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QUALITY MANAGEMENT SYSTEM IN COMPANY X. IMPROVEMENT ACCORDING TO ISO 9001:2015

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Title:
QUALITY MANAGEMENT SYSTEM IN COMPANY X. IMPLEMENTATION ACCORDING TO ISO 9001:2015 STANDARD.

Commissioned by:
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Abstract:
The choice of the topic for the thesis is justified by the need for a review of the quality management methods used in Company X. As a result of the thesis work an implementation plan for the quality management system improvement and appliance for the ISO 9001:2015 standard to be produced. The ISO (International Standardization Organization) standard 9001:2015 would be taken as the primary theoretical frame reference throughout the work. The ISO 9001: 2015 standard is based on a process approach in developing, implementing, and improving the effectiveness of the QMS.

As the thesis proposes to improve the current Quality Management System at Company X, from the standpoint of improving the procedure for conducting an internal audit of the Quality Management System documentation, the ISO 9001:2015 standard and its requirements are considered as the main concept though out the work.

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1 INTRODUCTION

Nowadays, Quality Control is the management basis for many organizations to control manufacturing processes and product quality. The effectiveness of quality control is determined by the level of its organization, and the degree of its methodological application. It is especially typical for ccertain industries due to their specific organizational and technological features.

In modern market situation, the main task for the enterprise is to maintain sustainable competitiveness. Enterprises use a variety of tools to achieve this goal. And one of the main tools is quality, since quality for the consumer was and remains the most critical aspect when buying a product or service (Garvin 1987). The production of quality products in current market conditions is a contribution to maintaining a sustainable competitiveness of an enterprise. To ensure high-quality production of products, quality control is necessary, the importance of which is exceptionally high for industrial enterprises. Quality has become the core solution and the principal prerequisite to increase the volume of goods supplied to internal and foreign markets. David Garvin states that carefully designed and efficiently functioning quality management systems ensure firms' profitability and a significant return on investment (Garvin 1987).

The thesis aims to explain the concept of quality control in production, list the benefits of Quality Management System (QMS) and describe the formation process of the Quality Control Department in Company X.

1.1 Concept of quality control

Quality control is a crucial function in quality management in an enterprise. Several sources give the following definitions of the term "control". In ISO 9000: 2015, control is defined as "determining conformity to specified requirements" (ISO 9000: 2015).

"Quality is the collection of products/services/systems/processes to meet the needs of customers and all relevant parties" (ISO9000: 2000). Quality Control is every scheduled and coordinated practice at an organization ensures that the products, facilities, and procedures executed meet the defined consumer expectations. It is also all the steps taken to ensure a consistent degree of quality of products, services, and processes. This definition comparison between actual and given values and which defines how well the goods, services, and processes executed satisfy the standards.

Product quality management is understood as establishing quality indicators, their assurance and maintenance during the development, production, and operation of a product through systematic control and targeted impacts on factors affecting its quality (Freeman 2019).

1.2 Types of quality control

The classification of quality control types bases on various criteria: the time and place of control in the technological cycle, the management effect of control action and the object of control. Let us consider the most common types of quality control (Figure 1).

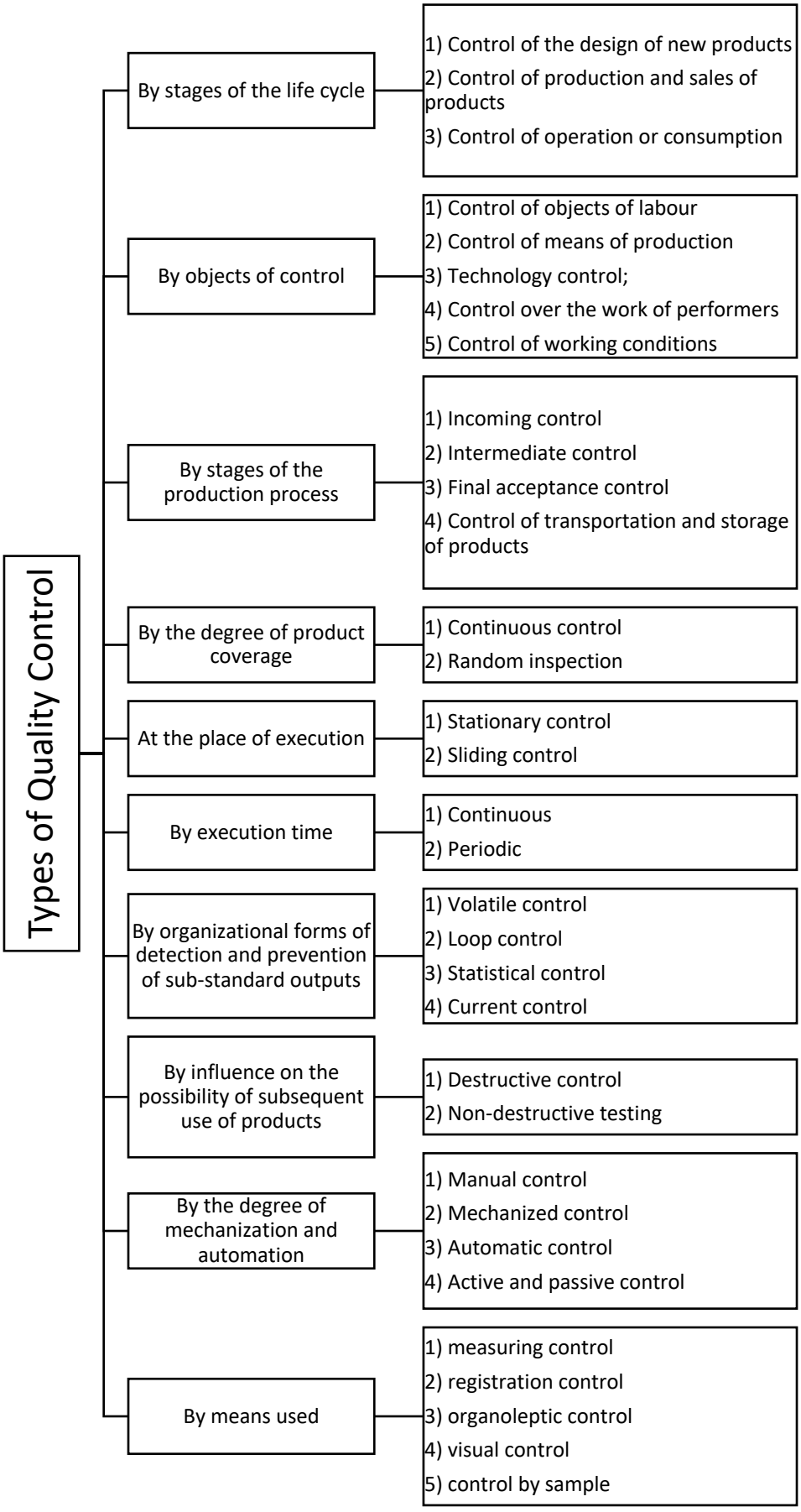

Figure 1. Types of quality control

According to Feigenbaum's "40 Steps to Quality Improvement" (1990) in stages of the production processes there are:

- Incoming inspection, designed to check the quality of materials, semi-finished products, tools and fixtures before the start of production.
- Intermediate control carried out in the course of the technological process (step by step).
- Final acceptance control, carried out over blanks, parts, assembly units, finished products.
- Control of transportation and storage of products.

According to Feigenbaum (1990), elective control is carried out not over the entire mass of products, but only over the sample. It is applied in the following cases:

- With a large number of identical parts.
- With a high degree of stability of the technological process.
- After minor modifications.

At the point of accomplishment there can be distinguished:
Stationary control:

- If it is necessary to check a large number of identical production facilities that require specially equipped control points (complex measuring equipment).
- If it is possible to include the work of a stationary control point in the flow of final operations of the production process.

Sliding control:

- When checking bulky products that are inconvenient for transportation.
- In the manufacture of a small number of identical products.
- If it is possible to use simple control and measuring instruments or devices.

