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Contemporary issues of quality management: relationship between conformity assessment and quality management

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Abstract

Conformity assessment is associated with quality and it can be used to assess the quality if explicit requirements for product quality exist. The aim of the paper is to analyse and evaluate relationship between conformity assessment and quality management. Research is done by studying and evaluating each component of the quality management, meanwhile identifying the actions to be taken in each of them. After evaluating the elements of quality management, the activities carried out within its framework and comparing them with the product conformity assessment activities, it is proved that conformity assessment is closely related to quality management, ensuring that compliant and reliable products are placed on the market, delivered for use and used.

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1. Introduction

Understanding the concept of ‘quality’ is not ambiguous; almost every individual perceives it subjectively and describes it differently. The general requirements set for part of products ensure their safety and reliability. However, they may differ from the requirements related to quality.

Quality management plays an important role in manufacturing of any product. When planning, acting, monitoring and evaluating it, the manufacturer performs a set of procedures in order to produce specified quality products, because the quality of products can be a decisive factor for the consumers taking decision about their purchase. The

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manufacturer evaluates product compliance with the initially set requirements and ensures that the manufactured product is safe. By performing conformity assessment during manufacturing process, the manufacturer observes the principles of quality management.

Nowadays solutions and technologies used in manufacturing are different from what they were in the industrialization era, thus conformity assessment for design and manufacturing stages and during usage become more significant. Manufacturers assess the product conformity with the initial requirements and ensure that the product being manufactured is safe and does not cause harm to human health, life and the environment.

Knowledge and understanding of conformity assessment and its related issues among entrepreneurs and the society is not sufficient, especially about the interrelation of quality and conformity assessment. Some individuals believe that the results of conformity assessment reflect the product quality. While others think that conformity assessment proves the product quality or reliability and conformity with certain requirements. At the same time, when performing the conformity assessment during the process of production, the manufacturer complies with quality management principles. Thus conformity assessment is associated with quality and it can be used to assess the quality if explicit requirements for product quality exist. But the question about the interrelation between these two concepts is still open. Therefore, the authors figured out necessity to evaluate associated concepts to make certain what interrelations between quality management and conformity assessment exist.

The aim of the paper is to analyse and evaluate relationship between conformity assessment and quality management.

Research is done by studying and evaluating the concepts 'quality', 'quality management' and 'conformity assessment', and evaluating each component of the quality management separately. Meanwhile the actions to be taken in each of them have been identified. After evaluating the components of quality management, the activities carried out within its framework and comparing them with the product conformity assessment process stages, it is proved that conformity assessment is closely related to quality management, ensuring that compliant and reliable products are placed on the market, delivered for use and used.

2. The concept of 'quality'

Quality is not a recent invention; it has been in existence for as long as the human race (Elshennawy, 2004). The Latin word 'qualitas' is translated as 'quality', 'characteristics', 'type', or 'order' (Geiger, 1995). It is derived from the word 'qualis', meaning 'what the real thing is' (Bergman & Klefsjö, 2010; Feng & Kapur, 2008) thus showing that quality characterizes the actual nature of an object (a product, service, process, etc.). Other authors also have noted that quality refers to those characteristics that make an object (mostly a product) suitable for a certain use (Giaccio, Canfora, & Del Signore, 2013; Kara, 2005).

The understanding of the concept of 'quality' is subjective. Every individual understands and perceives it differently, as shown by the different interpretations of the concept found in the literature. Over the years a number of definitions of quality have been developed, each reflecting the particular context in which it was formulated. Several authors have pointed out its diverse interpretation.

Crosby (1980) defined the concept of 'quality' as 'conformance to requirements', pointing to the need for conformity assessment to ensure that the product complies with the specified requirements. In the book "Quality Without Tears" he provided further explanations for his definition: 'conformance to requirements, not goodness' (Crosby, 1995). By this definition, the author tried to draw attention to the fact that quality is not something general, but on the contrary – it can be specifically identified and measured, thus confirming his view that requirements should be clearly defined in order to avoid any misinterpretation, and also consecutive measurements need to be performed to assess compliance with these requirements. When non-compliance is found, it is perceived as lack of quality (Crosby, 1980). In Crosby's definition it is indicated that explicit requirements shall be set for the product quality assessment, then the actual compliance of the product with the requirements shall be compared, and on the basis of this comparison, the quality shall be assessed. These activities are characterized by a set of conformity assessment activities. This is one of the definitions that clearly indicate the interrelations between quality and conformity assessment, and the fact that conformity assessment can be one part of the quality assessment process.

