CTO S.A.	**CENTRUM TECHNIKI OKRĘTOWEJ S.A.** Product Certification Division	Page/Pages: 1/11
I-01	**INSTRUCTION** **FACTORY PRODUCTION CONTROL REQUIREMENTS** **FOR CONSTRUCTION PRODUCTS**	

Issue: 5	Issue date: 09.05.2025	Change:							

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1. Objective and scope

1.1 Objective

The objective of this instruction is to define applicable requirements for the factory production control for construction product manufacturers applying for national certificates of constancy of performance or certificates of constancy of performance in the Product Certification Division of the Centrum Techniki Okrętowej S.A. (Maritime Advanced Research Centre).

1.2 Scope

This instruction is used by the Division for initial inspections and assessments of the factory production control of construction products for which no factory production control requirements are specified in the technical specification. It is also used for the purposes of planned inspections for surveillance over certified products and during special inspections.

2. Referenced documents

Documents are normatively referenced in this document, in whole or in part, and are necessary for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.1 Act of 16 April 2004 on construction products (Journal of Laws 2004, no. 92, item 881, as amended).

2.2 Ordinance of the Minister of Infrastructure and Construction of 17 November 2016 on the method of declaring performance of construction products and the method of marking them with the Polish “B” construction sign (Journal of Laws 2016 item 1966) as amended.

2.3 Regulation no. 305/2011 of the European Parliament and the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (EU O.J. L 88 of 4.4.2011) as amended.

2.4 Regulation no. 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (EU O.J. L 218 of 13.8.2008) as amended.

2.5 DACW-01 Accreditation for Product Certification Bodies, Detailed Requirements, Edit. 4.

2.6 DAN-01 Accreditation of bodies participating in the process of assessment and verification of constancy of performance of construction products, in relation to the Regulation no. 305/2011 (CPR) of the European Parliament and the Council, Edition 3, Polish Centre for Accreditation.

2.7 DAC-24 Accreditation of bodies assessing conformance in the framework national systems for assessment and verification of constancy of performance of construction products; Edition 3, Polish Centre for Accreditation.

2.8 Rules for using the identification number of the Notified body of Centrum Techniki Okrętowej S.A., Edition 4 of 05.02.2018.

2.9 NB-CPR/17/722r3 Guidance from the Group of Notified Bodies for the Construction Products Regulation (EU) No. 305/2011 Position Paper Guidance to notified bodies on the Assessment and Verification of Constancy of Performance under the Construction Products Regulation, edition of 08.11.2017.

3. Definitions

FACTORY PRODUCTION CONTROL (FPC) – documented, permanent and internal control of production in a factory, in accordance with the relevant harmonised or national technical specifications;

MANUFACTURER – a natural or legal person which manufactures a construction product or commissions designing or manufacturing of a construction product, and places on the market this product under its own name or trademark.

METROLOGICAL TRACEABILITY – a property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

4. Responsibility

The Division is responsible for:

- assessing construction product performance on the basis of examining samples taken by a certifying body, calculations, tabular values or descriptive product documentation;
- performing an initial inspection of a manufacturing plant and the factory production control;
- issuing a national certificate of constancy of performance / certificate of constancy of performance;
- continuing surveillance, assessment and evaluation of the factory production control.

The Manufacturer is responsible for:

- implementing and maintaining FPC;
- examining samples taken by the manufacturer in a manufacturing plant, in line with the established testing plan.

5. Procedure

5.1 Initial provisions

5.1.1 A manufacturer should establish, document, implement and maintain the FPC system in order to ensure that a marketed product maintains consistency of the declared performance in relation to the main characteristics defined in the technical specification.

5.1.2 The FPC system should include procedures, instructions, forms and regular controls and tests of products manufactured in a given plant.

5.1.3 The control results should be used to assess the finished product quality. Continuity of manufacturing control and finished product testing should be documented with applicable records.

5.1.4 In case a non-conformance is detected, the system should include a requirement to introduce corrections and take corrective and preventive actions.

5.1.5 The FPC system should be adjusted to the level of performance requirements for a product and specificity of a given manufacturing process (e.g. automation degree, personnel's competence degree).

5.1.6 If the requirements described in technical specifications and this document are complied with, a manufacturer having a system conforming to the PN-EN ISO 9001 standard meets the applicable FPC requirements.

5.1.7 In case (due to its function), a product being certified contains elements requiring certification, the Division recognises certificates for these elements issued by notified or accredited certifying bodies.

5.1.8 In the meaning of this Instruction, terms such as “to determine”, “to establish” and “to define” mean the same as “to document”.