1.3 Principles of quality management

Quality management can be applied in any industry, not only in manufacturing but also in other types of companies, from large to small, international to local. Quality management guarantees that the company's essential tasks are carried out accurately (Freeman 2019). Companies must develop and adapt appropriate quality control principles if they wish to succeed on the market.

"Quality Management Principles are a set of generally accepted core beliefs, standards, rules and values that can be used as a basis for quality management." The International Standardization Organization (ISO) standard uses these rules or principles as the basis for guiding an organization to improve its processes. These principles are developed and updated by international ISO experts responsible for developing and maintaining ISO quality management standards" (ISO 9001: 2015).

According to Graham Freeman (2019) the main principles of enterprise quality management are as follows:

1. Customer orientation:

The main focus of quality management is consumer satisfaction and the pursuit of transcending customer expectations. This principle clarifies an organization's aim and tops customer expectations regarding credence in product or service. Sustainable success is gained through the recognition of consumers' needs at all times.

2. The role of leadership:

Leaders build unity and establish conditions for people to strive in reaching the quality goals of the organization. Leaders form connections. Communication in strategy, in business policy, in concept and course, in the allocation of processes and resources. Leadership stands for achieving the goals of the company.

3. Involvement of workers:

Employees are the company's most valuable assets. An active participation of employees in ensuring product quality, expertise, and experience is vital to its growth. It is necessary to increase their ability to create and distribute the value of the product. The advancement of the human resources in an organization is the development of internal capital to improve its potential to achieve more outstanding quality. In the quality management system, the company's entire team, equally plays an essential role in implementing and maintaining the quality system. Team members should work diligently to increase the consistency of the

goods and services they offer to consumers. Each level of staff must carry out duties that are required from their role.

4. Process approach:

Steady and expected results are more valuable and efficient. Process approach means recognition and operation of processes as interrelated and work as a complete system. Through learning how a process reaches targets, a company can optimize its operations and increase productivity. A significant advantage for this is the achievement of "consistent and predictable results through a system of interrelated processes.

5. Continuous improvement:

Focus on innovative and progressive ways of improvement. Constant development is needed to keep organizations modern and competitive. When responding to external and internal modifications; it can change leadership, economic practices or form new possibilities and more concrete solutions.

6. Making decisions based on facts:

Choices based on evidence investigation and evaluation have a higher chance of helping a company reach its desired outcomes. The interconnection of variables does not indicate that a change in one variable is the cause of a change in another variable. It is crucial to ensure accurate analyses when making conclusions to bypass biased decisions based on inaccurate data. Research based decisions lead to objectivity and higher certainty.

7. Relationship management:

Businesses and vendors are intertwined, and commonly beneficial partnerships will help both sides to improve their strengths and add profit. To achieve common goals, the organization must build internal and external relationships. Similarly, as employees contribute to success, maintaining good relationships with suppliers can affect an organization's bottom line. Suppliers and stakeholders have an impact on a business and its success.

The above described seven principles of quality management are some of ISO quality management standards' core principles. They also form the basis for improving the productivity of organizations. These principles can be applied in different ways, as they depend on the organization's nature and the organization's specifications. Understanding the basics of the company, daily operations, targets, and visions is essential for the effective implementation of the standards.

Understanding and applying the seven principles is a solid foundation for building an ISO 9001 compliant quality management system to meet internal (organization) and external (customers) needs.

2 FEATURES OF BUILDING A QUALITY MANAGEMENT SYSTEM ACCORDING TO ISO 9001-2015 STANDARD

2.1 Requirements for a quality management system (ISO 9001-2015)

The International Organization for Standardization (ISO) released the first edition of the ISO 9000 series in 1987. Over the past 27 years, ISO 9000 standards have become the most widely used in the world. According to the ISO report for 2013 - 1,129,446, organizations in 187 countries have developed quality management systems (QMS) following the requirements of the ISO 9001: 2008 standard (ISO 2013, 53). In 2015, the fifth edition of these standards was released. An ISO / NP TS 9002 document has also been issued guiding the application of ISO 9001: 2015.

The development of a quality management system (QMS) is a strategic decision of the organization. An efficient QMS can improve its overall performance and form a necessary foundation for sustainable development, which means promoting quality and motivating organizations to look beyond meeting a set of requirements by applying innovative solutions.

The ISO Joint Technical Coordinating Group completed work on the structure, textual content and common terms and definitions for management system standards. This allowed for the link between not yet released and already revised standards and simplify their integration. Besides, these standards will become easier for users to understand. All management system standards are required to meet the conditions set out in the new Annex SL to Part 1 of the ISO / IEC Directives "Consolidated ISO Supplement. ISO Special Procedures". Annex SL formulates uniform requirements for structure, text, terms, and definitions, leaving standards developers freedom of action to resolve specific technical issues and develop requirements. A solid foundation has been prepared for the innovative sustainable development of the organization.

The ISO 9001: 2015 standard specifies three concepts that form the basis of the new document: the process approach, the application of the PDCA cycle and risk management in the QMS.

The ISO 9001: 2015 standard is based on a process approach in developing, implementing, and improving the effectiveness of the QMS (ISO 9001:2015, 23). It should be noted that only ISO 9001 is used for QMS certification.

A process is a set of related or interacting activities that convert inputs to outputs. A QMS is a system consisting of interrelated processes, has a set of goals, inputs and outputs, and is focused on the effective and efficient achievement of the organization's quality objectives. An organization cannot achieve these goals without a process approach.

The process approach provides the following benefits necessary for the implementation of innovative solutions (Hoyle 2007, 28):

- Integration and consistency of all processes to achieve designed outcomes.
- The capability to concentrate efforts on the process effectiveness and productivity.
- Assuring consumers and other affected stakeholders on the agreed actions of the company.

- Transparency of the organization's activities.
- Efficient use of resources, lower prices and a shorter production cycle.
- Improved, consistent and predictable results.
- Enhancing the involvement of employees and a clear definition of their responsibilities and authorities.

Compared to other methods, the process approach's main advantage is managing and controlling connections and interactions between processes.

It should be noted that the innovative character of the QMS is indicated by the terms of ISO 9001 regarding knowledge management in a business. The organization shall define the familiarity required for developing processes and the execution of products and services compliance by the standards' requirements. This experience must be supported in an operating order. When changes are required and patterns are identified, the organization can review existing data and gather additional information.

The requirements of the ISO 9001 standard are formulated following the procedure for planning and managing operations:

- Understanding the context of the organization, its QMS and processes (Section 4).
- Leadership, politics and responsibility (Section 5).
- Planning processes, consideration of risks and opportunities (Section 6).
- Supporting processes, including resources, personnel and information (Section 7).
- Manufacturing processes associated with customers, products and services (Section 8).
- Performance assessment processes (Section 9).
- Improvement processes (Section 10).

Clause 4.4 of ISO 9001: 2015 contains the requirements for implementing a process approach in an organization. The organization must define, enforce, manage, and continuously develop the QMS, including the required processes and their interactions, following the standard's specifications.

The organization must decide the procedures needed for the QMS and how they will be applied in the organization, including:

- The expected inputs and presumed outputs of specific processes.
- The distribution and synergy of certain processes.
- Principles, practices, analyses and related production indicators required for the efficient administration of particular processes.
- The resources required, as well as a guarantee that they would be available.
- Tasks and responsibilities for allocated processes.
- Following the conditions of 6.1, draft and perform relevant steps to approach them.
- Arrangements for monitoring and mapping, where relevant, and assessing processes and, wherever required, adjusting processes to guarantee that they reach outlined outcomes.
- Possibilities for the development of processes and the quality control system as a whole.
- The company shall keep documented reports to the degree required to guarantee the processes' performance and sustain the confidence that the processes operate as planned.

2.2 PDCA Cycle - A Tool for Driving Innovation

The PDCA cycle aims to enable managers’ and workers’ consistent focus on improvements, their execution and evaluation of success, further identifying other systems where those could be implemented (Lai & Cheng 2009, 124). All QMS include four main types of activities:

1. Planning

Any activity must be planned before being carried out. It is necessary to establish the system's objectives and processes and the required resources to obtain results according to customers' requirements and the organization's policies. All requirements formulated in the documentation form the basis of quality assessments.