The original definition of the concept of 'quality' by Juran (1970) was 'fitness for use'. Dale, Van der Wiele and Van Iwaarden (2007) used a similar interpretation of the concept – 'fitness for purpose'. These definitions show the

degree to which the product in use performs in accordance with its intended purpose (Halachmi & Bouckaert, 1995). The authors believe that the focus on ensuring fitness helps to avoid setting excessive requirements. At the same time it is an indication of the importance of conformity assessment in quality assurance and it confirms the need to perform it.

After examining the literature where the definition of the concept of ‘quality’ is included, it seemed that the most appropriate for the research are definitions given by Juran (1970) (the original definition), Crosby (1980), Dale, Van der Wiele, and Van Iwaarden (2007), which include the reference to explicit requirements, their execution and evaluation, corresponding to conformity assessment activities.

In total, ninety five definitions were reviewed performing quantitative evaluation of terms included in the definitions of the concept of ‘quality’ (Arter & Russell, 2008; Besterfield, Besterfield-Michna, Besterfield, & *et al.*, 2002; Budyansky, 2009; Certo, 1997, Crosby, 2006; Deming, 1986; Freigenbaum, 1991; Giroux, 2006; Goetsch & Davis, 2006; Hoyer & Hoyer, 2001; Kara, Lonial, Tarim, & Zaim, 2005; Kearney, Byrne, & Markham, 1991; La Lopa, & Marecki, 1999; Lash, 1989; Oakland, 1993; Sower & Fair, 2005; Standard 9000, 2005; Summers, 2005; Wicks & Rothlein, 2009, etc.). Through evaluation the authors found that the most frequently mentioned terms are: ‘product’ – 56, ‘customer’ – 34, ‘service’ – 29, ‘requirement’ – 26, ‘need’ – 25, ‘satisfy’ – 20, ‘conformity’ – 15, ‘characteristic’ – 15, ‘ability’ – 11, ‘feature’ – 10, and ‘expectations’ – 9 times. On the basis of this evaluation, the authors have grouped the related terms and identified five groups of terms that describe the quality and then depicted the interrelations between them (see Fig. 1). The terms that are related to product quality and coincide with Crosby’s definition are bolded.

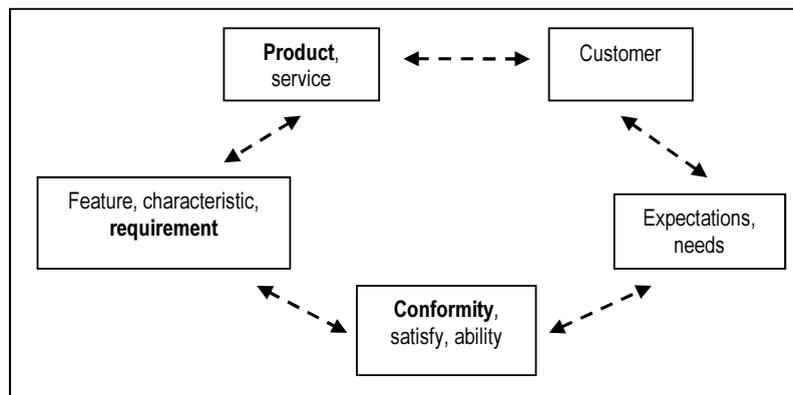


Fig. 1. The scheme of interrelations of the terminology related to the concept of ‘quality’

After analysing the definition and evaluation of the opinions about the concept of ‘quality’, it was concluded that most frequently the quality of a particular object (mostly a product) is assessed. That conforms to Kara (2005) and Van Kemendane, Pupius and Hardjono (2008) viewpoints. Requirements are one of the key aspects characterizing the quality, without them it is not possible to perform quality assessment. Requirements can be named also as ‘characteristics’, ‘features’, ‘standards’, etc. Comparing the requirements with the object, its compliance is assessed. To ensure manufacturing of adequate products and reliability of the conformity assessment procedures, also competent organizations / persons must be involved in the assessment process. Other authors named it as subject (Van Kemendane, Pupius, & Hardjono, 2008). As a result, it was concluded that the quality can be assessed objectively by taking into consideration the following aspects: object, requirements, compliance and competence.