5.2 FPC documentation

5.2.1 FPC documentation should be supervised, updated and complemented in case any changes (extensions) are introduced in FPC, product or manufacturing process. A person having necessary competences and authorisations should be appointed to supervise the documentation.

5.2.2 FPC documentation content

5.2.2.1 Procedures/instructions describing:

- surveillance of the manufacturing process;
- method of performing controls and tests, also of a product during its all manufacturing stages;
- method of assessing the constancy of product performance in relation to technical specification requirements, on the basis of tests conducted;
- method of handling non-conforming products and complaints;
- supervising the control and test equipment;
- introducing corrections, implementing corrective and preventive actions aimed at rectifying the causes of detected and/or potential non-conformances.

If necessary for correct functioning of FPC, also other procedures should be documented.

5.2.2.2 Specifications

- technical specifications (product standards, national technical assessments, technical approvals until their expiry date);
- technical specifications (technical documentation) of finished products and raw materials and/or materials used for manufacturing purposes (according to a reference document, depending on the intended use).

5.2.2.3 Informative documents

- organisation chart;
- legal requirements and regulations applicable to a product;
- technological description of the manufacturing process;
- product technical documentation;

A manufacturer should have a list of retained documentation, forms and records.

5.2.2.4 Technical documentation for a product, including its test results and declarations of performance/national declarations of performance, should be kept for a period of 10 years after the construction product has been placed on the market.

5.3 Organisational structure

5.3.1 A manufacturer should:

- define the organisation of actions connected with FPC (on the basis of e.g. an organisation chart);
- define the scope of activities connected with manufacturing of a product outside their organisation (if applicable);
- determine and document the rules of surveillance over outsourced processes.

5.3.2 Personnel's competencies

5.3.2.1 A manufacturer should:

- define requirements for competencies of the personnel performing, controlling and managing activities included in FPC;
- document required competencies for each employee;
- ensure personnel's access to FPC documentation;
- train the personnel whose actions influence the product quality.

5.3.3 Responsibility and authorisations

5.3.3.1 A manufacturer should:

- appoint a person responsible for management and surveillance over the FPC system and for ensuring that applicable system requirements are implemented and adhered to;
- define, document and update requirements for responsibilities and authorisations of the personnel performing, controlling and managing activities included in FPC.

5.4 Raw materials and materials for manufacturing processes

5.4.1 A manufacturer should:

- define the raw materials and materials used;
- define and document requirements for materials and raw materials as well as criteria for their conformance approvals;
- define rules for raw material and material storage with the view to securing their properties;
- define (if applicable) the requirements for environmental conditions connected with raw material storage;
- check, on the basis of implemented criteria, conformance of deliveries to orders (supplier's documentation confirming the delivery quality, tests and controls);
- define properties, methods and frequency of tests for raw materials accepted on the basis of tests;
- define persons responsible for releasing deliveries for the manufacturing process;
- determine the rules for purchases, select and assess suppliers and keep their lists;
- maintain records from the activities described above.

5.5 Manufacturing process

5.5.1 Manufacturing process preparation

5.5.1.1 A manufacturer should define requirements for a product on the basis of a technical specification, depending on the intended use by a customer/user.

5.5.1.2 These requirements should be documented.

5.5.2 Manufacturing process surveillance

5.5.2.1 A manufacturer should define:

- manufacturing process stages subject to surveillance, parameters applicable to a given stage, and define the sampling frequency for tests and controls as well as the criteria for releasing a semi-finished product for the next process stages;
- requirements for products during each manufacturing process stage;
- actions to be taken in case the established control values or assessment criteria are not met.

5.5.2.2 A manufacturer should ensure:

- availability of procedures / job instructions for workstations involved in a given process operation;
- availability of defined requirements for a product (e.g. a structural drawing);
- correct product security during internal processing and transferring to the next process stage;
- performing interoperational controls and tests during the manufacturing process.

5.5.2.3 The above-mentioned activities should be recorded.

5.6 Manufacturing machines and equipment

5.6.1 A manufacturer should ensure using manufacturing machines and equipment compatible with the process of manufacturing products conforming to requirements.

5.6.2 A manufacturer should:

- develop a schedule of maintenance, inspections and overhauls of machines and equipment, and supervise its implementation;
- define the method of controlling machines and equipment following a repair/overhaul;
- establish rules for every-day control of machine and equipment operating condition;
- ensure correct functioning of manufacturing equipment;
- maintain records from the activities described above.

5.7 Finished product testing

5.7.1 Regardless of the tests performed before a product is marketed, a manufacturer should define and document the method of performing controls and tests on finished products, in relation to the properties declared.