2. Performance of work.

The work must be carried out following the developed plan. Documented information should be retained to enable measurements.

3. Measurement.

Positive or negative performance should be measured under specified quality requirements. Monitor and measure means, products, services for compliance with standards, goals and needs and prepare reports on the results.

4. Improvement.

The measurement results will indicate the weaknesses in the implementation plan. Problems must be fixed, and processes must be improved.

These four basic blocks are part of the PDCA cycle (plan - do - check - act).
Clause 0.3.2 of ISO 9001: 2015 states that the PDCA methodology can be applied to all processes and the QMS in general. ISO 9001: 2015 requirements are broadly based on the PDCA cycle.

The PDCA cycle is a helpful tool for introducing innovative programs, new processes, products and services. In accordance with the recommendations of the ISO 19011: 2011 standard, the PDCA cycle also applies to the management of the quality audit program (ISO 2011, 72).

A systematic and independent quality audit is an essential tool for diagnosing the effectiveness of implementing QMS processes and identifying opportunities for further improvement. Since the achievement of quality objectives and customer satisfaction depends on the QMS processes, the audit program should focus on these processes. An internal audit, carried out by or on behalf of the organization, is one of the most crucial quality system processes. It is important not only for certification but also for the continuous improvement of the QMS. Internal audits should focus on process outputs, improving customer satisfaction, and communication with other parts of the organization. Internal auditors can identify

weaknesses in the QMS and become the driving force behind the change and improvement in areas vital to the organization.

The ISO 9001 standard emphasizes the need to improve organization operations to avoid deviations, enhance product and services quality, to satisfy anticipated customer expectations and needs, and improve QMS performance. The continuous improvement consists of corrective action, disruptive improvement, innovation, and reorganization.

2.3 Risks assessment in the QMS

Risk is the consequence of indecision on a foreseen outcome. One of the fundamental changes in ISO 9001: 2015 is establishing a systematic approach to risk. The risk-based approach is now included in all standard provisions and stated in clause 0.3.3 of the standard.

The organization remains proactive by using a risk-based strategy, avoiding, or minimizing unintended consequences and maintaining quality increase. Preventive behavior is a crucial component of a compliance strategy that is focused on risk analysis. ISO 9001: 2015 encourages a company to apply a process approach in conjunction with PDCA methodology and risk analysis to achieve QMS compliance with management system standards' requirements. Throughout the standard, ISO 9001: 2015 tackles risks, incorporating proactive action into strategic plans, day-to-day processes, and research.

Organizations can choose a more comprehensive risk-based approach than ISO 9001 suggests and take advantage of risk management guidance in ISO 31000: 2009, "Risk Management. Principles and guidelines" (ISO 2009, 26).

Nonconformities in procedures, goods, facilities, and programs do not all pose the same degree of risk to an organization's ability to meet its objectives. The effects of nonconformities in processes, products, services, and systems are not the same for all organizations. For some organizations, the delivery of inappropriate products and services results in minimal deviations from the customer's requirements; for others, it can be catastrophic. The probability of

meeting the set targets increases as uncertainties are considered in the enterprise, and the production is more aligned with the quality criteria. Customers should be assured that they will get the good or service that they paid for.

Risk-based approach:

- Increases the likelihood of achieving goals.
- Creates an extensive knowledge base.
- Builds a proactive practice of improvement.
- Provides confidence in the quality of products and services.
- Increases consumer confidence and satisfaction.
- Makes a precautionary approach an integral part of the QMS.

These are the stages of development of a QMS in an organization according to ISO 9001:2015:

The team for the QMS improvement, as a rule, includes specialists from the leading production departments. Quality department employees and members of the QMS implementation work group are usually trained in particular programs, consisting of ISO 9001, creating a quality management system, and drawing up all the necessary documentation.

When introducing a quality management system, the Quality Control manager must create the necessary prerequisites for the rapid implementation of all stages of creating a QMS. First of all, a decision must be made to start a project. The manager must notify the company's employees, appoint a project leader, usually a quality management specialist. The project leader, in turn, draws up a document that confirms the organizational structure of the project team. The working group is represented by employees designated by the heads of departments. The working group's responsibilities include attending meetings where the implementation plan, next steps and tasks are discussed, and, subsequently, the results of the implementation are discussed. Open questions and possible problems related to the performance of the QMS are brought up for meetings with the decision-making committee, which includes the CEO and CFO.

The CEOs involvement is necessary because the problems that require making a decision are often financial in nature.

An example of a document that shows a project team's organizational structure is shown in Figure 2.

To understand what period the team will spend on a particular task, it is recommended to integrate a planning calendar to track the progress of actions according to the program. This will help the project leader to track and adjust the project and the decision-making committee (senior management) in overseeing project implementation and ensuring timely decisions.

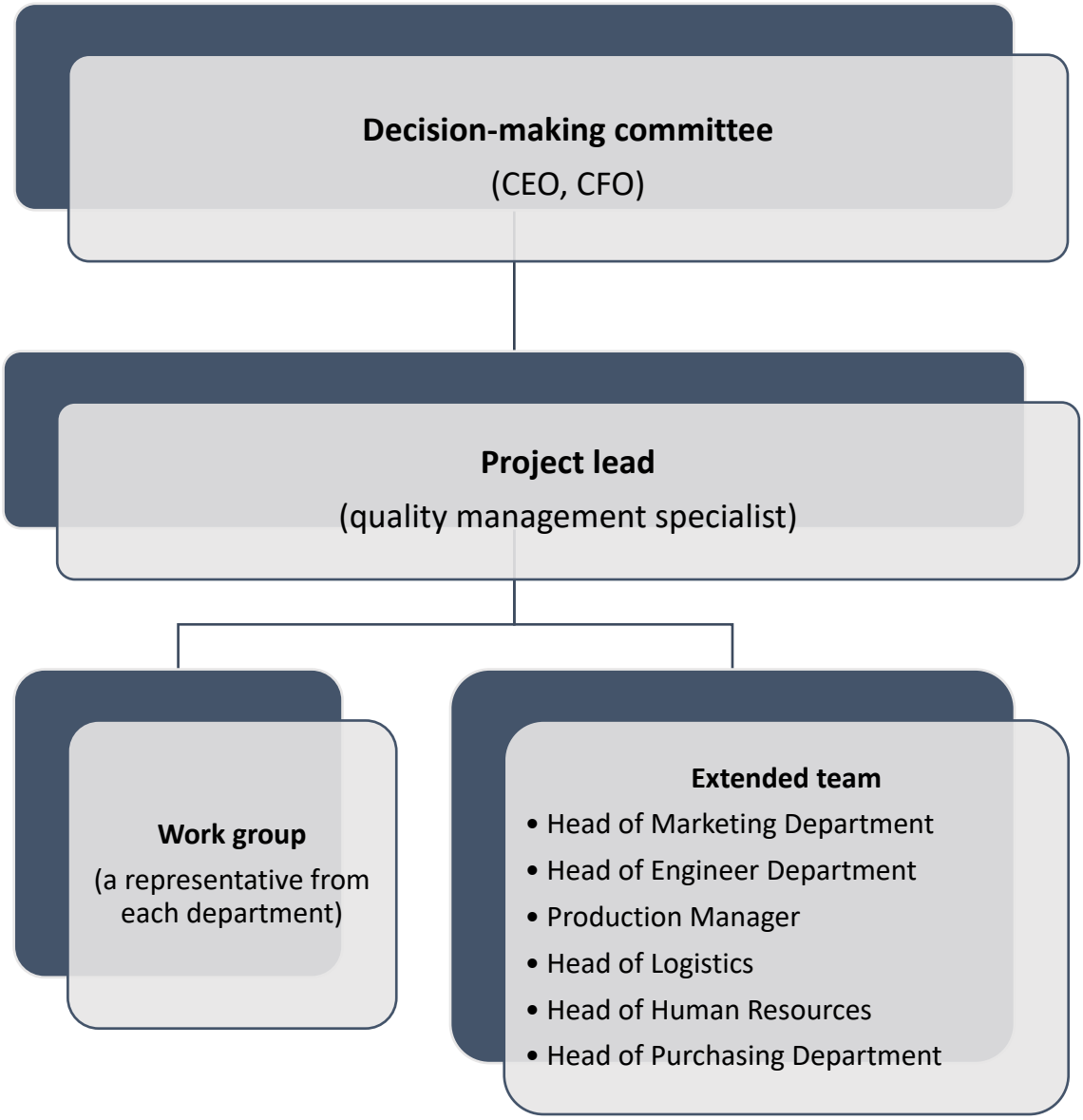

Figure 2. An example of a project team organizational structure.