Out of that the authors concluded that conformity assessment is associated with quality. There is strong linkage between them, because conformity assessment can be used to assess the quality if explicit requirements for an object (for example, a product) quality exist. And results of this assessment are credible for competent organizations / persons performing assessment process.

3. The concept of ‘quality management’

In order to build understanding of the concept of ‘quality management’, the authors compared different authors’ opinions (Juran & Gryna, 1998; Standard 9000, 2005, etc.). As a result, they found that quality management is necessary to identify, target, control and coordinate the various elements (aims, processes, resources, etc.) within the organization. Thus, quality management is the process whereby certain operations are performed to ensure the achievement of the objectives and improve the company performance.

At the same time, in the literature the authors found different types of quality management classification. In addition, taking into consideration that it is through the quality management division into specific activities (components) that connection with conformity assessment is sought, the authors initially identified quality management classifications in order to choose the most efficient and analyze it in depth.

One of the best known types of quality management classification was determined by Juran (1986), known as Quality Trilogy or Juran Trilogy. It is a set of three consecutive activities (planning control and improvement) that are repeated cyclically (Juran, 1986; Bisgaard, 2007; Godfrey & Kenett, 2007; Spurgeon, Marcinko, Mengele, & Lyman, 1990):

- quality planning – setting specific goals, identifying potential customers and their needs, defining the product features so that they meet customer needs, developing the process used for monitoring the process of manufacturing;
- quality control – meeting the quality objectives, conducting activities in accordance with the identified plan, evaluating performance, choosing the subjects that will be monitored and defining measurement units, taking measurements, assessing performance, determining the differences and defining further action;
- quality improvement – assessing the needs for improvement by identifying specific activities required, stating the activities and determining the causes of the problems, defining action required and assessing whether it will be sufficient to achieve the goal; performing repeated control.

In the literature also other types of quality management classification can be found. One of them is Three Spheres of Quality; this classification in activities (control, assurance and management) differs from Quality Trilogy and the actions to be taken (Foster, 2004):

- quality control – refers to monitoring of the missed opportunities, stability and performance of the processes, reduction of process variability, process optimization up to nominal measurements, sampling, preparation and maintenance of monitoring maps;
- quality assurance – refers to activities performed in order to guarantee product quality, provide an essential link with design, analysis of error types and impact, process improvement, product reliability and durability testing, etc.;
- quality management – includes all activities, including control and assurance activities (namely: planning quality improvement activities, creation of the organizational quality culture, training, retraining, etc.).

Nowadays, classification of quality management into four activities (planning, control, assurance and improvement) is most widely known, in accordance with the Standard ISO 9000: 2005. Such a set of activities is slightly different from previously mentioned quality management classification. Each of the activities under this classification includes the following (Standard 9000, 2005):

- quality planning – focused on setting quality objectives and clarifying the requirements, necessary operational processes and related resources in order to meet the quality objectives;
- quality control – focused on fulfilling quality requirements;
- quality assurance – focused on the belief that quality requirements will be met;
- quality improvement – focused on enhancing capacities for meeting the quality requirements.

After evaluating quality management classification in different literature sources, the authors believe that the most appropriate contemporary classification is given in the standard ISO 9000: 2005 “Quality management systems – Fundamentals and vocabulary”. The authors have approved a quality management classification as a consistent, continuous process where quality planning is recurrent next step after quality improvement; at the same time highlighting it visually (see Fig. 2). With this management approach it is possible to ensure continuous quality improvement.

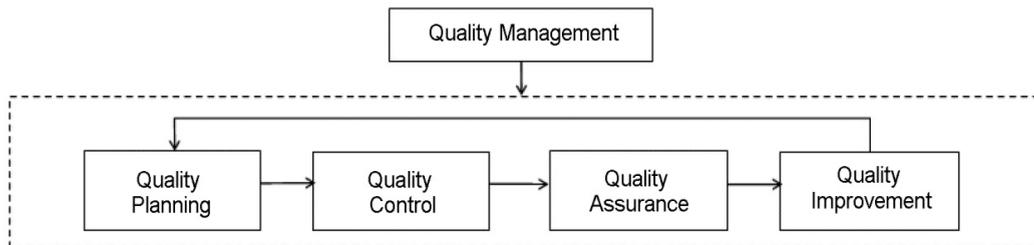


Fig. 2. Classification of the ‘quality management’ and links between classifications.