5.7.2 Controls and tests should be performed in line with a documented test plan complying with reference document requirements.

5.7.3 A finished product test plan should define:

- tested properties in relation to the intended use;
- test methods;
- test frequency;
- test location (in-house/external laboratory).

5.7.4 A manufacturer must have technical competencies to perform controls and tests or use services rendered by laboratories having such competencies.

5.7.5 A manufacturer should define:

- criteria for assessment of finished product control and test results including, e.g. acceptance limits for results obtained;
- batch of product;
- size and quantity of samples for controls and tests;
- method of taking samples for tests, types of related records;
- rules of releasing finished products from a warehouse.

5.7.6 Results of finished product tests and controls should be recorded as required. They should also include the following data:

- product type;
- production date;
- sampling date and place, a sample size;
- date of tests and/or controls;
- measuring and/or testing methods used;
- test and control results;
- assessment of conformance of the results to declared levels/classes/descriptions of performance;
- identification of persons taking the sample and performing tests/controls.

5.7.7 Tests should be performed in line with methods defined in a reference document. Intermediate testing is possible when:

- it is possible to establish a correlation between a property to be checked and another property that is safer or easier to measure;
- a manufacturer has evidence that the intermediate method used gives appropriate results.

5.8 Non-conforming product

5.8.1 A manufacturer should establish a procedure (classification change) to identify and supervise non-conforming products, including responsibilities and authorisations regarding actions taken in relation to non-conforming products.

5.8.2 A manufacturer should ensure that non-conforming products are correctly separated and labelled, in order to avoid their unintended use or dispatching to a customer.

5.8.3 In case a non-conforming product is manufactured, a manufacturer must take immediate actions including:

- correction of non-conformances found;
- requalification of a given product (if feasible);
- preventing the product from being used;
- corrective actions.

5.8.4 After a repair / requalification, a manufacturer should repeat product tests and/or controls in order to prove its conformance to requirements.

5.8.5 The actions taken in relation to a non-conforming products should be recorded.

5.9 Identification and traceability

5.9.1 Individual products, components or batches should be identifiable during the individual stages of:

- the manufacturing process;
- the finished product;
- storage and dispatch to customers.

5.9.2 If possible, a manufacturer should ensure traceability of a given product, i.e. a possibility to recreate the product manufacturing process history.

5.9.3 A manufacturer should retain records for individual products or batches manufactured by them, which also includes manufacturing process and testing records.

5.9.4 They should constitute the basis for recreating all critical product and manufacturing process information (including the production date, raw materials/materials used, batch of product, product type, intended use, method of labelling a product with a construction mark, date of releasing a product from a warehouse). It should be possible to determine the very first entity which obtained the product.

5.10 Control and test equipment

5.10.1 A manufacturer is obliged to:

- ensure that measurements are taken at the required accuracy and metrological traceability;
- define the control and measurement equipment of a required accuracy level, necessary to conduct individual measurements (including standards for internal checks);
- ensure availability and adequacy of the control and test equipment;
- maintain records of the control and test equipment containing data unambiguously identifying the equipment;
- develop a plan for control and measurement equipment calibrations / checks, which defines their required frequency, and supervise its implementation;
- specify acceptance criteria for the results of equipment checks,
- mark the equipment with its calibration / check status;

- ensure and monitor (where required) environmental conditions for measurements and controls;
- define procedures relating to damaged equipment;
- define personnel responsible for control and test equipment surveillance;
- make and retain records regarding the technical condition of equipment as well as its calibrations / checks;
- ensure surveillance over equipment used for testing and controlling purposes also when a given instrument does not belong to a manufacturer.

5.10.2 The control and measurement equipment should come with operation manuals accessible to the personnel. The equipment should be operated in line with its intended use and operation manuals.

5.10.3 Calibration / check records should contain:

- identification of standards used;
- measurement results and comparisons with standards;
- assessment of calibration / check results;
- calibration / check date;
- identification of persons responsible for calibrations / checks.

5.11 Declaration of performance and marking

5.11.1 Finished products can be marked only after a manufacturer has implemented and currently maintains the FPC system and has performed actions connected with assessment and verification of constancy of performance, and has issued a declaration of performance (according to document mentioned in 2.3)/ national declaration of performance (according to document mentioned in 2.2). This marking should comply with reference document requirements and legal provisions (CE marking according to document mentioned in 2.3/ Polish “B” construction sign according to document mentioned in 2.2).

