

2. Informative document about the factory production control documentation

Dear Recipient,

Let us inform you that the certification process according to our quotation begins with the preliminary inspection of the factory production control (FPC) documentation.

The manufacturer is responsible for preparing this documentation. In the absence of this it is not possible to fulfil contract by Service Provider.

The manufacturer needs to submit the Factory Production Control documentation in Hungarian or in English to ÉMI Non-profit Ltd. in order to enable ÉMI to perform the preliminary inspection.

The purpose of the factory production control documentation is to regulate and control the manufacturing and the factory production control. To comply with this requirement manufacturer needs regulatory documents and procedures, as well as forms, reports and warrants to document the functioning of the procedures and processes and make the manufacturing more transparent.

A regulatory document or procedure needs to contain the answers the following questions:

- What do they do?
- Who does it?
- When do they do it?
- How do they do it?
- With what do they do it?
- How and where are the results documented?

Procedure and process descriptions can be prepared for a multitude of activities, including: *Documents and Document management, Management Review, Purchasing (subcontractors, suppliers), sampling, testing, defect, complaint handling, corrective and preventive action*.

The production control system and the documentation can be based on the ISO 9001 standard and its requirements. Quality management system according to ISO 9001 is not required for the factory production control, but if manufacturer has an ISO 9001 system, it can cover some of the fields that need to be regulated by the factory production control system.

A factory production control handbook can be prepared, or the regulation of procedures can be in separate process descriptions, work instructions. There are no rules for the form of the documentation, the quality management documentation of the manufacturer (quality management handbook, process descriptions, work instructions, etc.) can be suitable if the requirements of the relevant technical specification have been considered during the preparation of the documentation.

The basis to the regulation of the requirements for the product and the production shall always be the relevant technical specification: harmonized product standard (hEN), Hungarian standard, National Technical Assessment, or European Technical Assessment.

Manufacturer needs to appoint the person responsible for the factory production system - the factory production control manager. The FPC manager's tasks, responsibilities and authority needs to be regulated. The scope of FPC manager's duties can be fulfilled independently or in conjunction with other functions.

The following topics and information needs to be governed by and be part of the FPC:

Determination of product type:

For which product/product family has the factory production control system been established.

- Handling of FPC documents:

Registration and handling of changing of documents.

- Revision of the FPC system:

The manufacturer's review of the system and the procedures applied and its efficiency at specified intervals.

- Handling of subcontractors and suppliers:

Recording and evaluation of subcontractors and suppliers based on the criteria chosen by manufacturer.

- Maintenance:

Description of the maintenance of the machinery carried out, its frequency, and the manner of its documentation.

- Organisation, personnel:

Regulation and monitoring the qualification, tasks, responsibility, authority and training of the personnel involved in the production.

- Production procedure:

The description of the manufacturing procedure.

- Raw material inspection:

The manner of inspection of the incoming material, control of raw materials, its evaluation and documentation.

- Factory Production Control tests:

How often and what checks are carried out during the production, concerning which product characteristics, how is it evaluated and documented.

- Ready product tests:

How often and what checks are carried out on the finished product, concerning which product characteristics, how is it evaluated and documented.

- Handling of testing machines and tools:

Registration, maintenance and calibration of the measuring equipment.

- Handling of nonconformities:

If the evaluation of the inspection of the incoming materials, the monitoring of production process or the final inspection discovers a discrepancy, how is it handled and documented.

- Product label and Declaration of Conformity:

Regulation of marking, labelling and attachment of delivery documents of the products. (Declaration of Performance)

- Complaint management/handling:

Treating of complaints concerning the product to be certified, its documentation and the regulation of actions to be realized.

- Communication with the Certification Body:

Nomination of Factory Production Control Manager and regulation about the obligation to notify the certification body about complaints concerning main product characteristics.