

## **BASEC FACTORY PRODUCTION CONTROL (FPC) REQUIREMENTS & GUIDANCE to BS EN 50575:2015+A1:2016**

### **Introduction**

*The manufacturer / distributor / importer (\*) shall establish, document and maintain an FPC system to ensure that the products placed on the market comply with the declared performance of the essential characteristics.*

(\*) An importer or distributor shall be considered a manufacturer for the purposes of Regulation (EU) No 305/2011 and shall be subject to the obligations of a manufacturer pursuant to Article 11, where he places a product on the market under his name or trademark or modifies a construction product already placed on the market in such a way that conformity with the declaration of performance may be affected - The word "manufacturer" below includes above consideration.

*The FPC system shall consist of:*

- *procedures, regular audits, tests and/or assessments;*
- *the use of results to control:*
  - *raw and other incoming materials or components,*
  - *equipment,*
  - *the production process and*
  - *the product.*

*When subcontracting takes place, the manufacturer still has the overall responsibility and retains the overall control of the product. The applied FPC of the subcontractor may be taken into account, where appropriate.*

*All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic manner in the form of written policies and procedures.*

*This factory production control system documentation shall ensure:*

- a. *a common understanding of the evaluation of the constancy of performance,*
- b. *enable the achievement of the required product performances and the effective operation of the production control system.*

*Factory production control therefore brings together operational techniques and all measures allowing maintenance and control of the compliance of the product with the declared performances of the essential characteristics.*

### **1. FPC Requirements**

BCL FPC requirements are the BS EN 50575:2014+A1:2016 clause 6.3 requirements.

The assessment is usually limited to a stage 2 assessment if clients 'ISO 9001 QMS' is certified by a CB accredited by an IAF member (a full certification cycle related Audit reports need to be available for review by BCL auditors).

A stage 1 audit is required when a site does not hold a QMS certificate to ISO 9001 by a CB accredited by an IAF member.

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All the FPC assessments – audits follow in general the existing BCL processes for ISO 9001 and BCL Product Certification Scheme Rules §2.6, certification audits.

Requirements in BS EN 50575:2014+A1:2016 §4.2 and §7 are also reviewed during the audit.

#### **2. FPC Guidance**

It is not suggested that below clarifications / guidance are raised as findings, however, their adoption may result in the continual improvement of the applied FPC system.

Below clauses refer to BS EN 50575:2014+A1:2016:

##### **6.3.2.2. Equipment**

###### **6.3.2.2.1 Testing**

Any measurement equipment from which a reading is taken or required shall be adequate for tests and measurements and calibrated / verified, with traceability to national or international references.

For each test, there shall be a definition of the measurement accuracy required, the equipment and method to be used in the measurement.

Reference standards of measurement held by the laboratory or QC, shall be used for calibration only, and kept in a laboratory environment.

Where relevant, testing equipment including test software shall be subject to in-service checks between routine calibrations.

Calibration / verification shall be conducted against standards traceable to national or international measurement standards. Where no such standards exists the basis for calibration shall be recorded. Equipment shall be maintained in good order within the calibration system, identified in order to determine status, and safeguarded from adjustments, damage or deterioration that would invalidate calibration status or subsequent measurements. Where available, calibration services accredited to ISO/IEC 17025 should be used.

###### **6.3.2.2.2 Manufacturing**

The plant and process capability to manufacture any product within the range for which a Certificate applies shall be defined and documented, (for instance in the Quality Manual).

###### **6.3.2.2.3 Raw materials and components**

There shall be documented identification of the characteristics to be inspected, tested or examined, including subjective criteria.

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There shall be adequate instructions for the inspection, test or process control and the definition of acceptance/ rejection criteria.

#### **6.3.2.4 Traceability and marking**

There shall be positive identification of raw materials, semi-finished and final product at all stages of receipt, storage, manufacture and despatch.

#### **6.3.2.5 Controls during manufacturing process**

There shall be machine/ process set up and running parameters for each cable.

All instruments/ controllers, test/ inspection equipment and software which are used to ensure set up and running parameters or product related characteristics, shall be calibrated or otherwise verified as appropriate.

“Indication only” equipment does not require calibration, but it shall be included in the preventative maintenance to ensure that it is working correctly and it should be labelled accordingly.

