Factory Production Control and Initial Type Testing Presentation for CE Marking Construction Products Conference

By

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ARC Management Systems
Topics for discussion:

• Identification of Attestation Level

• Factory Production Control
  • Documentation & Process Required
  • Audit Process & Requirements
  • Potential Issues

• Product Testing
  • Requirements for Testing
  • Testing Types
  • Potential Issues

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Key Points:

• Implementation Deadline – 1\textsuperscript{st} July 2013

• 2/3 Month Lead Time on Factory Production Control Audits

• Expected backlogs at Product Testing Laboratories
ASSESSMENT & VERTIFICATION OF CONSISTANCY OF PERFORMANCE
(AVCP or Attestation level)
Annex ZA – An Overview

• Scope and Relevant Clauses for the hEN – Which clauses are applicable to CE marking of the product.

• AVCP (Attestation) level for your product

• Example of CE Marking – What information is required to be displayed on your CE Badge or Marking.

• FPC and Testing Requirements

<table>
<thead>
<tr>
<th>Product</th>
<th>Intended use</th>
<th>Level(s) or class(es)</th>
<th>Attestation of conformity system(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertical road signs - permanent fixed signs</td>
<td>Permanent traffic signs installed permanently for the information, guidance, warning and direction of vehicle drivers and pedestrians.</td>
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<td></td>
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</tbody>
</table>

System 1: See Directive 89/106/EEC (CPD) Annex II.2.(i), without audit testing of samples

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## Assessment and Verification of Constancy of Performance

### ANNEX ZA

<table>
<thead>
<tr>
<th>System Type</th>
<th>Responsibility</th>
<th>Type of Notified Body</th>
<th>Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>System 1+</td>
<td>Notified Body</td>
<td>Product Certification Body</td>
<td>Initial Inspection of the FPC system, Continuous Surveillance of the FPC system, Determination of product type, Audit testing</td>
</tr>
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<td></td>
<td>Manufacturer</td>
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<td>System 2+</td>
<td>Notified Body</td>
<td>Factory Production Control Certification Body</td>
<td>Initial Inspection of the FPC system, Continuous Surveillance of the FPC system</td>
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<td></td>
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</tr>
<tr>
<td>System 3</td>
<td>Notified Body</td>
<td>Test Laboratory</td>
<td>Determination of Product Type</td>
</tr>
<tr>
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<td>Manufacturer</td>
<td></td>
<td>Factory production Control</td>
</tr>
<tr>
<td>System 4</td>
<td>Manufacturer</td>
<td>No Independent Involvement</td>
<td>Factory production Control, Determination of Product Type</td>
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System 4

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<tr>
<th>System4</th>
<th>Manufacturer</th>
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<th>Factory production Control Determination of Product Type</th>
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</table>

Manufacturer may preform all tasks internally

- Factory Production Control -
- Determination of Product Type – Previously referred to as Initial Type Testing

No Involvement of 3rd Parties.
System 3

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<thead>
<tr>
<th>System 3</th>
<th>Notified Body</th>
<th>Test Laboratory</th>
<th>Determination of Product Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td></td>
<td></td>
<td>Factory production Control</td>
</tr>
</tbody>
</table>

Manufacturer may preform:

- Factory Production Control

A Test Laboratory is Required for:

- Determination of Product Type

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## System 2+

| System 2+ | Notified Body | Factory Production Control Certification Body | Initial Inspection of the FPC system  
Continuous Surveillance of the FPC system |
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**Manufacturer may perform:**

- Factory Production Control
- Testing of Samples
- Determination of Product Type

**A Notified Body is Required for:**

- Initial Inspection of FPC
- Continuous Surveillance of FPC

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Manufacture may preform:

- Factory Production Control
- Testing of Samples

A Notified Body is Required for:

- Initial Inspection of FPC
- Continuous Surveillance of FPC
- Determination of Product Type

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# System 1+

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A Notified Body is Required for:

| | • Initial Inspection of FPC |
| | • Continuous Surveillance of FPC |
| | • Determination of Product Type |
| | • Audit Testing |

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FACTORY PRODUCTION CONTROL
What are the Requirements for FPC?

The manufacture is responsible for organising an effective FPC system, and nominating a delegate to:

• Identify procedures to demonstrate conformity

• Identify and record any instance of non-conformity

• Identify procedures to correct instances of non-conformity
What might the Requirements include?