The creation of the QMS begins as soon as the working group develops a work plan, which the enterprise's head must approve. The plan defines the phases, types of work, timing, actors, and project implementation scope.

The second stage involves a detailed review of the organization's quality control of goods and services and the development of a QMS design. Before proceeding to this stage, it is necessary to analyze the existing management system to identify the organization's strengths and weaknesses in quality, organizational structure, and applied quality control methods.

All departments and services of the enterprise, which need to provide the quality department with the necessary information, participate in the analysis. It is essential to determine whether the enterprise documentation is suitable for use in the QMS and meets the minimum requirements. After analyzing the existing enterprise management model, a conceptual model of the quality management system is developed. Based on the analysis results, the development schedule and adjustment of the QMS documentation are carried out.

The quality management system documentation is created at the third level and is essential for the QMS to operate correctly. It implies the execution of functions by specifying the types and modes of encounters and the information input and output. Initially, the QMS documentation (according to ISO 9001-2008) included a quality manual, which is documented information necessary to coordinate various activities that were supposed to ensure the effective functioning of the QMS. Quality databases often confirm the quality of goods, services, or works that include the recorded values of control parameters.

The head of the enterprise approves the QMS documentation only after it has been agreed upon with all the performers. Most likely, when switching to the ISO 9001 standard from 2015, enterprises adhere to this procedure, since although the modified version of the standard does not require the use of documented policies and quality manuals, their use is not prohibited either. Considering that the new version of the ISO 9001 standard from 2015 proposes applying a risk management model, it is necessary to work out, document and monitor all possible risks of the QMS. The fourth stage requires the work connected with the implementation of quality management systems. Each employee of the organization can be familiarized with the QMS documentation system and trained to work in its functioning conditions.

The quality service should analyze all deviations from the norm recognized when implementing the QMS to determine the reason for their occurrence and correct the relevant documentation, if necessary. The quality service also conducts internal audits to establish the operability of the QMS. Thanks to these audits, it is possible to determine how the QMS complies with the standard's requirements

(verification of adequacy) and how well employees understand and carry out the planned activities (proof of compliance).

The final fifth stage consists of tasks related to the certification of the QMS. After receiving evaluations on the quality service documents, this service includes the appropriate adjustments and determines the organization's date of the external audit. After eliminating possible deviations, a certificate of conformity is issued for three years. The certification body supervises the activities of the QMS in the organization, conducting inspection control every year. If serious violations are detected, the certificate is suspended.

To introduce the standard at an organization, a more detailed description of the steps, methods and implementation tools is needed. Figure 3 describes the main steps for implementing a quality management system with comments on the standard's latest version.

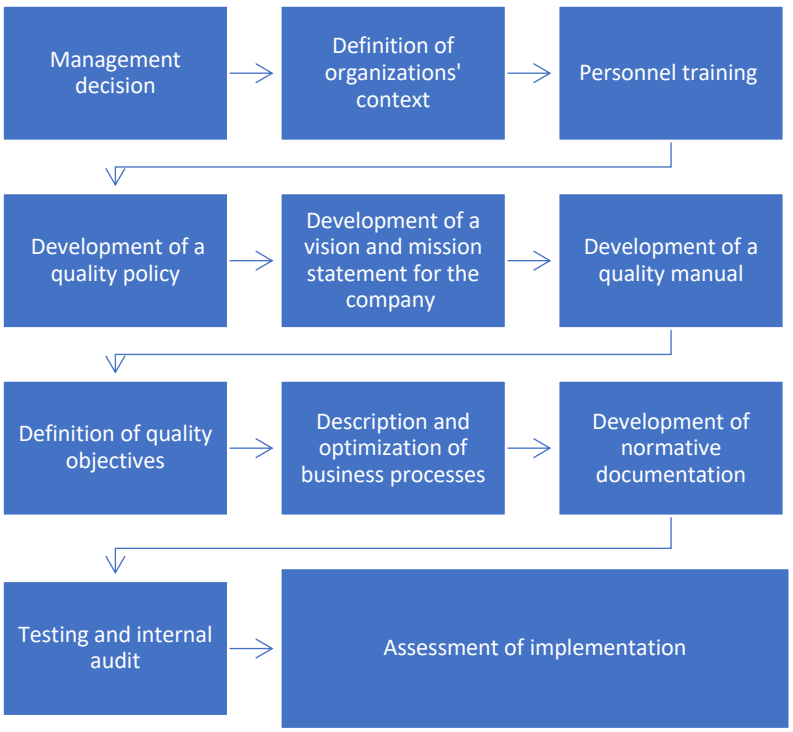

Figure 3. Stages of QMS implementation.

It can be argued that efforts are now being made to increase the ISO 9001 usefulness for all users of the standard.

The considered process is universal. It can be used at various enterprises, considering the specifics of the products. The introduction of a quality management system at an enterprise helps to evaluate organization’s management strengths and weaknesses. Also, it grants continuous growth and development, as well as company’s products or services quality. The QMS development model has changed with transition to the new version of the ISO 9001 standard, version 2015. In the updated version it is altered with risk management instead of preventive actions. Even a slight increase in product quality over similar competitors' products entails attracting many consumers to their products. This makes the development and implementation of a quality management system even more necessary and essential for any organization's growth and functioning.

3 QUALITY CONTROL IN PRODUCTION

Regardless of types of methods used for quality control in production, it presupposes separating good products from bad ones. Naturally, the quality of the product does not increase due to the rejection of substandard ones. In some enterprises, for example, in the electronics industry, due to the miniature size of products, it is often impossible to fix a defect at all. Therefore, modern firms focus not on detecting defects but on preventing them, on careful control of the production process, and carrying out activities according to the concept of "quality control".

The control process consists of analyzing production to detect deviations from the specified parameters, establish the reasons for these deviations, and, after their elimination, check if the quality standard is met (Basovskiy 2020).

3.2 Manufacturing quality control process in a QMS

Quality management necessitates the isolation of relevant goods from faulty ones, regardless of the techniques employed. Rejecting a product does not

improve its efficiency. An efficient quality management mechanism leads to the immediate avoidance or elimination of nonconformities, defects, mistakes, and their improvement with minor material expenses. As a result, particular consideration is given to the accurate monitoring of manufacturing processes and the avoidance of rejects during the quality control process.

Quality management, in general, ensures that defined specifications for processes and goods are fulfilled (Figure 4).