#### **6.3.2.6 Product testing and evaluation**

The initial test frequency may be reduced as long as no changes in materials, production process or machines are introduced for 2 successive years. It is suggested to test related performance characteristics for every change of materials or design.

#### **6.3.2.7 Non-complying products**

The procedures governing any repair or rework shall be documented and related records kept. For these purposes, the following definitions shall apply: Rework; the repeat of a normal manufacturing process or operation, e.g. strip and re-sheath. Repair: an operation different from a production operation, which incorporates the making good of a non-conforming feature, e.g. the repair of pinholes

#### **6.3.2.8 Corrective action**

An investigation of trends resulting e.g. from root causes identified, is a suggested practice.

#### **6.3.2.9 Handling, storage and packaging**

The Client, when the goods are not picked up by his customer, shall ensure that the product is delivered to the customer in good condition.

The product or its drum/reel or other packaging, shall in addition to any requirement of the detailed specification include:

- cable type and specification number; and,
- unique identifier (for traceability); and,
- length of cable including the unit of measurement; and,

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- name of manufacturer, as in the certificate of constancy of performance of the product.

#### **6.3.3 Product specific requirements**

No specific clarifications/ guidance.

#### **6.3.4. Initial inspection of factory and FPC**

Initial inspection of the factory and of FPC for products covered by AVCP system 1+ shall be carried out when the production process has been finalised and in operation. The FPC documentation shall be assessed, to verify that the requirements of 6.3.2 and 6.3.3 are fulfilled.

Each assessment and its results shall be documented in the audit report.

#### **6.3.5. Continuous surveillance of FPC (for products covered by AVCP system 1+)**

Surveillance of the FPC is undertaken twice per year. The surveillance of the FPC shall include a review of the FPC test plan(s) and production process (-es) for each product to determine if any changes have been made since the last assessment or surveillance. The significance of any changes shall be assessed. Related input is provided in the report and independently by the client.

Reaction to fire characteristics shall be subject to the tests indicated in Clause 5.

Samples shall be selected from finished goods which have been released for sale by the manufacturer.

#### **6.3.6. Procedure for modifications**

No specific clarifications/ guidance.

#### **6.3.7 One-off products, pre-production products (e.g. prototypes) and products produced in very low quantities.**

No specific clarifications/ guidance.

### **7. Marking, Labelling, Packaging**

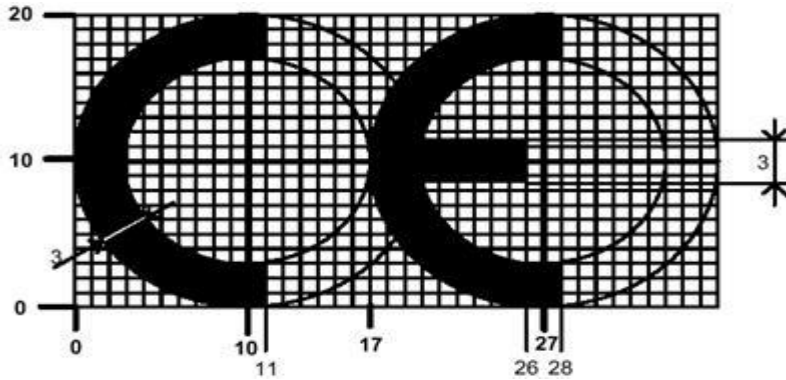
#### **7.1 Marking**

CE marking needs to follow below example and to be legible (see 7.3). Related guidance can be found in:

[http://ec.europa.eu/growth/single-market/ce-marking/index\\_en.htm](http://ec.europa.eu/growth/single-market/ce-marking/index_en.htm)

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The CE marking shall be affixed distinctly, visibly, legibly and indelibly. It is prohibited to affix any marks or inscriptions that are likely to mislead third parties as to the meaning and form of the CE marking. The requirement for visibility means that the CE marking must be easily accessible for market surveillance authorities as well as visible for customers and users. For reasons of legibility a minimum height of 5 mm of the CE marking is required. This minimum dimension may be waived for small-scale products. The requirement for indelibility means that the marking must not be removed from the product without leaving traces noticeable under normal circumstances. It should be noted that the C and E are not formed by perfect semi-circles, i.e. the top and bottom arms extend one square beyond the semi-circles, and the middle arm of the E stops one square short.

