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Recertification of a Quality Management System based on ISO 9001 - is it a must for a modern manufacturing company?

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Abstract
The ISO 9000 series of standards are among the best-known standards developed by the International Organisation for Standardisation ISO. They provide guidance and guidelines for companies and organisations that want their products and services to satisfy customer requirements and their quality to be continuously improved. However, the need for recertification of the Quality Management System (QMS) based on ISO 9001 is increasingly being discussed by managers. The questions asked are: is it necessary to have such a certificate in order to maintain high product quality and customer satisfaction? What is the balance of benefits and losses for maintaining a certificate of this standard? The authors of the paper will try to answer these questions based on the experience of a medium-sized metal manufacturing company.

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1. Introduction

The implemented and certified system can bring many benefits. However, it should be noted that these benefits can only be seen if the Quality Management System (QMS) is skillfully targeted. Theoretically, the introduction of QMS should be common, with minimal costs and significant benefits. Unfortunately, in organizational practice there are many obstacles that destroy this ideal image of an organization operating on the basis of the ISO 9001 management model (Pacana and Ulewicz 2020; Anttila and Jussila 2021).

In the early 2000s, there was a general view among entrepreneurs that it was necessary to have a QMS in order to meet the quality requirements in a systematic way, as they saw it as a very effective tool to achieve satisfaction not only among customers, but also among employees, suppliers, owners and society (Midor, 2008; Amesem, 2015; Trela, 2015). The ISO 9000 series of standards continues to provide guidance and tools for companies and organizations that want their products and services to meet customer requirements consistently and their quality to be at an increasingly high level. The most important ISO standard in the 9000 series is ISO 9001, which defines the criteria for a Quality Management System and is the only standard in the series that can be certified (although this is not a requirement) (Committee 09, 2021; Fonseca, 2016).

The ISO 9000 series standards has been in operation for more than 30 years and are still very popular among the standards issued by the International Organization for Standardization ISO. Since the publication of the first standards of the ISO 9000 series in 1987, there have been several significant changes to the content. The most important of them took place in 2000, where there were significant changes to the structure of the standard, a process approach was introduced and ISO 9002 and 9003 were abolished. On September 15, 2015 the International Organization for Standardization ISO published a new edition of ISO 9001. It was introduced to the Polish Standards by Polish Committee for Standardization (Polski Komitet Normalizacyjny – PKN) by the recognition method on October 07, 2015 as PN-EN ISO 9001:2015-10 - English version, Quality management systems - Requirements. The publication of the Polish language version of ISO 9001:2015 was released in the middle of 2016 (PN-EN ISO 9001:2015-10). This standard introduced several significant changes in relation to the previous one, including the occurrence of risk management, even greater empowerment of the customer,

a stronger emphasis on motivation and an increased role of top management in the implementation of the requirements of the standard. The ISO 9001 standard can be applied to any organization, regardless of the industry in which the company operates. There are currently more than one million companies and institutions in more than 170 countries that are certified according to ISO 9001. Figure 1 shows the number of certificates of conformity to ISO 9001 issued to Polish companies from 1993 to 2017 (Sujová and Čierna 2018; Strecuła et. al 2017)

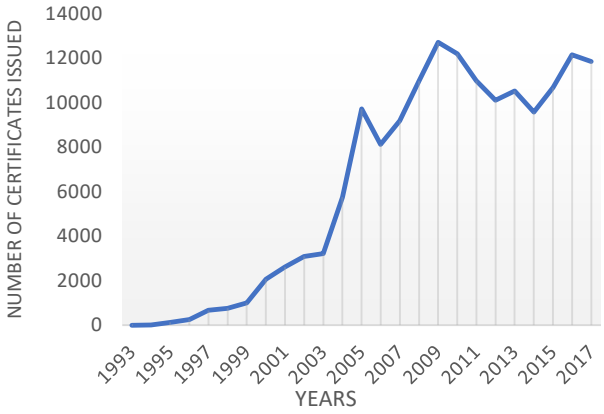

Fig. 1. The number of certificates of compliance with ISO 9001 issued to Polish companies over the period 1993-2017.
Source: Own study based on (Committee 09, 2021)

While analyzing Figure 1, it can be seen that the highest number of certificates issued took place between 2008 and 2010. In 2017, 11846 certificates were granted to Polish companies (PN-EN ISO 9001:2015). Since 2010 we can see a significant decrease in the interest of entrepreneurs in QMS certification. Another important question is the number of companies certified before 2015 that decided to recertify their systems according to the requirements of ISO 9001:2015. Figure 2 shows this relationship. All companies that were certified before the introduction of the new edition of the standard had a three-year transition period to adapt their management system to its requirements (Amesem, 2015).