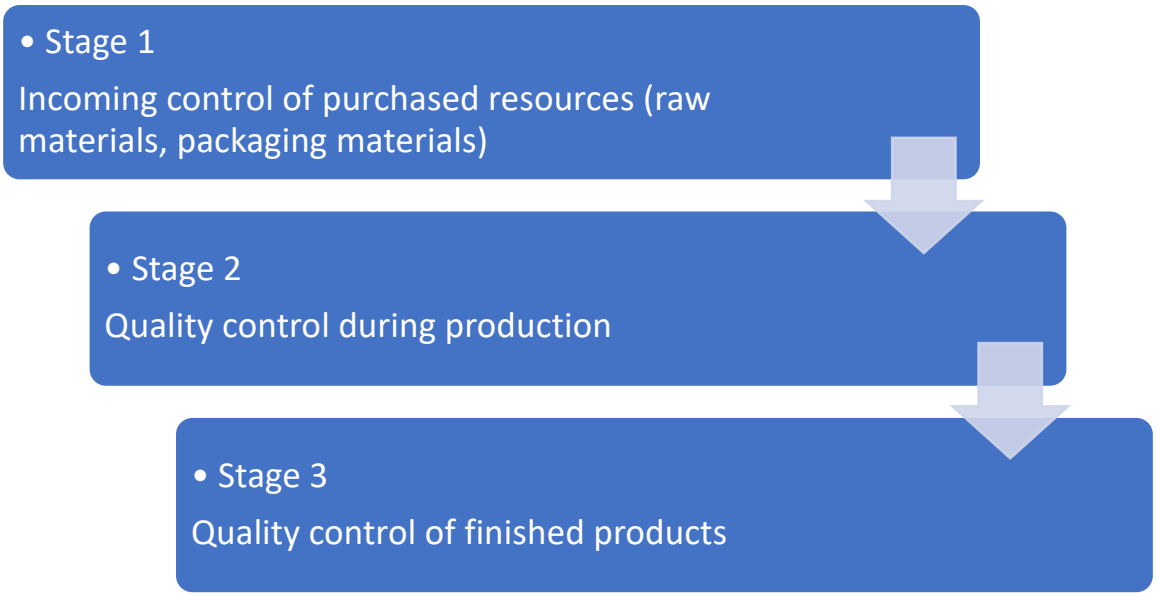

Figure 4. Manufacturing quality control process established requirements.

3.2.1 Incoming quality control

Incoming control is carried out to prevent the launch into the production of products that do not meet the requirements of supply contracts and regulatory and technical documentation.

To ensure the high quality of products, a unique role is played by improving an industrial enterprise's incoming quality control system. This eliminates the risks of using products, raw materials, supplies, semi-finished products, components, and tools with deviations from quality requirements indicated in supply contracts. The improvement of the incoming control system is carried out in the following areas:

- Revision of the control process itself.
- Improvement of controls.
- Professional development of personnel.
- Improving the documentation of the incoming control system.

The essence and implementation of the quality management system "Relationship Management" is formulated and presented in the ISO 9001 series standards.

Following the requirements of ISO 9001-2015, "the organization must guarantee that the processes, products and services provided by external suppliers do not negatively affect the organization's ability to supply appropriate products and services to its customers consistently." (ISO 9001 - 2015).

Incoming control is a check of the quality of raw materials and auxiliary materials entering production. Incoming quality control of purchased products is carried out to confirm the conformity of product quality to the consumer's established requirements for individual indicators.

The principal responsibilities of incoming quality control are:

- Control of the availability of decent documentation for products.
- Inspection of consistency of goods concerning design and technical documentation.
- Analytics on the quality of the incoming goods, recommendations for its improvement and, revising the criteria of standardization documents for products.
- Periodic check of conditions of the storage of suppliers' goods.

3.2.2 Quality control during production

Control in the production process is associated with monitoring quality directly during production. The selection of samples and control of their quality are carried

out. It is important not to process sub-standard products in the production stages, to avoid unnecessary expenses on recycling or disposal of such products.

Production Quality Control involves checking products for compliance with quality standards, including appearance parameters, correct labelling, and technical condition. The main goal is to identify deviations on time and, if necessary, adjust technological processes to ensure the quality of manufactured products. It is essential to manage the quality of the products and the processes. It is necessary to monitor compliance with the requirements of technological instructions and standard operating procedures (SOPs) at all stages of the production cycle, including the steps of storage and transportation, during which product damage is also possible.

Good order in the workplace improves the quality of products and increases productivity. Confusion leads to carelessness and mistakes at production, an increase in deviations from the established quality standards.

3.2.3 Quality control of finished products

The purpose of finished product quality control is to establish compliance of finished products with regulatory requirements and protect consumers from receiving sub-standard products. This type of control is the final stage. Finished products can be sold only when their quality meets the established requirements of regulatory documents.

The quality outcome of the manufactured products and the state of the technological process is based on the control of the manufactured products' quality standards. After obtaining control data confirming the required quality of the finished product, the boundaries of the process parameters' values are assigned, which should not exceed the values during the production of a specific product (Juran 2016, 23.21).

3.2.4 Quality control department

A Quality Control department is independent from other manufacturing departments. This allows the efficient operation of the quality control mechanism at enterprises.

A Quality Control Department is an independent structural unit of the Quality Service and reports directly to the Quality Control Manager. Quality Control in its activities is guided by national legislation, orders, instructions, as well as instructions of enterprise's management, the organization's quality policy, the requirements of the current normative and technical documentation (NTD) for the directions of the Quality Control department, and the production work plan. The structural divisions of the quality control department are shown in Figure 5.

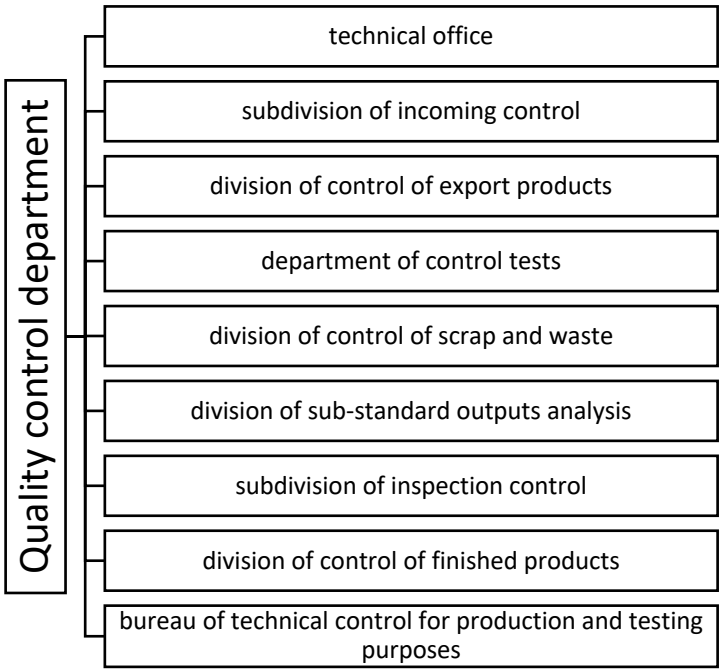

Figure 5. Structural divisions of the Quality Control Department.

Quality Control carries out the following tasks:

- Preventing the release of products that do not meet the requirements of standards and specifications, design and technological documentation, approved samples, delivery terms and contracts.
- Preventing the launch of materials that do not meet the established requirements into production.

- Ensuring the timely conduct of periodic, standard, qualification, certification tests, control tests for reliability and other software tests of products.
- Carrying out works on certification of the Organization's Quality Management System.
- Implementation of technical control of product quality in the production process.

The Quality Control Department has a sole function in ensuring the detection and prevention of defects and the reliability of control results, checking the supply for defective goods. However, Quality Control is not the only unit responsible for product quality; manufacturing staff still play a role in this regard. Employees working in the Quality Control Department are mainly responsible for administering, testing, and comparing results to the established specifications to assess compliance.

Thus, the implementation and optimization of QMS and quality control, particularly at the enterprise, will optimize the company's existing processes and contribute to the emergence of new approaches necessary to increase efficiency, both in organizational and financial terms. The enterprise's certified quality management system contributes to companies' flourishing existence within the framework of high competition in the market. It helps to attract significant national and foreign investors.

4 ANALYSIS OF THE QUALITY CONTROL DEPARTMENT IN COMPANY X

4.1 Brief description of the organization

Company X is a fast-growing e-commerce company that operates in the retail of refurbished electronics market. It is a company with over 400 employees working in operations site. The principal departments of Company X are Diagnostics,

Repair, and Outbound. In the Diagnostics department, employees are in charge of testing a product's functionality and inspecting cosmetical damages. The Repair Department receives products with diagnostics reports and fixes the defects. The Outbound Department prepares products for customers, fulfils orders, cleans, packs, and dispatches the goods.

Indicator of Repair quality is the number of fixed products which are returned to Repair with new faults caused by repairers' mistakes. The substandard product gets back to the same repairer and requires rework. Thus, employees learn from their own mistakes and get feedback.

The idea of creating quality control in Company X came when the number of substandard products going through the production line had started to grow (Figure 6).

