

A MODERN APPROACH TO QUALITY CONTROL IN THE ELECTROTECHNICAL INDUSTRY: FROM THEORY TO PROCESS OPTIMIZATION

Małgorzata MICHALCEWICZ-KANIOWSKA^{1*}, Małgorzata ZAJDEL²,
Dorian NALAZEK³

¹ Politechnika Bydgoska; malgorzata.michalcewicz@pbs.edu.pl, ORCID: 0000-0003-2154-5838

² Politechnika Bydgoska; m.zajdel@pbs.edu.pl, ORCID: 0000-0003-4535-2897

³ Politechnika Bydgoska; dornal000@pbs.edu.pl

*Correspondence author

Purpose: The aim of the study is to identify the causes of non-compliant products and evaluate the effectiveness of the implemented EOL system. In particular, the work focuses on identifying the causes of non-compliant products and implementing improvements in the form of an End of Line (EOL) system, enabling full control of products. These activities are aimed at improving key quality indicators (PPM - Parts Per Million and FPY - First Pass Yield) and increasing the reliability of products. The evaluation was based on key quality indicators: PPM (Parts Per Million) and FPY (First Pass Yield).

Design/methodology/approach: The study was of an applied nature and was based on the analysis of the internal documentation of the company, participant observation of the production process and the analysis of PPM and FPY quality indicators. In order to identify the causes of quality problems, quality management tools were used, in particular the Ishikawa diagram and process data analysis. Then, an improvement was implemented in the form of an EOL database system enabling 100% control of products and recording of results in real time.

Findings: As a result of the implementation of the EOL database, the effectiveness of the quality control process in the cable harness manufacturing company was significantly improved. Before implementation, the average PPM was around 8500, which meant a relatively high number of defective products reaching customers. After the implementation of the system and stabilization of the process, the PPM value dropped to 0 in weeks W41-W44, which confirmed the complete elimination of non-compliant products shipped to recipients. At the same time, FPY initially declined significantly, as closer control allowed to detect previously hidden quality problems. After stabilizing the process, FPY reached a level of about 93-97%, which indicates improved production efficiency and greater efficiency in detecting and eliminating defects in the process.

Limitations/implications of research: The limitation of the conducted research is its implementation in one manufacturing company, which may limit the possibility of direct generalization of the results to other industries or organizations with different specifics of production processes. At the same time, the results obtained indicate a great potential for the use of integrated IT systems and full product inspection as an effective tool for improving quality processes in industrial enterprises.

Practical implications: The implementation of the EOL system made it possible to significantly increase the effectiveness of quality control through full traceability of products and the elimination of defective products before they were shipped to the customer. The results obtained indicate that the integration of IT tools with the quality control process can significantly reduce the costs of complaints, improve product reliability and increase the competitiveness of the company.

Social implications: The implementation of more effective quality control systems contributes to increasing the safety of end users, especially in highly responsible industries such as the medical sector. At the same time, improving product quality and reliability strengthens customer confidence in manufacturers and supports the development of responsible and safe technologies in society.

Originality/value: The originality of the work consists in combining classic quality management tools with the practical implementation of an IT solution supporting full product control in the manufacturing company. The value of the study is to present a real case of optimization of the quality control process and to confirm the effectiveness of the solutions used on the basis of measurable quality indicators.

Keywords: quality control, quality management, electrotechnical industry, Industry 4.0, process optimization.

Category of the paper: Empirical article.