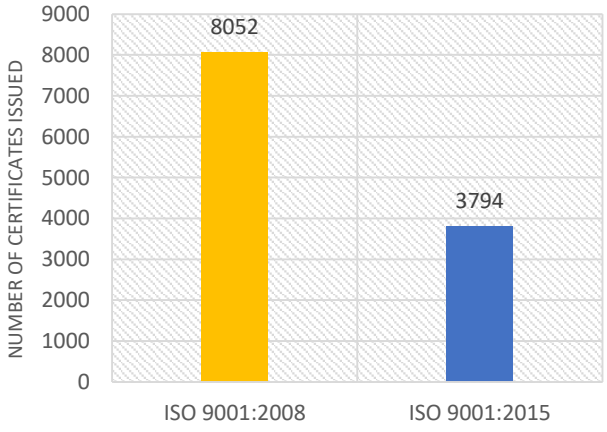

Fig. 2. Number of ISO 9001 certificates of 2008 and 2015 granted to Polish companies.
Source: Own study based on (Committee 09, 2021)

It can be clearly observed from the data presented within Figure 2 that less than one in two companies have decided to undertake re-certification to the 2015 ISO 9001 standard. This may suggest that companies are resigning from the certificate, believing that there is no longer as much pressure from customers to have such a quality management system. Looking at the example of the company analyzed in the paper, it can be concluded as well that the reasons for not undertaking the system recertification were caused by the economic situation of the companies.

However, it is generally accepted, having a certified management system ceases to be seen only as an aspect of competitiveness and is slowly becoming a necessity resulting from customer pressure. More and more organizations are starting to treat such a system not only as a mechanism to achieve the assumed organizational performance, but also as a starting point for the construction of more complex, integrated management systems. The international ISO 9001:2015 standard favors this. As a large number of organizations have already implemented a QMS based on ISO 9001, it seems advisable to reevaluate the implementation conditions and recertification as well as the planned and achieved benefits to enable the skillful implementation of such a system in the medium-sized enterprises (Pacana and Ulewicz 2020; Heras-Saizarbitoria et. al 2016; Kot et. al 2020; Nowicka-Skowron and Ulewicz, 2016; Klimecka and Ingaldi, 2020, Ulewicz et al., 2021). Having such a quality management system means, among others the implementation of systematic process modeling techniques (Pietraszek and Goroshko, 2014), which significantly improves the prediction of process behavior, and thus improves also the quality of industrial recipients at further stages of the processing chain (Zorawski et al., 2008; Ulewicz et al., 2014; Szczotok et al., 2017, Bołos and Midor 2018; Jonsta et al., 2016; Klimecka et al., 2021) and end recipients with particularly high requirements, e.g. the biotechnology industry (Skrzypczak-Pietraszek et al., 1993).

The aim of the paper was to analyze the need of the recertification of a Quality Management System based on ISO 9001, which was carried out on the experience of a medium-sized metal manufacturing company. On this basis, it was assessed whether it is worth recertifying QMS nowadays and what this recertification means for enterprises.

2. Identification of the research problem

The research problem of this paper is to find an answer whether it is necessary for a contemporary medium-sized enterprise in the metal industry to maintain a certified quality management system in order to keep its products at the current level of quality and maintain customer satisfaction.

The research methods used in the paper are as follows: source data analysis, data analysis provided in a metal gear transmission manufacturing company, direct interview.

Characteristics of the examined enterprise were performed, taking into account the number of ISO 9001 certifications for basic metal and fabricated metal products industry and gear transmission manufacturing process. 4 main procedures that allow it to achieve a stable production process, in terms of

quality and repeatability, were presented. There was also a discussion of the results in terms of the quality of manufactured products and the operation of QMS in the research enterprise.