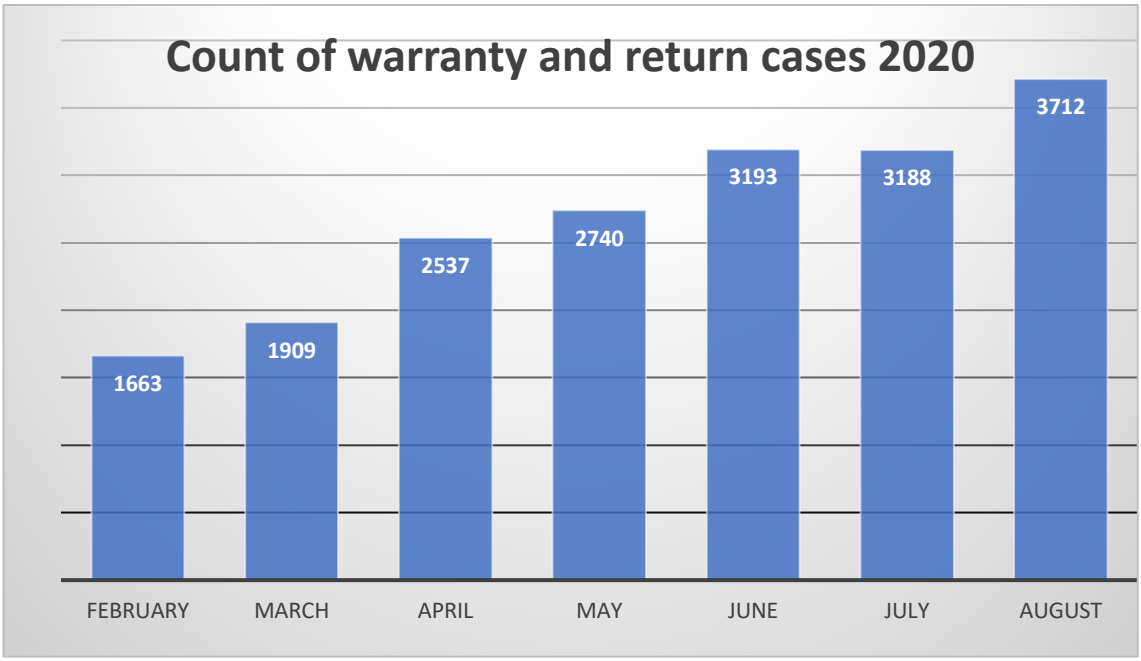

Figure 6. Count of warranty and return cases for February - August 2020.

To point out the need for structural changes and the establishment of Quality Control in diagnostics, a meeting with the operations manager and diagnostics department manager took place. An explanation of the new quality management tool's importance was the primary goal. The meeting outcome was an agreed two-week trial period and a promise of quality increase visible in numbers and a

report. After the trial period, the management decided to establish a Quality Control Department (QCD).

4.2 Reviewing the quality control system in a tech startup

Due to the higher requirements and expectations from the management regarding the size of the team and the formal implementation of the Quality Control Department, the emphasis was placed on more comprehensive quality control in all principal departments of Company X. The management of the company determined the solution of the following tasks in accordance with the ISO 9001 standard: 2015:

- Identification of problems, the elimination of which will contribute to compliance with the requirements of the standard.
- It is recommended to appoint a group of responsible persons of up to five people from the enterprise (Quality Control Department of the QMS).
- To appoint the deputy general director as the responsible manager of the product quality.
- Change the responsibilities of personnel responsible for quality control.
- Develop a plan for improving the QMS at the enterprise.
- Improvement of the QMS documentation.
- Analysis of proposals for strengthening the QMS.
- Providing training for all personnel that affect product quality results.

The company's management has identified the following stages of product quality control:

- Incoming control of raw materials.
- Quality control and testing of products in the production process.
- Operational control.
- Acceptance control.
- Final control of the finished products.

Also, a quality roadmap was composed to improve the QMS.

1. Incoming inspection

Incoming control - checking the quality of raw materials and auxiliary materials supplied to the repair department. Constant monitoring of the quality of supplied raw materials allows an influence on the supplier products, subsequently improving its quality.

Product quality control during the production process includes all types of product control and testing performed during the technological process (operational control).

Compliance with production technology is a prerequisite and basis for ensuring the desired quality of manufactured products.

Technological quality control is multistage and is subdivided into continuous, periodic, and extraordinary. A brief description of the types of control over technical order compliance is given in Table 1.

Type of control	Stage №	Control executor	Periodicity	Control volume
Continuous	I	1. Employee of the repair department, head of the repair department, employee of the QCD	During the work day	Execution of operations at workplaces in accordance with technological documentation and control scheme
Continuous	II	2. Head of the repair department, employee of the QCD	During the work day	Compliance technologies Production products, quality products and used by materials
		3. Head of the repair department, head of the QCD, An employee of the repair department and an employee of the QCD	Weekly	Product quality analysis

Periodic	III	Company X commission	Monthly, according to plan	According to the requirements ISO 9001: 2015
Periodic	IV	Company X commission	Monthly, according to plan	According to the requirements ISO 9001: 2015
Extraordinary	V	Company X commission	As directed by the top management of the company	According to the requirements ISO 9001: 2015

Table 1. Description of types of control in Company X.

2. Operational control

During operational control, compliance with the requirements of technological instructions, standards, technical conditions, and other regulatory documents is checked. The control scheme ensures the continuity of control at all stages of the production process.

The results of operational control are recorded by an employee of the repair department in particular sheets (Excel file).

The control of the first stage is carried out by employees of the repair department, the head of the department, and employees of the Quality Control Department. Control is carried out directly at workplaces during the working day. The control results are recorded in quality sheets (Excel file).

Control of the second stage is carried out by the head of the Repair Department and the head of the Quality Control Department. Control is carried out daily. The daily quality data is available for all the departments. In the control process at the second stage, the employees' compliance with the production process technology, product quality, and materials are checked. Periodic control provides for the third and fourth stages. The company commission carries out the third stage. The control is carried out once a month according to the schedule approved of by the head of the commission:

- The head of the repair department.
- The chief specialist of the repair department.
- Employees of the Quality Control.

Based on the results of the commission's work, an order is issued for the repair department, which reflects:

- All identified inconsistencies with an indication of the timing of their elimination and executors.
- Commission documentation in accordance with ISO 9001: 2015 is developed.

The Repair Department Lead carries out the preparation of the commission's work schedule and procedures based on the results of inspections. An order for the department formalizes the assignment of responsibilities for the performance of this work to another manager.

The company commission carries out the fourth step. Control is carried out once a month in every department of the company. The control results are documented in an act signed by the commission members and approved by the checked departments' lead. The technical service carries out the preparation of a schedule for checking compliance with the production process technology by the company's commission and acts based on their results. Based on the identified inconsistencies, measures are developed to eliminate them, indicating the deadlines for elimination and performers.

The head of the commission determines the number of specified inconsistencies and the development of corrective actions to eliminate them. The head of the audited department is responsible for corrective actions; the development of corrective actions is drawn up in the form of a table and sent: the original to the head of the commission, and copies to the head of the company department. One copy is kept in the Quality Control department, and another goes to operations manager.

Control over implementing measures to eliminate the identified inconsistencies and corrective actions is carried out at quality meetings with department heads. Heads of departments provide information on the implementation of measures to eliminate the identified inconsistencies and corrective actions.

The fifth stage - extraordinary control, is carried out in the direction of the company's management. The grounds for carrying out an extraordinary control over the observance of the production technology are inconsistencies identified in the technological process that require a collective solution by specialists from different departments.

The Chief Engineer heads the commission. The commission includes the head of the company's technical department and the leading specialists in the areas. The results of the check are formalized by order of the CEO of Company X. The employees of the Quality Control carry out control over the implementation of measures to eliminate the identified inconsistencies and make corrective actions.

3. Acceptance inspection

The Quality Control Department and Diagnostics Department carries out acceptance control of products that went through the Repair Department, to obtain evidence that the products have passed all the prescribed types of control and tests. For acceptance control, the test results of samples are used, along with measurement and visual inspection of the appearance. The control is carried out using the "checklist" method.

