



DOI: 10.17512/bozpe.2022.11.12



**Construction of optimized energy potential**  
Budownictwo o zoptymalizowanym potencjale energetycznym

ISSN 2299-8535 e-ISSN 2544-963X



## **ISO 9001:2015 vs. Factory Production Control (FPC) to ensure the quality of construction products used in road and bridge engineering**

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**Abstract:** The study aims to define the elements of common FPC requirements and the ISO 9001:2015 standard in plants producing construction products of road and bridge engineering. The quality management system ISO 9001: 2015 may be recognized as an FPC system by-product certification organization and by the producers themselves, provided that specific requirements specified in the product standard or national technical assessment are also met.

**Keywords:** ISO 9001, Factory Production Control, FPC, road and bridge engineering products

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**Please, quote this article as follows:**

Prasalska-Nikoniuk J., Urbański M., Ulewicz R., ISO 9001:2015 vs. Factory Production Control (FPC) to ensure the quality of construction products used in road and bridge engineering, *Construction of Optimized Energy Potential (CoOEP)*, Vol. 11, 2022, 103-111, DOI: 10.17512/bozpe.2022.11.12

### **Introduction**

The development of civilization and technology causes construction products to change and be adapted to user needs much more frequently. An important task in every company is to care about the quality of processes that play a fundamental role in shaping the quality of the construction product. The Factory Production Control (FPC) checks that the product is manufactured in a repeatable manner. Implementation of the Factory Production Control is based on the requirements of ISO 9001, i.e. the requirements to be met by the organization within the quality management system. This article is an attempt to answer the question of what

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the similarities and differences of the two systems are and what benefits can be achieved from the case of implementing the ISO 9001:2015 system in a construction company producing road and bridge engineering products.

## 1. Fundamentals of quality assurance systems in construction

Poland's accession to the European Union has changed the way construction products are marketed. Poland had to implement the requirements of the "Construction Directive", and then the requirements of Regulation (EU) No. 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC, known as the Construction Products Regulation (CPR). The implementation of the CPR requirements into Polish legislation became the Construction Products Act (Act items 881, 2004) along with secondary legislation (Regulation items 1966, 2016; Regulation items 1233, 2018; Regulation items 1176, 2019; Regulation items 2164, 2019; Regulation items 2297, 2020). These regulations still determine the mode of marketing construction products in Poland, for which no harmonized standard has been established and no European Technical Assessment has been issued. In the domestic area, the documents that determine the performance of products and the requirements for factory production control (FPC) include Polish standards that do not have the status of harmonized standards or national technical assessments. A third possibility to market products is to apply the principle of the so-called mutual recognition (Regulation Journal of Laws EU L 91, 2019)

According to the applicable legal regulations, products are divided into five conformity assessment systems – 1, 1+, 2+, 3 and 4. The basic requirements are defined in the CPR (CPR Regulation 305, 2011).

Products that are included in the first three systems are subject to certification by an independent certification body (Regulation items 1966, 2016; Regulation items 1233, 2018; Regulation items 1176, 2019; Regulation items 2164, 2019; Regulation items 2297, 2020). If the document specifying the requirements for the product is a harmonized standard or a European technical assessment, a notified certification body or a notified testing laboratory, in addition to the manufacturer, shall participate in the conformity assessment.

Manufacturers of all products were required to implement and maintain the FPC system. The Factory Production Control system is understood as a documented, permanent and internal control measure of production in a manufacturing plant, in accordance with applied technical specifications, which may be: Polish standard, national technical assessment, European technical assessment, harmonized standard (Regulation CPR 305, 2011; Regulation items 1968, 2016). Each of these technical specifications may define the requirements for the FPC system differently, but most of the areas that form the basis of the FPC system are identical. Manufacturers of all construction products had to start working on implementing the new system. It quickly became apparent that it was much easier to prove ownership of such

a system to manufacturers who already had a quality management system in place that met the requirements of the PN-EN ISO 9001:2015 standard, which is a complex management facilitation tool for various organizations (Midor & Wilkowski, 2021). FPC is one of the conditions for marketing construction products required by Regulation 305/2011 (CPR). An additional difficulty for many companies is the need for FPC system certification, this requirement applies to products qualified under the following rating systems: 1+, 1 and 2+. This paper presents a comparative analysis of the system according to ISO 9001:2015 and the FPC system, for which the requirements are defined in technical specifications with particular reference to national technical assessments (NTAs) issued to manufacturers of the product used in road and bridge engineering. The inspiration for the study is the growing popularity of ISO 9001:2015 in companies manufacturing construction products for road and bridge construction as well as the need for comparison with the mandatory requirements of the FPC system.