3. Characteristics of the research subject

The research problem was analyzed on the example of a manufacturing company focused on gears used in the drives of equipment operating in the mining, crane and agricultural industries. The second production keystone of the company is the delivery of machining and heat treatment services to contractors from other industries, both domestic as well as German, Czech or Ukrainian. The production plant, where the analysis was carried out, has a very extensive experience in the production of spare parts for the automotive industry. In the 1960s and 1970s, it was a leading manufacturer of gearbox and rear axle parts for STAR, JELCZ and BERIET cars. In the 80s and 90s, it gradually stopped production for the automotive industry and entered the segment of production for the mining industry. The beginning of the 21st century is a period of a difficult stage of acquiring new contractors, not only domestic but also foreign ones. In connection with the above, the company's Management Board decided to introduce the ISO 9001 Quality Management System. Thanks to the previously introduced recommendations for the work of individual organizational units, the process of preparation for the certification audit ran very quickly. The certification audit was conducted by DNV in 2006, with a positive result. For the next six years, all the company's organizational units followed the procedures required by the ISO 9001 management system. The year 2012 brought changes in the Management Board's approach to the continued functioning of the ISO 9001 quality management system in the company for purely economic reasons. As a result, a decision was taken not to further recertify the system. However, the most important procedures necessary for the continued operation of the plant were retained, including in particular the design, technology and quality control departments. Furthermore, the procedures related to marketing, purchasing, production and the personnel department were maintained. The company analyzed continues to apply the procedures necessary for the efficient operation of the plant despite the lack of an up-to-date certificate.

The description of the actions taken by the company, as a consequence of which, in 2012, it resigns from further maintenance of the certified quality management system, confirms the mood prevailing at that time in the majority of Polish companies, as it can be seen in Figure 1, where the number of certificates granted at that time significantly decreases. Taking into account the metal industry in 2018 - 2019 it can also be seen a further significant decrease in the interest of companies in quality management system certification - Figure 3.

As previously mentioned, while abandoning the recertification of the QMS, the company has left some procedures that enable it to continue to maintain the level of quality required by its customers. In order to fully understand which procedures have been maintained, a brief characterization of the gearbox transmission manufacturing process will be presented.

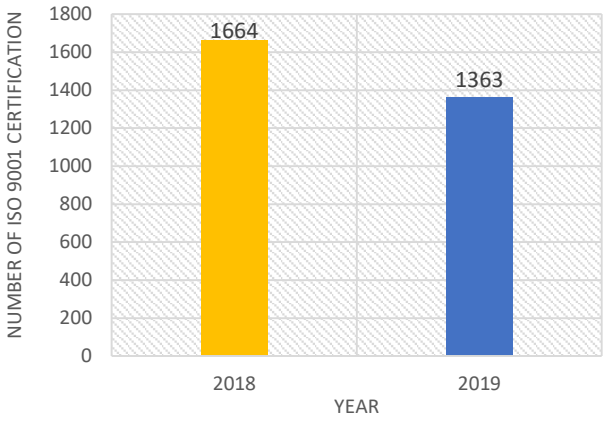

Fig. 3. Number of ISO 9001 certifications for Basic metal and fabricated metal products industry in 2018 - 2019.
Source: Own study based on (Committee 09, 2021)

4. Characteristics of the gear transmission manufacturing process

The production of gear transmission systems usually takes place from input materials such as:

- Iron and steel castings from which gear transmission bodies are usually made.
- Forgings (drop-forged or slow-forged), which are the main input material for the production of gears.
- Sheets as an input material from which mainly covers are made.
- Rolled or forged bars used as an input material for the production of gear shafts.

The technological process, as an essential part of the production process, is generally divided into two types:

- A technological process during which there is a change in the shape of an object, a change in its dimensions, during machining, and a change in the mechanical properties of materials occurring during heat treatment. An example of a technological process is the transformation of an input material (e.g. a slow-forged forging) into a completed product (e.g. a gear wheel).
- An assembly technological process involving a specific set of operations necessary to join individual parts or subassemblies into an assembly (e.g. a gear).