1. Introduction

Modern manufacturing companies, including those in the electrotechnical industry, operate in conditions of growing market competition and increasingly stringent customer requirements regarding the reliability and quality of products. In highly responsible industries such as medical, telecommunications or automotive, ensuring flawless quality control is no longer just an optional choice, but an absolute necessity under international standards such as ISO 9001 or IATF 16949. Any non-compliance of a product that reaches the customer – e.g. in the form of defective cable harnesses used in electronic devices – generates not only direct costs of complaints and alterations, but above all a long-term risk of loss of consumer trust, a decline in market share and regulatory penalties. The modern approach to quality control is evolving from traditional manual methods towards advanced, integrated digital systems that fit into the concept of Industry 4.0 and Quality 4.0, combining the theory of quality management with technologies such as artificial intelligence (AI), the Internet of Things (IoT), Big Data analysis and vision systems. The following white paper illustrates the process of diagnosing and improving quality control steps using the example of a cable harness company, illustrating the transition from theoretical foundations – such as quality control (defect monitoring) and quality assurance (systematic planning) – to practical process optimization using tools such as FMEA (Failure Mode and Effects Analysis), Pareto diagrams or predictive AI models.

2. The evolution of the concept of quality in the literature on the subject

There is no single, universally accepted definition of quality in the literature, which results from its complexity and subjective nature, and the modern approach presented by newer literature (e.g. Hamrol, 2020; Kowalik, 2017) has evolved from simple compliance with the specification to comprehensive customer satisfaction management.

One way to understand quality is to define it as compliance with a specification, which means that a product or service should meet established requirements and standards in order to be considered high-quality products (Feigenbaum, 1951).

Quality can be defined as achieving the highest level of standard, i.e. the production of a product that effectively fulfils its purpose for the user. It can also be considered by the presence or absence of certain product features, as well as by minimizing and preventing potential losses (Tuchman, 1980; Juran, Gryna, 1988; Taguchi, 1987).

According to C. A. Reeves and D. Bednar, quality can be defined as value, compliance with specifications or meeting the customer's expectations, while K. Ishikawa emphasized that quality control is a process involving research, development and design, which requires the involvement of the entire organization – from top management to operational staff, and in more recent studies (Mroczko, 2012) quality is defined as a feature that determines the degree of excellence of a product or service. A key element of quality management systems are standards such as ISO 9001 (general management system) or the industry-specific ISO 13485 dedicated to medical devices, which force manufacturers to switch from control focused only on detecting errors to preventive actions, and the historical analysis of the concept of quality indicates its dynamic development – from simple technical inspection to comprehensive management systems covering every aspect of the organization's functioning, where quality has ceased to be perceived only as a feature of the finished product, and has become the philosophy of the entire company.

Initially, as can be seen in the genesis of quality systems, the emphasis was mainly on the final inspection of the product, and early standards such as the military standards MIL-Q-9858 of 1959 or the NATO AQAP standards of 1968 began to systematically push this boundary, with the key change in the evolution of thinking about quality being the understanding that the inspection of the finished product itself is a costly and inefficient process. because it only allows you to detect errors that have already occurred. Contemporary literature (Wawak, 2016) indicates that the foundation of an effective system is quality assurance, which means shifting attention from the output of the process (finished product) to its input – i.e. to the parameters of materials, input information and the course of production processes themselves, and such a preventive approach is considered a milestone in the development of management sciences.

The multidimensionality of quality is best reflected in the definitions of the classics, which have evolved with the needs of the market: W. Edwards Deming and Joseph Juran (whose work is the foundation of the modern approach) defined quality as "fitness for use", which for the first time put the consumer and his needs so strongly at the center of the manufacturer's interest, Philip Crosby introduced the concept of "compliance with requirements", which became the basis for many normative systems such as ISO 9001, and Kaoru Ishikawa, who was particularly relevant to the subject matter, revolutionized the concept of quality, claiming that the responsibility for quality control rested not solely with the quality control department, but with all employees – from top management to operational employees, promoting the integration of research, design and development activities into one coherent system aimed at customer satisfaction.

Quality control is a system of activities aimed at maintaining and improving the quality of products and services while meeting customer expectations. Responsibility for its implementation lies with all employees, not just the quality control department. Achieving the appropriate quality of products requires the use of appropriate methods of control and control of the production process. This allows for quick detection of non-conformities and the introduction of necessary corrections in the manufacturing process (Suhaili, 2008; Karaszewski, 2005).