**7.2 Form of marked elements**

No specific clarifications/ guidance.

**7.3 Legibility of marking**

Non-degradable may be assessed as the requirements for durability:

The durability of printed marking or of colour shall be checked by trying to remove the marking or colour by rubbing lightly 10 times with a piece of cotton wool or cloth soaked in water (see BS EN 50396:2005+A1:2011 – Non electrical test methods for low voltage energy cables).

**3. Applicability of BS EN 50575:2015 + A1:2016 requirements for non-manufacturing sites**

Ref.	FPC Requirement	Applies to Distributor?
	* = primarily undertaken at the factory producing the cables	
6.3.2.1	Tasks and responsibilities in the production control organisation shall be documented and this documentation shall be kept up-to-date	Yes

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Ref.	FPC Requirement * = primarily undertaken at the factory producing the cables	Applies to Distributor?
6.3.2.1	The responsibility, authority and the relationship between personnel that manages, performs or verifies work affecting product constancy, shall be defined (Applies in particular to personnel that need to initiate actions preventing product non-constancies from occurring, actions in case of no constancies and to identify and register product constancy problems)	Yes
6.3.2.1	Personnel performing work affecting constancy of performance shall be competent on the basis of appropriate education, training, skills and experience for which records shall be maintained	Yes
6.3.2.1	Has the manufacturer draw up and keep up-to-date documents defining the factory production control?  This involves:  a) the preparation of documented procedures and instructions relating to factory production control operations, in accordance with the requirements of the technical specification to which reference is made;  b) the effective implementation of these procedures and instructions;  c) the recording of these operations and their results;  d) the use of these results to correct any deviations, repair the effects of such deviations, treat any resulting instances of non-conformity and, if necessary, revise the FPC to rectify the cause of no constancy of performance.	Yes
6.3.2.1	Is subcontracting of the products referred to in related quotation, take place?	Yes
6.3.2.1	<b>If yes:</b>  Does the manufacturer retain the overall control of the product and ensure that he receives all the information that is necessary to fulfil his responsibilities according to this European Standard?	Yes
6.3.2.1	Is part of the product designed, manufactured, assembled, packed, processed and /or labelled by a subcontractor?	Yes
6.3.2.1	If yes, has the FPC of the subcontractor taken into account by the Client  &  Is related info available to the Notified Body	Yes  Yes
6.2.3, 6.3.3	Are FPC related records retained for at least for 5 years and all Test Reports for at least 10 years?	Yes

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Ref.	FPC Requirement * = primarily undertaken at the factory producing the cables	Applies to Distributor?
6.3.2.2.1	Is all weighing, measuring and testing equipment available, calibrated and regularly inspected according to documented procedures, frequencies and criteria?	No (unless Distributor also tests or cuts) *
6.3.2.2.2	Is the equipment used in the manufacturing process regularly inspected and maintained to ensure use, wear or failure does not cause inconsistency in the manufacturing process?	No *
6.3.2.2.2	Is the related procedure documented and applied?	No *
6.3.2.2.2	Are related records kept?	No *
6.3.2.3	Are the specifications of all incoming raw materials and components documented?	No *
6.3.2.3	Does the applied inspection scheme ensure raw materials compliance?	No *
6.3.2.4	Are individual cable batches identifiable and traceable with regard to their production origin ( <i>operators, machines, raw materials</i> )?	Yes *
6.3.2.4	Does the manufacturer have written procedures ensuring that processes related to affixing traceability codes and/or markings are inspected regularly?	Yes *
6.3.2.5	Does the manufacturer plan and carry out production under controlled conditions, appropriate to the particular manufacturing process?	No *
6.3.2.6	Are there procedures to ensure that the stated values of the characteristics declared by the manufacturer are maintained?  <i>Note :</i>  <i>The characteristics and the means of control, are:</i>  <i>Reaction to fire characteristics shall be subject to the tests indicated in Clause 5 of BS EN 50575:2014/A1:2016, at least once per year.</i>  <i>Only one product sample shall be selected from each product family.</i>  <i>The test frequency may be reduced as long as no changes are introduced for 2 successive years (BCL's approval required)</i>	Yes, but may be jointly with manufacturer
6.3.2.7	Does the manufacturer have written procedures which specify how non-complying products shall be dealt with?	Yes *
6.3.2.7	Are any such events recorded as they occur and these records kept?	Yes *
6.3.2.7	Is the necessary corrective action immediately taken and the products or batches not complying, isolated and properly identified?	Yes *