5.11.2 The tasks of certification body do not include assessment of the manufacturer’s declaration of performance, CE marking or other declarations/markings of construction products. Nevertheless, the declaration of performance is one of the starting points for understanding the scope of the FPC and knowledge of the content of the declaration is necessary when assessing the effectiveness of the FPC. Certification body are not expected to assess neither the declaration nor the marking for which the manufacturer is solely responsible. Nonetheless, the certification body should inform the manufacturer if it becomes aware of any error or omission in the declaration or the marking.

5.12 Packing, storage and transport

5.12.1 A manufacturer should establish a procedure for finished product handling, i.e. packing, storage, security and transport, in order to prevent any possible damage or alteration of properties during storage and transport to customers. These processes should be controlled.

5.12.2 In justified cases, a manufacturer should run a periodical control of stored products in order to detect any possible damage or alteration of properties.

5.12.3 The activities connected with product acceptance or release should be recorded.

5.13 Complaints

5.13.1. A manufacturer should define and document a method of handling possible complaints:

- made by customers and/or users;
- made by themselves to manufacturers of raw materials, materials and components used in the manufacturing process.

5.13.2. A manufacturer is obliged to:

- document and archive all records connected with all complaints / warranties;
- take correct actions in relation to each complaint made / warranty issued;
- analyse the reasons for product non-conformances and take the required corrective actions aimed at their elimination, and analyse the effectiveness of actions taken; keeping records in this respect,
- use their own complaints for periodical assessments of providers of raw materials, materials and components.

5.14 Corrective and preventative actions

5.14.1 In case a non-conformance is detected, a manufacturer should:

- take corrective actions eliminating the reasons for non-conformances in order to prevent their future occurrence;
- take actions eliminating the reasons for potential non-conformances to prevent their occurrence in the future.

5.14.2 A non-conformance analysis should be conducted in a form or records. It should include: an analysis of the reasons for non-conformance occurrence, actions taken and assessment of their effectiveness.

5.14.3 All corrections made as well as corrective and preventative actions taken should be recorded.

5.15 Using certificates (refers only to inspections in the supervision)

A manufacturer should:

- use a certificate only for products meeting applicable requirements;
- invoke a certificate according to rules established;
- use the name and certifying body's ID number in a manner that is not misleading (certification in the national system);
- use the notified body's ID number/name in line with the rules that is not misleading European system certification).

5.16 Corrective actions as a follow-up of an inspection (only inspections in supervision, if applicable)

5.16.1 In case any observations are made and non-conformances are detected during the previous inspection, a manufacturer should take appropriate and effective corrective actions in relation to all observations and non-conformances.

5.16.2 Records/evidence regarding all corrective actions taken should be available.

6 Forms

Form no.	Title
FI-01/01	PLAN OF INITIAL[1/] FACTORY PRODUCTION CONTROL INSPECTION
FI-01/02	The form has been removed, its content is part of form FI-01/05
FI-01/03	LIST OF NON-CONFORMANCES (N) DETECTED DURING INITIAL[1/] MANUFACTURING QUALITY CONTROL
FI-01/04	REPORT ON FACTORY PRODUCTION CONTROL DOCUMENTATION ASSESSMENT
FI-01/05	REPORT ON[1/] FACTORY PRODUCTION CONTROL INSPECTION
FI-01/06	ATTENDANCE LIST
FI-01/07	The form was removed and a Register of FPC inspection reports was created on the RCP, which contains identical columns as the form FI-01/07

1/ use this term only for an initial inspection

Changes

Change date	Change symbol	Refers to section	Change approved by: (signature and stamp)
16.05.2013	A	2.5, 2.6, 5.1.7, 5.1.8, 5.2.2.1, 5.11, 5.15, 5.16	
19.12.2013	B	Form FI-01/06	
08.04.2015	C	1.1, 1.2, 2.1, 2.3, 2.4, 2.5, 2.6, 2.7, 3, 4, 5.1.7, 5.1.8, 5.2.2.4, 5.11.1, 5.11.2, 5.11.3, 5.11.4, 5.11.5, 5.11.6, 5.11.7, 5.15, 6.	
25.08.2016	D	Section 2.5	
12.01.2017	Edition 4	item 2, 3, 4, 5.2.2.2, 5.2.2.4, 5.11.1, 5.11.3, 5.11.6.	
14.07.2017	A	Register of inspection reports	
20.05.2019	B	Title page, pkt. 2	
01.10.2019	C	Title page, 2.2, 2.6, 2,7, 2.8, 2.9, 5.2.2.2, 5.2.2.3, 5.9.4, 5.10.1, 5.11, deleted 5.11.3÷7, 5.12.3, deleted 5.12.4, 5.13.2, 5.14, 5.14.1, 6	
31.03.2021	D	p. 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 5.15	
09.05.2025	Edition 5	Title page, form FI-01/01.	

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