The next stage of evolution was the pursuit of unification of quality requirements at the international level, where the need to assess the quality capabilities of suppliers led to the creation of the British standard BS 5750 in 1979, which became the direct basis for the international ISO 9000 series standards published in 1987, and this evolution led to the creation of industry systems even more restrictive and precise: ISO 13485 – dedicated to the medical industry (key for the audited company), where quality is defined not only through the prism of satisfaction, but above all patient safety and product reliability, IATF 16949 (formerly TS 16949) – in the automotive industry emphasizing the reduction of volatility and losses in the supply chain, and TL 9000 – a standard for telecommunications taking into account specific data transmission parameters.

Currently, the concept of quality in the literature (Hamrol, 2020; Szczepańska, 2011) is inextricably linked to the concept of TQM (Total Quality Management) and the process approach, where quality is no longer a static state, but a process of continuous improvement, and modern companies such as Company XYZ interpret quality through the prism of indicators such as PPM (Parts Per Million) and FPY (First Pass Yield), however, in the era of the fourth industrial revolution (Industry 4.0), quality is also defined by traceability, i.e. the ability to reconstruct the full history of the product: who, when and from what components made it.

3. Quality Control Instruments: Classic and Modern Tools

The research object was the production activity of Company XYZ, which is part of an international capital group operating in the field of electrical components and cabling systems. The processes of manufacturing selected elements of electrical installations, in particular power cables and other cable connectors used in various industries, were analyzed. The research focused on the organization of production in one of the production plants located in Poland, which is a key link in the global production system of Group XYZ. The plants belonging to the XYZ Group supply their products directly to many well-known manufacturers. One of the company's long-term partners is Philips, with which the company cooperates in the production of medical devices, such as defibrillators. The company's products also go to companies involved in the assembly of advanced electronic devices, including companies such as Apple, Microsoft and Dyson. The premise for undertaking the research was the diagnosed high permeability of non-compliant products at the final inspection stage during statistical random control (AQL), which generated unacceptable risks to patient safety and high complaint costs. One of the most important elements of the company's strategy is care for the high quality of the products offered. The company implements a quality policy that is based on continuous improvement of processes, reduction of errors and development of employee competencies. In the field of quality control, various tools and techniques of workshop diagnostics are used, such as 3D measurements, 5Why, FMEA analyses, Pareto diagrams, visual inspection, statistical quality control, non-destructive testing, and traceability systems. Currently, the management systems implemented in the production plant are in accordance with international standards: ISO 9001, ISO 14001, ISO 13485 (Quality Management System for Medical Devices), and ISO 45001.

The research was of an applied nature and was based on the analysis of internal documentation, qualitative indicators and participant observation. Two key indicators were used:

- PPM (Parts Per Million): The number of defective pieces per million products.
- FPY (First Pass Yield): The percentage of products that pass inspection the first time without corrections.

During the analysis of the final inspection stage (Stage III), it was found that the main cause of defects passing inspection was the statistical control used (according to AQL levels). Quality inspectors only checked a random sample from the batch. In the case of scattered (random) defects, there was a high probability that a defective item would not be included in the sample and would leave the plant.

Using the Ishikawa Diagram, the main causes of the problem were identified in the following areas:

- Methods: No 100% control and statistical limitations.
- People: Time pressure and lack of time for inspectors to check more samples.
- Machines: Lack of full test automation.

To systematically identify the root causes of non-compliant products reaching the customer, an Ishikawa diagram was developed (see Figure 1). The primary problem analyzed was the high leakage of defects, evidenced by an average PPM of 8500 during the pre-implementation phase. The analysis of the final inspection stage (Stage III) revealed several critical factors categorized into three main areas:

- Methods: The core issue was the reliance on statistical random control (AQL levels), which allowed scattered (random) defects to bypass inspection since inspectors only verified a sample of the batch.
- People: Inspectors worked under significant time pressure, which limited their ability to conduct more thorough or frequent verifications.
- Machines: A lack of full test automation and the absence of an integrated IT system for real-time data recording prevented 100% control and traceability.