## 2. Comparison of the requirements of ISO 9001: 2015 and the FPC

The following assumptions were made for the comparison analysis of the system against ISO 9001:2015 and FPC requirements:

- the comparison was made based on the text of the PN-EN ISO 9001:2015 standard and the FPC requirements contained in national technical assessments issued by the Road and Bridge Research Institute for products used in road and bridge engineering,
- two comparative statements are presented: general and detailed,
- the criteria for comparison in the overview were based on the analysis of system documentation and literature analysis,
- the criteria for comparison in the detailed statement were derived directly from the clauses of the ISO 9001:2015 standard,
- the research used the preliminary results of a survey conducted among manufacturers of construction products used in road and bridge engineering.

In analysing the requirements for a Factory Production Control system, according to national technical assessments, a set of common elements can be defined. It includes the following areas: personnel, subcontracting, production equipment and facilities, production process, inspection and testing equipment, requirements for raw materials and finished products, inspection and testing and use of their results, handling of nonconforming product, complaints, internal audits, corrective and preventive actions, product storage and transportation, and product labelling.

The FPC system, unlike ISO 9001:2015, does not require risk identification (Deszcz, 2015). However, this statement does not capture what is involved in the procedures used to formulate the requirements for a mandatory conformity assessment system with the intended use and the hazard analysis subtracted at that time. The unpredictability of the market, the removal of trade barriers and the possibility of marketing products by little-known manufacturers, the increasing complexity

of products, safety requirements and changing regulations make the establishment and implementation of system solutions for the identification of assessment and management of risk particularly justified in the management systems of those organizations that strive to achieve demanding objectives. Implementation of the FPC is a legal requirement, targeting the right well-defined products (Pastuszka, 2012). Implementation of ISO 9001:2015 requirements in an organization is voluntary (Wolniak, 2021). The organization cannot use these systems interchangeably (Grudowski & Kałuża, 2018). Meeting the FPC requirements is equivalent to meeting many ISO 9001:2015 requirements. Meeting the risk requirements will allow the organization to identify risks that exist, improve process operations, and manage the entire organization (Pacana & Ulewicz, 2020). The general differences between the two systems are summarized in Table 1.

**Table 1.** A general comparison of ISO 9001:2015 and the FPC

| Area of comparison                         | ISO 9001:2015   | FPC  |
|--|---|--|
| Specification determining the requirements | PN-EN 9001 standard   | – Polish standard<br>– national technical assessment<br>– European technical assessment<br>– harmonised standard |
| Uniformity of requirements                 | one set of requirements   | different scopes of requirements depending on specifications   |
| Requirement to hold                        | voluntary system  | legal regulation system implementation mandatory   |
| Scope of application                       | all sectors of economy  | manufacture of construction products   |
|  | – production<br>– contractorship<br>– services                            | production only  |
| Scope of recognition                       | all sectors of economy  | manufacture of construction products   |
| Need for certification                     | voluntary nature  | in some cases a legal requirement  |
| Primary objective of implementation        | – effective company management<br>– cost reduction<br>– image improvement | ensuring conformity of the construction product with the requirements defined in the specification               |
| Defining of processes                      | multiple processes possible   | one production process   |
| Objectives set                             | measurable and non-measurable   | there is no need to set objectives if they are that measurable   |

Due to the recognition that the quality management system according to ISO 9001:2015 is a more complex system, a defined area in the comparative analysis was determined according to the following points of EN-ISO 9001:2015. Of the 138 companies manufacturing road and bridge engineering construction products that participated in the study, 79 have the ISO 9001:2015 system which is 57% of the study group. Table 2 provides a detailed comparison of ISO 9001:2015 and FPC.