Random sampling measures the quality of Outbound. A certain percentage of parcels gets opened to inspect the quality of packing, product cleanliness and order completeness. The random sampling procedure in packing relies on standards. Several meetings with the Outbound Department lead and experienced employees were organized to get an opinion of the packing quality and how it should be evaluated (Figure 7) to set the standards.

	A	B	C	D	E	F	G	H	I	J	K	L
1												
2					4.9	4.5	4.8	4.8	4.2			4.6
3	Date	Packet ID	Delivery	Packer	Screen	Temppered Glass	Back	Edges	Grills, Aux & Mute	Missing Acc.	hat was missi	Average Scrore
1630	12/9/2020	[redacted]3392	Posti	[redacted]	-	5.0	5.0	5.0	5.0	No		5
1631	12/9/2020	4874	Posti		-	5.0	5.0	5.0	5.0	No		5
1632	12/10/2020	72899	DHL		5.0	-	5.0	5.0	3.5	No		4.625
1633	12/10/2020	67271	DHL		5.0	-	5.0	5.0	5.0	No		5
1634	12/10/2020	39652	DHL		5.0	-	5.0	5.0	5.0	No		5
1635	12/10/2020	63	UPS		4.0	-	5.0	5.0	3.0	No		4.25
1636	12/10/2020	66207	DHL		5.0	-	5.0	5.0	5.0	No		5

Figure 7. Random sampling and evaluation matrix for the Outbound department.

Acceptance of products is done by the staff of the Quality Control and registered in Excel sheets.

4. Final inspection

During the final control, the conformity of products is assessed. The final control includes products manufactured following technical requirements, which have passed all types of control and tests with positive results.

The products are not allowed to be sent to the consumer until the procedures provided by the control schemes are followed while obtaining satisfactory results.

If any nonconformity is revealed during product control, the Quality Control Department (QCD) employee or the head of the department takes measures to eliminate the quality inconsistencies. In Table 2, an assessment of the existing quality management system in the company is presented.

Clause of the standard	Name	Note
5.2.	Improving quality policy	Corresponds to reality
6.3	Change planning	Performed following the standard
8.1	Planning and management of activities at the stages of the life cycle of products and services	Performed following the standard
8.3	Products and services form and extent	Performed following the standard
8.4	Management of processes, products and services supplied by external suppliers	Performed following the standard
8.5	Production of products and provision of services	Performed following the standard
9.1	Monitoring, measurement, analysis and evaluation	Carried out, but not enough
9.2	Internal audit	There are gaps in the organization of the internal audit system
9.3	Management review	There are problems in the quality control system

Table 2. Assessment of the existing quality management system at the enterprise according to ISO 9001: 2015.

The organization has different control and quality control methods. The following shortcomings were also identified: monitoring, measurement, analysis, and assessment are not carried out according to the stated requirements. There are deficiencies in the organization of the internal audit system; there are problems in the quality control system.

5 DEVELOPMENT MEASURES TO IMPROVE QMS IN THE ORGANIZATION

5.1 Development of a schedule for improving the QMS

To improve the current quality management system from the standpoint of improving the procedure for conducting an internal audit of the QMS documentation.

Three years are given to implement all the requirements of ISO 9001-2015.
Here is the Quality Management System Improvement Program:

- Stage one – preparing the QMS documentation and Quality Manual.
- Stage two - implementation of missing requirements according to ISO 9001-2015.
- Stage three - conducting internal audits of the quality system, control of the work performed.

To perform the improvement stages, it is necessary to create the required conditions in the company. Persons responsible for the organization and implementation of work to improve the quality management system should be from top and middle management. It is necessary to outline the goals, the objectives, and the basic principles of the quality management system for all personnel. The lack of explanatory conversations and training can lead to a decrease in results. In this regard, it is crucial to involve all personnel in the process of improving the QMS. The schedule for improving the quality management system is presented in Appendix 1.

Measures to improve the quality management system are very laborious and take much time to implement all stages. Therefore, the role of preparation and implementation is assigned to top and middle management. The CEO is the main responsible person for enforcing the implementation of the new, improved quality management system. He/she gives assignments to responsible persons for the implementation plan of the QMS improvement. He/she monitors its execution, while responsibility for the progress of the process is assigned to the Operation Director for Quality, who reports to the CEO on the progress of the procedures (Appendix 2).

5.2 Development of stages to improve the QMS in the organization

Improvement of the Quality Management System is a set of activities that affect the enterprise and its sub-system - the strategic management sub-system, the production sub-system, the logistics sub-system, staff management, intra-communications, and paper flow. In this regard, improving the QMS is a tricky, lengthy, and difficult task, and it consists of several stages.

The following Table 3 presents the process map for each department and division of Company X.

Process name	Responsible for the process	Process purpose
Financial Management	Financial Department	Planning, analysis, and control of budget execution of the need for financial resources for the implementation of production, investment, and social programs
Logistics Process	Sales Department	Delivery of finished products of the enterprise in the appropriate volume and within the appropriate time frame

Accounting	Financial Department	Formation of complete and reliable reporting on activities, to monitor compliance with EU (Finland) legislation in the implementation of business transactions and their feasibility, the presence and movement of property and obligations in accordance with the approved standards
Management Review	Quality Control Department	Assessment of the effectiveness of the QMS
Production	Technical Department	Implementation of planned indicators
Product Control and Analysis	Quality Control Department	Conducting timely control of products in accordance with the inspection schedule
Providing the Enterprise with the Necessary Technical Documentation for the Work	Technical Department	Ensuring compliance of technical documentation with design solutions, actual conditions, development of prospects for the development of works and related activities and proposals
Management of the Economic Activity of the Enterprise	Financial Department	Organization of planning and analysis of economic activities of the enterprise

Table 3. Process map.

The top management of the enterprise must ensure that the quality objectives, including those necessary to fulfil the requirements for the product, have been established in the relevant departments on proper levels. Quality objectives should be measurable and consistent with the quality policy.

5.3 Improving internal audit

To improve the quality management system in the organization for compliance with the requirements of ISO 9001-2015, an improvement in the internal audit of the QMS is required.

To maintain the QMS of the enterprise in working order and continuously develop its functioning, it is necessary to enhance and improve its processes constantly. When identifying priority areas for improvement, it is crucial to keep in mind the benefits of the internal audit process.

Internal auditing is the main method for determining the reliability of the QMS. The ISO 19011 standard defines an audit as: “A systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which agreed audit criteria has been met”. Clause 9.2 of ISO 9001-2015 specifies the need to conduct the internal audits of the QMS. The internal audit process refers to measurement processes.

Internal audits (checks) of the QMS are usually carried out by the organization itself for internal purposes. For example, an audit can serve as the basis for a declaration of compliance of the internal quality management system with the requirements of international quality standards (Jones 2017, 528). The development of an internal audit as an integral part of the internal control system is primarily needed for continuous operational control of activities and effective management.

Internal audit of the management system solves the following tasks:

- Analysis and elimination of the causes of the recognized deviations.
- Confirmation of the compliance of the organization's activities and their consequences in the management system with the established requirements.
- Evaluation of the effectiveness of the management methods.
- Preventing the occurrence of quality problems.

- Evaluating the personnel awareness of the goals, objectives and requirements described by the documents of the management system.
- Confirmation of the implementation of corrective and preventive actions.
- Determination of ways to further improve the quality management system.

The organization and planning of internal audit consist of the distribution of responsibility and authority for its implementation. The organization's management ensures the independent conduct of internal audit and analysis of the QMS. Stakeholders, shareholders and interacting parties in the process of internal audit and its stages are indicated in the matrix of distribution of responsibility (Table 4). Before conducting an internal audit, it is necessary to fill out an ISO 9001:2015 questionnaire. The questionnaire serves as a guide for successful audit preparation.

The assessment of the provided information is used to determine the company's readiness to conduct a certification audit for compliance with the requirements of ISO 9001-2015.