Production of machine parts (gear elements, bodies, casings, covers) assembled in gear transmissions is very diverse, both in terms of difficulty of manufacturing and maintaining the required quality, as well as costs of manufacturing individual components of a given gear transmission. During the technological development, particular attention should be paid to the quality requirements of a given product and to minimising the costs of manufacturing the given components.

The most common types of toothing used in gear transmissions are gears and shafts with straight and helical (oblique) teeth, most often used in helical and planetary gears. The technological process of manufacturing this type of toothed elements is very complex in terms of the number of individual

operations necessary to properly manufacture each wheel or shaft.

An operation is a part of the technological process on one piece (object), at a specific workstation (machine tool, assembly station), by one worker or a team of workers. An operation is the basic unit of production planning.

An exemplary list of operations of the technological process of making a gear wheel.

Gear wheel z=51; m=12; β=8°; toothing accuracy class 7; material 40 HM, tempered, teeth surface hardened. Input material slow-forged forging.

Framework technological process of production:

- Check material.
- Turn roughly with an allowance of 3 mm per side on all surfaces of the wheel.
- Harden to 260 - 280 HB.
- Finish turning all surfaces leaving a 0.25 mm allowance per side.
- Milling of toothing with 0.6 mm allowance in tooth thickness.
- Chamfer the toothing.
- Harden the toothing by induction to 50-54 HRC, to a depth of 1.6 – 1.8 mm.
- Grind the hole according to the drawing.
- Grind the toothing according to the drawing.
- Check the workmanship.

Properly defined rules of proceeding in the execution of individual operations of the technological process and their absolute observance during its execution greatly simplify the maintenance of a high-quality level of manufactured products. Simplification of the technological process (limiting the number of operations) ensures reduction of the intensity of inter-operational control (control after each operation), causing cost reduction. The most important is the reduction of the number of potential errors that may occur during the control of individual details during the production process.

5. The characteristics of the company's maintained procedures

The company has maintained 4 main procedures that allow it to achieve a stable production process in terms of quality and repeatability. These procedures are briefly described below.

Documentation workflow.

The purpose of the procedure is to determine the manner and methods of proceeding in the workflow of documents from the receipt of the enquiry, through the calculation of the cost of production of the product, acceptance of the order, realisation, control and dispatch of the finished product to the customer.

Production and archiving of technological documentation.

The purpose of the procedure is to determine the principles of storage and archiving of technological documentation, including:

- instructions of technological processes,
- construction documentation of the manufactured products,
- documentation of special tooling.

Technological documentation is a set which contains all the necessary information and recommendations needed to carry out the technological process of the product correctly. The document containing all the necessary information for the correct execution of the technological process is the processing instruction, which includes:

- the type and form of the input material,
- description of individual operations, specifying the positions at which they are to take place,
- norms of working time of carrying out the given operation,
- setting charts of machine tools,
- notes on both inter-operational and final checks. Storage and archiving of the above-mentioned documentation is conducted in a harmonious and well-ordered manner.

Archiving of individual machining instructions is supported by a special computer software that allows efficient searching of individual items (machining instructions).

Rules of proceeding in the case of modifications to technological documentation.

The essential aim of the process is the procedure for introducing changes to technological documentation, which determines the execution of production on the basis of current constructional and technological documentation. Changes are introduced and supervised by the technological department.

Examples of reasons for changes in processing instructions:

- change in own or customer's design documentation (e.g. change of material grade),
- change of technological process (e.g. caused by increase of productivity),
- change in customer requirements and expectations (e.g. introduction of non-destructive testing).

Input, inter-operational and final control.

Input control involves checking the input materials used in the technological process of the product. Bars, forgings and scoria are checked before the production of the product or products before pre-processing. Castings are checked by carrying out a scribing operation to determine the amount of allowance for machining and to determine the machining bases necessary for setting the workpiece on the machine table.

The purpose of the inter-operational control is to check, during the execution of technological operations, the correctness of the execution of individual operations. The purpose of this type of control is to prevent further processing of faulty semi-finished products.

The analysed plant has two types of inter-operational control implemented. An inter-operational controller employed in the control department and a production worker with a self-inspection. The self-inspection of production workers is granted by the Head of Quality Control at the request of the head of the production department, these are employees with many years of work experience, distinguished by great expertise and commitment to the work of the plant.