**Table 2.** A detailed comparison of ISO 9001:2015 and the FPC

| Defined area  | Management system components as per ISO 9001:2015  | FPC system components as per National Technical Assessment (NTA)   |
|---|--|--|
| 1   | 2  | 3  |
| General provisions  | <ul style="list-style-type: none"> <li>– described purpose of implementation</li> <li>– identification of potential benefits of implementation</li> <li>– definition of parties, and scope of application</li> <li>– drawing of applied approaches</li> <li>– determination of verbal forms</li> </ul>   | no requirements and instructions   |
| Determination of quality management principles                          | <ul style="list-style-type: none"> <li>– determination of 7 principles</li> </ul>  | no requirements and instructions   |
| Determination of the approach in developing, implementing and improving | <ul style="list-style-type: none"> <li>– adopting a process approach with its benefits identified</li> <li>– defining the PDCA “plan – do – check – act” cycle</li> <li>– adopting a risk-based approach</li> </ul>  | no requirements and instructions   |
| Identification of the link to other normative documents                 | <ul style="list-style-type: none"> <li>– link to ISO 9000 and 9004 series standards</li> </ul>   | determination of the link of the FPC system to the QMS system according to ISO 9001:2015   |
| Determination of the scope of document application                      | <ul style="list-style-type: none"> <li>– defining the scope of application regardless of the type, size or goods and services provided</li> </ul>  | a NTA dedicated to one manufacturer of a specific construction product   |
| Identification of normative references for terminology                  | <ul style="list-style-type: none"> <li>– defining a standard for terminology</li> <li>– defining tasks concerning normative references – dating</li> </ul>   | no requirements and instructions   |
| Organization  | <ul style="list-style-type: none"> <li>– identification of external and internal factors relevant to the purpose and strategic direction</li> <li>– defining instructions for actions related to the aforementioned factors</li> <li>– instructions for identifying stakeholders who have a significant impact on the system</li> <li>– instructions for defining the scope of the quality management system</li> <li>– general instructions for identifying and defining processes</li> </ul> | – requirement to define and have an organizational structure (organizational chart)  |
| Management / Leadership   | <ul style="list-style-type: none"> <li>– detailing the tasks of management in the organization</li> <li>– defining management tasks in the area of customer orientation</li> <li>– defining the quality policy together with the main elements and instructions of the policy</li> <li>– identification and allocation of responsibilities and authority for persons performing significant functions</li> </ul>   | – defining personnel requirements (qualifications, authorizations, responsibilities for specific elements of the FPC, trainings)   |
| Planning activities   | <ul style="list-style-type: none"> <li>– instructions concerning the risks and opportunities analysis for the determination of objectives</li> <li>– instructions for defining the quality objectives together with their characteristics</li> <li>– defining the activities that must accompany the setting of objectives</li> <li>– instructions concerning planned changes in the management system</li> </ul>  | <ul style="list-style-type: none"> <li>– defining requirements for raw material, and for raw materials inspection and testing plan</li> <li>– specifying the parameters of the control, documents and records accompanying that control</li> </ul> |

Cont. Table 2

| 1   | 2  | 3  |
|---|--|--|
| Resources   | <ul style="list-style-type: none"> <li>– instructions for determining the resources needed in the management system</li> <li>– instructions for human, infrastructure, environmental, monitoring and measurement resources, ensuring consistency of measurements and related to the knowledge necessary to achieve compliance of products and services</li> <li>– identification of competency and personnel awareness requirements</li> <li>– instructions for internal and external communication regarding the management system</li> <li>– defining the scope of documented information and handling and supervision over the documents</li> </ul> | <ul style="list-style-type: none"> <li>– defining personnel requirements (qualifications, authorizations, responsibilities for specific elements of the FPC, trainings)</li> <li>– determination of supervision requirements for test and production equipment with measurement traceability</li> </ul>  |
| Operations  | <ul style="list-style-type: none"> <li>– defining principles for the planning and supervision over defined processes needed to meet the requirements for the supply of products and services</li> <li>– defining the scope of communication with the customer</li> <li>– instructions for specifying requirements for products and services (general)</li> </ul>   | <ul style="list-style-type: none"> <li>– determination of the mode of supervision over the production process, including determination of the scope of conducted inspections and inter-operational tests</li> </ul>  |
| Target requirements   | <ul style="list-style-type: none"> <li>– defining areas related to the requirements for products and services</li> <li>– defining the scope of communication with the customer</li> <li>– specifying the requirements for products and services</li> <li>– determination of the scope and requirements subject to review of the requirements for products and services</li> <li>– specifying the procedure for making changes to the requirements for products and services</li> </ul>   | <ul style="list-style-type: none"> <li>– defining the scope for raw material inspection and testing plan</li> <li>– determination of the scope of the finished product inspection and testing plan</li> <li>– specification of specific requirements, including test methods and the scope of acceptance of product conformity with the requirements specified in the NTA</li> </ul>       |
| Design and development of products and services                     | <ul style="list-style-type: none"> <li>– defining requirements for the design and development process, including identification of input and output data, defining supervision over these processes and identification of requirements in case of decisions on changes in these processes</li> </ul>   | no requirements and instructions   |
| Supervision of externally supplied processes, products and services | <ul style="list-style-type: none"> <li>– defining the requirements for externally supplied processes, products and services</li> </ul>   | <ul style="list-style-type: none"> <li>– the requirement to define the scope of subcontracted work and the mode of supervision of the subcontracting area</li> </ul>   |
| Production and service provision                                    | <ul style="list-style-type: none"> <li>– defining requirements for supervising production and service provision</li> <li>– determination of conformity assurance data of products and services – identification and traceability together with security of input data during production and service provision</li> <li>– determination of supervision over property owned by customers or suppliers external</li> <li>– defining the scope of activities after the delivery of products and services</li> <li>– determination of the scope and supervision over changes in production and service delivery</li> </ul>                                  | <ul style="list-style-type: none"> <li>– determination of the mode of supervision over the production process, including determination of the scope of conducted inspections and inter-operational tests</li> <li>– determination of packaging, transport and storage mode and the method of product marking</li> <li>– determination of requirements over production equipment</li> </ul> |