Suggestions and recommendations based on the questionnaire help improve the efficiency of the internal audit process and the internal control system. Enhancing the effectiveness of an internal audit largely depends on the correct method of its work. An internal audit provides audit evidence. The evidence obtained must be objective, as it can influence decisions regarding the achievement of the goals of an enterprise as a whole and its divisions. Errors and inconsistencies that can affect customer satisfaction are identified during an internal audit.

Responsible persons →	Operations Director
	Operations Manager
	Technical Director
	Head of Quality Control Department

Stages ↓					Audit Team Leader	Head of the audited unit
1. 1 Development of a draft annual program of internal audits of the Integrated Management Systems (IMS)	I	A	A	E	I	
2. Approval of the annual program	I	D	D	A	I	I
3. Preparation of internal audit plans				E	I	
4. Approval of internal audit plans		D	D	A		I
5. Preparing information on audited units and holding a meeting with audit team leaders				E	I	A
6. Preparing the audit team for the audit				A	E	A
7. Conducting a preliminary meeting in the auditee					E	A
8. Collection and verification of information				I	E	A
9. Conduct a closing meeting					E	A
10. Registration of audit results				I	E	I
11 Development of the corrective action plan (CAP)				A	I	E
12. Assessment of CAP for sufficiency				E	I	I
13. Implementation of the CAP					I	E

14. Checking the execution of CAP		I	I	A	E	A
15. Assessment of the effectiveness of CAP		I	I	I	E	I
16. Analysis of the results of audits and the implementation of the IMS internal audit program at the end of the year	I	I	I	E	I	I

Table 4. Matrix of distribution of responsibility by stages of the procedure "Internal audit of management systems."

Legend:

- D - responsibility for decision making.
- E - responsibility for execution.
- A - responsibility for assistance.
- I - getting information.

The internal work to improve the QMS in the company includes:

- Work planning.
- Creation of a working group.
- Execution of works according to the work schedule.
- Development of stages to improve the QMS in the company.
- Improvement of the company's internal audit.
- Control of the timing and quality of implementation.

6 CONCLUSION

Quality Control is an essential function for quality management system in an enterprise. The ISO 9001 standard is a business management tool built on sound principles that improve the organization's performance and reduce risks.

The quality management system works in conjunction with all enterprise activities (technical, organizational, technological, legal, economic, social). It covers the

work of the personnel of all operations departments that provide material and technical supply (procurement), design, production, testing and product control, labelling, preparation of quality documentation, conservation, transportation, packaging, storage, delivery, and disposal.

The development and performance of a QMS is a distinct set of tasks including different aspects of the organization, including paper flow, staff management, operations subsystem, intra-communication, strategic control subsystem, logistics subsystem and purchasing subsystem.

Therefore, the development and implementation of QMS is a very laborious and lengthy process, which, as a rule, is implemented in several stages. However, the typical scheme is as follows. The management of the organization determines the goals, policy, and commitments in the field of quality at the first stage of QMS development. An essential step is that the policy serves as the foundation for deciding the objectives required to maximize product consistency; the quality policy is integrated into the company's general strategy and vision.

The process of implementing a Quality Management System includes a whole range of works. All this can affect various aspects of the enterprise. The implementation process affects the subsystems of the Quality Management System, the logistics subsystem, the production subsystem, the strategic management subsystem of the company, the personnel management subsystem, and many others. It can be concluded that the need to implement a quality management system is a rather laborious and time-consuming task.

When creating a QMS, the Operations Director issues an order to start work on the quality system. This indicates: the purpose and time of commencement of work; the responsibilities of the implementation of the quality system from the management of the organization; the composition of the working group on the implementation of the quality system. The responsibilities of the Operations Director include the general direction of the work and making strategic decisions on the development and implementation of the ISO standard. The leader, as a rule, is responsible for the result of the work.

In most cases, the development and implementation of a quality management system are carried out in several stages:

- Analysis of the current situation in the enterprise, as well as personnel training.
- The development of the necessary documentation and changes in the schedule and working conditions of employees.
- An internal audit of the quality management system.

Following these stages is a time-consuming process that includes the implementation of complex and voluminous work. The most extensive and most demanding step is the change in the schedule and the development of the quality manual documentation for the enterprise's employees. The first stage is the most critical when implementing this system. The development and subsequent implementation of quality management is an essential and vital task.

The quality management system increases customer satisfaction and creates the market demand due to the stable quality of the product or service. This is an excellent position for competition in the market. An organization should always adhere or increase an established level of quality, as a negative process can adversely affect company image and success. An efficient QMS will help to control the quality of products and services at the required level.

REFERENCES

ISO 9001. 2015. Quality Management Systems – Requirements. The International Organization for Standardization.

Freeman, G. 2019. What is Quality Management and Why Does it Matter? Quality Magazine, BNP Media. https://www.qualitymag.com/articles/95237-what-is-quality-management-and-why-does-it-matter. 5.04.2021.

Feigenbaum, A. 1990. Federal Total Quality Management Handbook, Appendix 1A: “How to Get Started”. http://www.jdunman.com/ww/Business/TQM/Feigenbaums%2040%20steps%20to%20Quality%20Control.htm. 5.04.2021.

Feigenbaum, A. V. 1991. Total quality control. New York, USA: McGraw – Hill, Inc.

ISO 19011. 2011. Guidelines For Auditing Management Systems. The International Organization for Standardization.

ISO 31000. 2009. Risk Management – Principles And Guidelines. The International Organization for Standardization.

The International Organization for Standardization. 2014. The ISO Survey of Management System Standard Certifications – 2014. Executive summary. https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/iso_survey_executive-summary.pdf. 8.04.2021.

Lai, K., Cheng, T. 2009. Just-in-Time Logistics. Surrey: Gower Publishing Limited.

Hoyle, D. 2007. Quality Management Essentials. Oxford, UK: Elsevier Limited.

Juran, J. M. 2016. Juran's Quality Handbook: The Complete Guide to Performance Excellence, 7. ed. New York, USA: McGraw-Hill book co.

Basovskiy, L. E. 2020. Quality management: textbook. 3rd Edition. Moscow, Russia: INFRA-M.

Jones, E. 2017. Quality Management for Organizations Using Lean Six Sigma Techniques. Routledge; 1st edition.

Appendices

Appendix 1. Schedule for improving the quality management system

Name of the event	Number of days	Responsibility for implementation and control	Deadlines
Creation of a working group	3	Deputy General Director	06.08.2021
Work planning	5	Quality Council	07.08.2021 - 10.08.2021
Preparation and holding of meetings for the assessment of the QMS	5	Head of Quality Control	11.08.2021 - 15.08.2021
Customer satisfaction surveys	7	Heads of Repair and Quality Control Departments	16.08.2021 - 22.08.2021
Analysis of the needs of customers, personnel, suppliers	3	Heads of Repair and Quality Control Departments	23.08.2021 - 25.08.2021
Analysis of the current QMS	4	Director of c Company X, head of the QCD, chief engineer	26.08.2021 - 29.08.2021
Analysis of suggestions for improvement	3	Head of QCD, Chief Engineer	30.08.2021 - 2.09.2021
Improving the change control and analysis plan	5	Head of QCD	3.09.2021 - 7.08.2021

Modernization of the plan for responding to possible risks	3	Head of QCD	08.09.2021 - 10.09.2021
Planning to achieve quality objectives	5	Head of QCD	11.09.2021 - 15.09.2021
Identifying suitable resources	5	Head of QCD	16.09.2021 - 20.09.2021
Conducting training on a new quality standard	7	Head of QCD	21.09.2021 - 27.10.2021
Analysis of activities from the side of management	4	Company X Director	28.09.2021 - 31.10.2021
Internal audits	14	Head of the QCD with the support of the specialists of the audit company	1.10.2021 - 14.10.2021
Elimination of inconsistencies	8	Head of QCD	15.10.2021 - 22. 10.2021
Preparing for a certification audit	10	Director of Company X, head of the QCD, specialists of the audit company	23. 10.2021 - 02.11.2021
QMS certification for compliance with the requirements of ISO 9001: 2015	14	Representatives of the certification company accompanied by the audit by the specialists of the audit company	03.11.2021 - 16.11.2021

Appendix 2. Block diagram "Analysis by senior management".