The final inspection, the task of which is to check the finished products intended for sale or assembly, is located at the end of the technological process. After checking the product, the final control issues quality certificates, guarantee cards for the gear transmissions manufactured, or, at the customer's request, measurement cards (actual dimensions made during processing).

Rules of proceeding in case of a non-compliant product.

Separation of the principles of proceeding with a non-compliant product with the documentation is aimed at ensuring that the non-compliant product will not be admitted to the further production process and, in this way, the number of deficiencies of finished products will be reduced. The procedure of dealing with non-compliant product created during the production process is as follows.

In the case when a nonconformity has been detected at any stage of the production process, the employee should immediately inform the Quality Control Manager or another person authorised by them. The technological department, to which the information about the noncompliance is sent, analyses taking corrective steps and estimates the costs of repairing the given semi-finished product. The repair technology should take into account both minimising the costs of the repair process and maintaining the quality and durability parameters of the manufactured detail. The found inconsistency and the proposed process of removing the defect is passed on to the ordering party (customer). After the acceptance of repair guidelines, the repair process of the product is carried out under strict inter-operational control. In case of minor deviations the decision to allow further production is taken by the Technical Director, signing the agreement in the book of deviations of the inter-operational control.

6. Discussion on the results of data analysis

The primary objective of the operation of a manufacturing enterprise should be to maintain a high level of product quality. The quality of products should satisfy the customer's needs through the application of management methods which are a guarantee of maintaining a sufficiently high level of quality. Increasing the competitiveness of the enterprise by achieving a higher and higher quality level of products should be clearly justified economically, otherwise the enterprise may be burdened with unforeseen costs, significantly reducing the enterprise's profit.

The interview with the top management of the company shows that the reasons why the company resigned from the recertification of the QMS according to ISO 9001 are as follows:

1. Reducing costs:
- audits,
- system maintenance in the company,
- elimination of records required only for audits, which significantly affected work efficiency.
2. Lack of tangible benefits from possessing ISO:
- insignificant interest of customers in possessing the ISO 9001 certificate.
3. The same possibilities of ensuring a high level of product quality without holding the certificate.
4. The possibility to continue to apply the main procedures introduced during certification.

The company also noted the disadvantages of not having a certified QMS. These are:

- The "relaxation" of the workforce (lack of audits) causing, among other things, an increase in the number of cautions to employees who do not follow the rules of the plant.
- The insignificant worsening of the company's image in the international and domestic arena, not affecting the maintenance of regular customers, as well as the acquisition of new contractors.

7. Summary and conclusion

Answering the question from the title of the paper, on the basis of the conducted analysis, it can be stated that a modern enterprise, in order to maintain a high level of quality of its goods, is not required to have a certified QMS. However, it is worth noting and asking another question whether the developed system in the enterprise allowing for continuous maintenance of high product quality would be possible without prior introduction and certification of the Quality Management System compliant with ISO 9001. The answer given by the authors of the paper is negative.

It should not be forgotten that quality management in the organisation should be first of all an idea which, of course, focuses on the customer needs, but by changing the way of thinking and, above all, on the cooperation of all employees, including the top management, what is provided by the implementation and certification of the QMS (Amesem, 2015). However, many companies treat the ISO 9001 certificate only as a marketing element, as a result of which after the implementation of this system there are no corrective, adjustment or improvement actions taken in the organisations. This is exemplified by the savings the company makes as a result of eliminating records required only for audits, what should not be the case in a well-functioning QMS.

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基于 ISO 9001 的质量管理体系重新认证 – 现代制造公司必须这样做吗？

關鍵詞
ISO 9001:2015
质量管理
金属工业
重新认证

摘要
ISO 9000 系列标准是国际标准化组织 ISO 制定的最著名的标准之一。 它们为希望其产品和服务满足客户要求并持续改进其质量的公司和组织提供指导和指南。 然而，管理人员越来越多地讨论重新认证基于 ISO 9001 的质量管理体系的必要性。 提出的问题是：是否有必要拥有这样的证书才能保持较高的产品质量和客户满意度？ 维持本标准证书的收益和损失平衡是多少？ 本文的作者将尝试根据一家中型金属制造公司的经验来回答这些问题。