| 1                                    | 2  | 3   |
|--------------------------------------|--|---|
| Release of goods and services        | <ul style="list-style-type: none"> <li>– defining the planned arrangements for confirming the conformity of products and services at the various stages of manufacture</li> </ul>  | <ul style="list-style-type: none"> <li>– determination of the mode of supervision over the production process, including determination of the scope of conducted inspections and inter-operational tests</li> <li>– determination of supervision requirements for inspection and testing equipment with measurement traceability</li> </ul> |
| Supervision of non-compliant outputs | <ul style="list-style-type: none"> <li>– determination of actions related to nonconforming product or service and the scope of documented information related to this area</li> </ul>  | <ul style="list-style-type: none"> <li>– determination of the procedure for handling non-conforming products and complaints</li> </ul>  |
| Evaluation of performance            | <ul style="list-style-type: none"> <li>– defining the area of monitoring and measurement together with the scope of methods and the mode of these actions, and for</li> <li>– analysis and evaluation of monitoring and measurement results</li> <li>– instruction concerning the necessity of assessment of effects and effectiveness of the QMS, together with the requirements for documentation</li> <li>– determination of the requirement for monitoring customer satisfaction</li> <li>– specifying the requirement for internal audits</li> <li>– determination of the requirements for management reviews with their scope – input and output data</li> </ul> | <ul style="list-style-type: none"> <li>– determination of supervision requirements for inspection and testing equipment with measurement traceability</li> <li>– requirement to conduct internal audits</li> <li>– requirement to implement corrective and preventive actions</li> <li>– supervision over documents and records</li> </ul>  |
| Improvement                          | <ul style="list-style-type: none"> <li>– identification of opportunities for improvement</li> <li>– implementation of actions to meet customer requirements and increase customer satisfaction</li> <li>– determination of procedure for handling non-conformities, and procedure for taking corrective actions</li> <li>– defining the requirement for continuous improvement</li> </ul>  | <ul style="list-style-type: none"> <li>– requirement to implement corrective actions</li> <li>– requirement to supplement FPC documentation with technical documentation, product standards, testing standards, European and national technical assessments, legislation</li> </ul>   |

## Conclusions

Despite the lapse of time and the emergence of many management systems based on different standards and guidelines, the management system according to ISO 9001:2015 is still the most recognized and adequate system for companies manufacturing construction products. Many companies, despite the voluntary nature of this system, maintain and certify it while maintaining the FPC system.

The introduction of factory production control has not affected the abandonment of ISO 9001:2015, and many companies treat ISO 9001:2015 as part of the FPC system. Companies decide to maintain a voluntary system because it produces tangible and intangible effects. The FPC system, due to its mandatory nature, is not a marketing tool and, compared to ISO 9001:2015 is a more straightforward system and is a substitute for what ISO 9001 can offer.

Perhaps a change in the rules for marketing construction products, including an increase in the scope of the set of harmonized standards will make the FPC system

described in these standards more of a tool for business management, and not just a tool to ensure product conformity with the requirements. The distinguishing element of ISO 9001:2015 is the aspect of risk analysis, the area of improvement, and planning in a broad sense. ISO 9001:2015 certification carries with it the improvement of the company's image, the FPC system certification is the fulfilment of a legal requirement and does not apply to all construction products.

FPC does not require the improvement of communication within the company, the sharing of experience, nor does it require the involvement of all employees and this is what ISO 9001:2015 entails. Implementation of ISO 9001 will not ensure that FPC requirements are met. The goals of the standards which include voluntary ISO 9001:2015 certification and meeting regulatory requirements for FPC, are aligned but differ in the detail. A pilot study conducted among 138 companies manufacturing road and bridge engineering products with a national technical assessment issued by IBDiM showed that almost 60% of companies, despite the requirement to implement the FPC system, maintain a certified ISO 9001:2015 management system, treating it as the FPC while detailing certain requirements in accordance with the national technical evaluation, e.g. by specific test result values or specific product performances. Both systems affect the quality of manufactured products, but the ISO gives more opportunities to control quality and adapt to market needs, technical trends or directions of development, such as sustainable development, and also unlike the FPC, will allow the organization to identify existing threats, improve the functioning of processes and the management of the entire organization.

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