p>	
3	<p>For the products to be certified, does the manufacturer have a system to document the production process from purchasing/delivery of the basic materials through to the storage and the delivery of the finished products?</p> <p>Is this FPC manual maintained when appropriate?</p>	
4	Is the manner, extent and frequency of FPC in accordance with the documented system?	
5	Does the manufacturer have direct control of the appropriate machinery and for the production of the products to be certified, or are key elements of the production with respect to the essential characteristics subcontracted to others on or off the site?	
6	Is it clear which person has overall responsibility for the FPC and its implementation, and which persons have responsibility for individual parts of it?	
7	Is the maintenance of this machinery and the measuring equipment carried out properly, regularly, and is this documented?	
8	Are the personnel involved in the production sufficiently qualified and trained to operate and maintain the production equipment?	

	<b>Questions to be considered</b>	<b>Comments</b>
9	<p>Are all processes and procedures of the production recorded at regular intervals or continuously (automatically)?</p> <p>How is the documentation organized?</p>	
10	<p>Is an inspection of the incoming material carried out, and if yes, how and at what intervals?</p>	
11	<p>Which characteristics of the products are tested and recorded in the course of the production process and/or on the final products or documented in any other manner?</p>	
12	<p>What are the test methods and equipment used?</p> <p>Are the test methods and test equipment used directly related to the technical specifications or are proxy values of characteristics used?</p> <p>Have appropriate measurements been performed and documented linking the test methods and equipment used with the technical specification?</p> <p>Do the findings of these tests correlate with the ITT results, or the requirements laid down in the technical specification for initial type testing or for testing as part of the FPC, as appropriate?</p>	
13	<p>Is the testing equipment correctly maintained and calibrated on a continuous basis to ensure constant accuracy of the tests performed during FPC and surveillance?</p>	
14	<p>Does the manufacturer apply an adequate documented system that allows the detection of defects and deviations quickly enough to identify unambiguously those products that are not in accordance with the product specification so that they are removed prior to delivery?</p> <p>In which way is the marking of such products performed?</p>	
15	<p>For the products to be certified, does the manufacturer apply an adequate documented system concerning product complaints received, and that is integrated into the FPC?</p> <p>Does the system include appropriate measures to avoid or correct these deficiencies?</p>	

## II. Specific questions related to the technical specification

	Questions to be considered	<i>Comments</i>

## III. Summary of results and corrective measures required

<b>Summary of the results by the inspection body and the specification of the measures to be taken for correction if necessary</b>

## Check list for the continuous surveillance

In the course of a continuous surveillance the following criteria have to be considered:

### I. General questions

	Questions to be considered	Comments
1	For which product/product family has a FPC been established and an initial type testing of the product been carried out?	
2	Does the manufacturer still apply a quality management system that covers the FPC of the certified products, and is there a valid certificate?  <i>NOTE: In all cases the NB shall assess the FPC in accordance with the relevant harmonized technical specification. The FPC system may be part of an existing quality management system (e.g. in accordance with EN ISO 9001), the scope of which covers the manufacture of the products. In this case if a notified certification body, or a body sub-contracted to the NB (see Commission Guidance Paper 'A' §3.4), has issued an EN ISO 9001 certificate for the quality management system of the manufacturer, information from that certification may be used in support of the FPC.</i>	
3	For the products to be certified, does the manufacturer have a system to document the production process, from purchasing/delivery of the basic materials through to the storage and the delivery of the finished products, as before?  Is this FPC manual maintained when appropriate?	
4	Has the production and/or the technical specification changed since the last continuous surveillance of products/product family?  If yes, has the manufacturer adapted the documentation accordingly?	
5	Is the manner, extent and frequency of FPC still in accordance with the provisions of the technical specification?	
6	Is it clear which person has overall responsibility for the FPC and its implementation, and which persons have responsibility for individual parts of it?	
7	Is the maintenance of machinery and measuring equipment carried out properly and regularly as before, and is this documented and is the documentation up to date?	
8	Are the personnel involved in the production sufficiently qualified and trained to operate and maintain the production equipment as before?  Have there been alterations in key staff since the initial or the last continuous surveillance?	

	<b>Questions to be considered</b>	<b>Comments</b>
9	<p>Are all processes and procedures of the production recorded at regular intervals or continuously (automatically) as before?</p> <p>Have there been changes in the manner of recording or documentation since the initial or the last continuous surveillance?</p>	
10	<p>Is an inspection of the incoming material carried out as before, and if so have there been any changes in the way it is done and/or the intervals?</p> <p>Have the provisions for procurement of the basic materials and/or the suppliers been changed?</p>	
11	<p>Have any changes been made concerning test methods and/or testing equipment?</p> <p>If so, have appropriate comparable measurements been performed and documented?</p> <p>Do the findings of these tests correlate with the ITT results, or the requirements laid down in the technical specification for initial type testing or for testing as part of the FPC, as appropriate?</p>	
12	<p>Do the values measured during FPC correspond with those values determined on products within the initial type testing?</p>	
13	<p>Is the testing equipment correctly maintained and calibrated as before to ensure consistent accuracy of the tests performed during FPC and its surveillance?</p>	
14	<p>Does the manufacturer apply, as before, an adequate documented system that allows the detection of defects and deviations quickly enough to identify and mark unambiguously those products that are not in accordance with the product specification in order to remove them?</p>	
15	<p>For the products to be certified, does the manufacturer apply an adequate documented system concerning product complaints received that is integrated into the FPC – as before?</p> <p>Are appropriate measures to correct non-conformities with the technical specifications being used and are these measures documented?</p>	

**NOTE** *Under the CPD there is no direct responsibility for a NB to check that a manufacturer is CE marking his products correctly. However, this may be required by the harmonized technical specification, Member State authorities, or accreditation requirements. Independently of the task of FPC conformity assessment, if the NB encounters what it considers may be errors in the way the manufacturer is CE marking its products, it should draw the attention of the manufacturer to these.*

## II. Specific Questions related to the technical specification

	Questions to be considered	<i>Comments</i>

## III. Summary of results and corrective measures required

<b>Summary of the results by the inspection body and the specification of the measures to be taken for correction if necessary</b>