• Documentation
• Production Control
• Verification of Tests
• Test Plans
• Test Records
• Treatment of Non-Conformities
• Traceability
Documentation

The FPC system should achieve an appropriate level of confidence in the conformity of the product:

- Documented Procedure and instructions for FPC operation
- Effective Implementation of Procedures and Instructions
- Records of these operations and results
- Use of results to correct deviations and improve the system
Production Control

Production control can include some or all of the following:

• The specification and verification of raw materials and constituents

• The controls and test to be carried out during manufacturing
Verification and Tests

The manufacture or sub-contracted test house will require the equipment and personnel which enable them to carry out the necessary verification and test to meet the following:

• There must be records maintained of the calibration and controls used during test procedures.

• The equipment to be used must be used in conformity with the specification or test reference system

• The personnel using the equipment must be trained in its use and the if required the interpretation of results.

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Tests Plans

Tests will be preformed based on a test plan developed in accordance with the technical specifications.

Depending on the level of AVCP these will be conducted in house or in an appropriate test laboratory.
Test Records

The manufacture should establish and maintain records which provide evidence that the product has been tested.

These records must demonstrate the product meets the requirements of the standard.

Non-conformities must be recorded.

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Treatment of Non-Conformities

• Procedures to handle non-conforming products or batches need to be established

• This may include isolation and tagging

• Once corrected, retest procedures are used

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Traceability

• It is the manufacturers or agents responsibility to keep full records of individual products or batches of products

• Using these records a high level of traceability must be achievable, within reason.
Certification of FPC System

- FPC systems under AVCP level 1+ 1 and 2+ require certification under a notified body.

- Certification may only be applied for by an organisation with a fully implemented FPC system
Initial Inspection FPC Questions

• Does the FPC system document all stages of the product from purchasing and suppliers to final sale.

• Is there clearly defined responsibility at all stages

• Is there Training and qualification of staff involved
Initial Inspection FPC Questions

• Is a Documentation control system in place?

• Is a Customer complaint handling process in place?

• Is there Inspection of materials and where required suppliers?
Continuous FPC Surveillance – Additional Questions

• For which product/product family has the FPC system been established and does the original scope still cover the existing system

• Has the production and/or the technical specification changed since the last inspection
Continuous FPC Surveillance – Additional Questions

• Are the personnel involved that hold key responsibility the same as on last inspection, have need appointments been adequately trained.

• Do the values of measurements taken still reflect the requirements of the standard.
PRODUCT TESTING
Product Testing

• Requirements for product testing must be established for your specific product.

• These requirements may vary substantially based on your AVCP level and product type.

• These requirements are in the product hEN or ETA.

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Standards

• The Annex ZA details the requirements for:

  • Factory Production Control

  • Product Testing

  • Notified Body Involvement

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ETAs

• Developed at the request of the manufacture, generally with a long lead time, when there is no harmonised standard in place

• Provides similar guidance to a harmonised standard
Determination of Product Type

Determination of Product type not only covers physical testing but also includes:

• Calculations

• Conventionally accepted performance

• Tabulated Reference Data – Standard performance data.
Testing & Production Types That Can Apply to Companies

In order to reduce test costs and simplify the test processes there are several options open to companies:

• Shared Test Results
• Cascading Test Results
• Conventional Series Production
• Series Production
• Individual (and non-series) Production
Shared Test Results

A manufacture may use determination of product type results obtained by another manufacture. However the product must have

- the same design,
- raw materials and
- identical physical dimensions and
- properties relevant to performance.
Cascading Test Results

• A manufacturer may use Determination of product type results from a component supplier provided they were obtained from a notified body.

Those components individual performance attributes do not have to be retested.
Conventional Series Production

Where the same product is manufactured in large volumes over periods of time:

- As long as the product and manufacturing process remains unchanged there is no need to repeat the determination of product type testing as there is generally no limit or expiration date on ITT reports.
Series Production – Products With Varying Properties

Where there is series production but the finished product has potentially different performances (i.e. due to size etc).

• The technical specification will state which values may be tested as series production values to reduce the test burden and which must be individually tested on a per product/batch level. This relates specifically to Product Ranges etc.
Individual Production – 1 Off’s

• Individual Production may use determination of product type based on conventionally accepted methods of testing/determining performances

• Factory production control is sufficient to attest the conformity with the technical specifications and allow CE marking

However:

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Individual Production – 1 Off’s

• Product must be completely individual and non-series.

• Individual design and installed in a known works/installation

• Custom made for specific order to obtain one or several end use performance differences.
SUMMARY
Step 1. Using Annex ZA, determine the AVCP (attestation Level) of your product.

Step 2. Determine & implement the requirements of your Factory Production Control System using the HEN and Annex ZA.

Step 3. Determine & conduct/gather the Product Test Requirements again using the HEN.

Step 4. Submit to FPC Audit.

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