This diagnostic process confirmed that the existing quality control tools were insufficient for the requirements of high-risk industries, such as the medical sector. These findings provided the necessary justification for the implementation of the EOL (End of Line) system, moving the company from statistical sampling to 100% preventive inspection to ensure compliance with ISO 13485 standards.

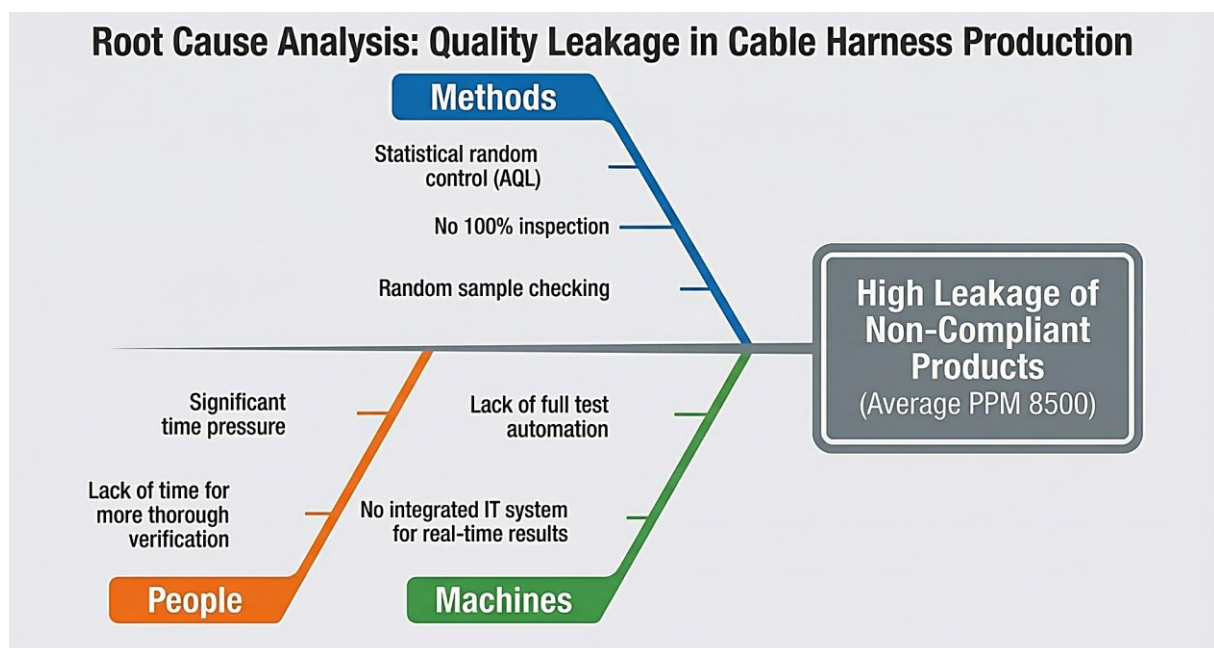


Figure 1. Ishikawa diagram for the causes of high defect leakage.

Source: own study.

4. Implementation of improvements: EOL Database - End of Line

As part of our own research, improvements were implemented in the quality control process by creating and integrating an EOL (End of Line) database at a dedicated control station in a cable harness manufacturing company, while the genesis of the project resulted from the diagnosed high permeability of non-compliant products at the final inspection stage, where the existing system based on statistical random control (AQL levels) did not allow for effective detection of defects distributed population, which in the medical industry – with a key customer such as Philips – generated unacceptable risks to patient safety and numerous complaints. The goal of the implementation was to switch to 100% inspection of each item, eliminating defective products before shipment to the customer, and the EOL database, built in the MS Access system and integrated with ERP, enabled the automation of Shop Order data retrieval, standardization of "Inspection Requirements" for each product model (Item), real-time recording of results with full traceability assigned to the serial number and operator.