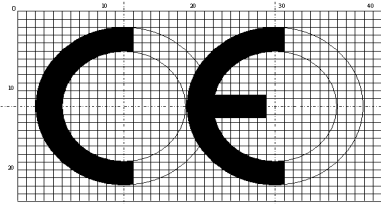
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6.3.2.7	Once the fault has been corrected, is the test or verification in question repeated?	Yes *
6.3.2.7	Are the results of controls and tests properly recorded?  (The product description, date of manufacture, test method used, test results and acceptance criteria shall be entered in test records under the signature ( <i>where applicable</i> ) of the person responsible for the control / test)	Yes *
6.3.2.7	With regards to any control result not meeting the requirements of this European Standard, are the corrective measures taken to rectify the situation (e.g. further test carried out, modification of manufacturing process, scrapping or correction of product) indicated in the records?	Yes *
6.3.2.8	Does the manufacturer have documented procedures that initiate action to eliminate the cause of non-conformities in order to prevent recurrence?	Yes *
6.3.2.8	Is the way these procedures applied effective?	Yes *
6.3.2.9	Does the manufacturer have procedures providing methods of product handling?	Yes
6.3.2.9	Does the manufacturer provide suitable storage areas preventing damage or deterioration?	Yes
6.3.3	Is a product specific FPC test plan available?	Yes *
6.3.3	Does the FPC test plan include the :  a. controls and tests to be carried out prior to & during production?  b. Verifications and tests to be carried out on finished products?  c. Frequencies / methods / ref to instructions- procedures for the above?	Yes *



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Ref.	FPC Requirement  * = primarily undertaken at the factory producing the cables	Applies to Distributor?
7	<p>Is the CE marking symbol in accordance with the general principles set out in Article 30 of Regulation (EC) No. 765/2008 and affixed visibly, legibly and indelibly to the product labels affixed to the reels, coils or drums of the power, control and communication cables?</p>  <p><i>Note: CE marking covers the requirements of all applicable EU Directives and EU regulations.</i></p>	Yes
7.1	<p>Are power, control and communication cables marked with:</p> <ul style="list-style-type: none"> <li>a) an indication of origin consisting of the marking of the manufacturer's name or trademark, or (if legally protected) identification number;</li> <li>b) the product description or code designation;</li> <li>c) the reaction to fire class</li> </ul> <p><i>(The marking may be on the cable or on its packaging or on its labelling or any combination of the preceding)</i></p>	Yes
7.1	<p>Are (in addition) power, control and communication cables also marked with the following elements:</p> <ul style="list-style-type: none"> <li>d) any information required by other standards relevant to the product;</li> <li>e) the year of production;</li> <li>f) voluntary certification marks;</li> <li>g) any additional information as wished by the manufacturer provided that it does not conflict with, nor confuse any of the other required marking.</li> </ul> <p><i>Where regulatory marking provisions require information on some or all items listed in this clause, the requirements of this clause concerning those common items are deemed to be met.</i></p>	Yes
7.2	<p>Marking when applied on the cable shall be applied by printing, embossing or indenting on the sheath or (for unsheathed cables) on the insulation. The marking shall be continuous and the distance between the end of the marking and the beginning of the next identical marking shall not exceed 1100 mm.</p>	Yes *
7.3	<p>Marking shall be legible and printed marking shall not be de-gradable.</p>	Yes *

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6.3.7	During the audit, it has been verified:  <i>(Note: All locations where final manufacture and final testing of the relevant product is performed shall be assessed to verify that the below conditions a) to c) are in place and implemented)</i>  a) that all resources necessary for the achievement of the product characteristics required by BS EN 50575:2014/A1:2016 are in place and correctly implemented,	Yes *
6.3.7	b) that the FPC-procedures in accordance with the FPC documentation are followed in practice,	Yes
6.3.7	c) that the product complies with the product-type samples, for which compliance of the product performance to the DoP has been verified.	Yes

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