The implementation process was carried out in March-April 2025 by an interdisciplinary team (quality, production, engineering) according to the schedule: in the preparation phase (03.03–12.03.2025), a requirements analysis was carried out and a team was appointed; during the installation period (13.03–17.03.2025), a physical station was prepared and the system was integrated with ERP; Subsequently, documentation was developed and training was carried out (18.03–08.04.2025); Finally, a pilot and full implementation (24.03–11.04.2025) was carried out with tests on batches of products and rebalancing of the line. The redefined process of final inspection (Stage III) has become two-stage: in the first step, the operator logs in to the EOL database, enters the order and line number, and then confirms the checklist of activities (no mechanical damage, verification of dimensions/lengths, correctness of contacts/orientations, label check), giving the status "OK" or "N-OK" with a description of the defect – "N-OK" products are placed in the quarantine zone at the engineer's decision. In the second step, the quality inspector performs a statistical verification of the sample as an additional layer of security.

The effects of the implementation were assessed on the basis of key quality indicators: the PPM (Parts Per Million) index dropped from an average of 8500 before implementation to 0 in weeks W41-W44, which confirmed the complete elimination of defective products reaching customers, while the FPY (First Pass Yield) indicator initially revealed real problems (a drop to 62.32% in W24 thanks to reliable detection), stabilizing at about 93% after stabilizing the process, which reflects real improvements in internal efficiency and compliance with Industry 4.0 requirements.

5. Analysis of the effects and conclusions

The results of the implementation of the EOL database in the process of quality control of cable harnesses were analyzed in three key time periods: before implementation (weeks (W) W12–W23 2025), during diagnosis and stabilization (W24–W32) and after full implementation (W33–W44), using industry standard indicators PPM (Parts Per Million) and FPY (First Pass Yield), which allowed for an objective assessment of the effectiveness of changes in the context of Industry 4.0 requirements and ISO 13485 standards for the medical sector. In the pre-implementation period (W12–W23), the average PPM rate reached a high level of 8500, indicating a significant number of defective products reaching customers (m.in. Philips), while the FPY was ostensibly 99.7%, which was due to insufficient error detection by operators on the production line – defects were passed on and only disclosed in external complaints, generating logistics, image and regulatory risks in the critical responsibility industry.

In the diagnosis and initial implementation phase (W24–W32), a sharp decrease in FPY was observed up to 62.32%, which was the result of increased reliability of fault identification within the plant thanks to the introduction of the EOL database and checklist – operators began to catch defects earlier, which revealed hidden process problems, at the same time PPM began to systematically decrease thanks to a better selection of "N-OK" products sent to quarantine, confirming the Pareto principle in the analysis of causes sources. After the process was stabilized and fully implemented (W33–W44), the PPM rate dropped to virtually zero (exactly 0 in weeks W41–W44), which meant that defective bundles reaching customers were completely eliminated and zero complaints during this period, while FPY stabilized at a satisfactory level of 93–97%, reflecting the balanced efficiency of the line with an additional 100% inspection step supported by traceability in the database.

Practical conclusions from our own research emphasize that the introduction of the EOL IT tool (integrated with ERP) at a dedicated workstation made it possible to move from statistical to preventive control, completely eliminating complaints and significantly improving reliability in high-risk industry conditions, while despite the increase in labor intensity by about 10–15% on the line (resulting from a full inspection), savings from avoided complaint costs (logistics, alterations, loss of confidence) turned out to be many times higher – an estimated reduction of losses by over 90% in the analyzed period. Further process improvement should focus on the full integration of the EOL database with MES/ERP systems for automatic real-time reporting, the implementation of AI for the analysis of quality trends (e.g. defect prediction based on historical data), and the extension of automation to vision sensors and electrical tests, which will strengthen compliance with the Industry 4.0 concept and allow for further FPY growth above 98%.

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