In order to identify the link to conformity assessment, each of the four quality management activities (planning, control, assessment and improvement) were analysed separately.

After evaluating the definitions of the concept of ‘quality planning’ (Goetsch & Davis, 2006; Juran & Gryna, 1998; Oakland, 1993, etc.) the authors conclude that quality planning relates to the following activities: product development, implementation of the idea, assessment and improvement. Quality planning is done both in the early stages of the organization and when identifying activities to be performed and setting new objectives in accordance with the findings in the quality improvement process.

Historically, the understanding of the concept of ‘quality control’ is associated with inspection, i.e. mandatory monitoring of the manufacturing process. With the development of technologies and the formation of the quality management science, the understanding of production monitoring has also changed – transferring from strict inspection of each product unit to general supervision of the manufacturing processes, which means not only the inspection of the product alone. Quality control was perceived as a systematized process in which each fault provides information not only about the particular product, but also about the manufacturing process as a whole and the need to improve it.

When evaluating the definitions of the concept of ‘quality control’ (Costin, 1994; Ebert & Griffin, 2000; Evans & *et al.*, 1990; Juran & Gryna, 1998; Oakland, 1993; etc.), the authors concluded that when implementing quality control the main tasks are: to ensure the compliance with the requirements and standards, to achieve the set objectives, to ensure product suitability for use and to meet customer expectations. Quality control is implemented by monitoring, analysis, measurements, comparison, management, harmonization, testing of operations and products, verifying their compliance with the requirements, acting in cases when non-compliance and deviations are detected. Controls are performed so that their results can be compared, analysed and used for decision-making. For objective controls, they shall be done regularly and in accordance with certain criteria. The authors believe that the nature of ‘quality control’ is best described by the statement of Juran and Gryna (1998: 24): “Quality control is a systematic process during which the actual quality compliance measurements are done, compared with the quality objectives and action is taken in the event of a discrepancy”, and the authors support the above statement.

Quality assurance has been rapidly improved in the last few decades. After the Second World War, inspection was widely used in manufacturing final inspection of manufactured products, identifying defective products and then disposing or recycling them. Quality assurance activities had to help monitor the implementation of the plan and evaluate customer satisfaction. When evaluating the definitions of the term ‘quality assurance’ (Certo, 1997; Costin, 1994; Evans & *et al.*, 1990; Juran & Gryna, 1998, etc.), the authors concluded that quality is guaranteed by ensuring product compliance with the specified requirements. It comprises both preventive and corrective actions. The definition given in Standard ISO 9000: 2005: “Quality assurance – part of quality management focused on

providing confidence about meeting the quality requirements” is considered to be the most appropriate. Quality assurance solutions may be defined by each organization in accordance with its discretion and necessity. The organizational activities can be arranged using a variety of quality control methods and management solutions (Mazais, Lapiņa, & Liepiņa, 2012).

After evaluating the definitions of the term ‘quality improvement’ (Costin, 1994; Juran & Gryna, 1998, etc.), the authors identified three ‘quality improvement’ objectives:

- 1) To reach a level of quality that is higher than the previous;
- 2) To increase the business opportunities, meeting the quality requirements;
- 3) To ensure the growth (development) of the business and act effectively.

Thus, quality improvement is a continuous process that focuses on improvement and development. Its mission is to improve business performance by identifying gaps/weaknesses and eliminating them, by discovering ways to improve operational efficiency and optimize resources.

In order to understand and identify the link between quality management and conformity assessment, initially quality management classification was evaluated in detail. Based on the evaluation and analysis of quality component definitions, the authors believe that the optimal quality control classification would be as follows: quality planning, quality control, quality assurance and quality improvement. At the same time it is emphasized that they are performed successively one after the other; and quality planning always is the next step after quality improvement. And, consequently, the link between quality management and conformity assessment should be sought in direct interrelation between quality management components and conformity assessment elements and activities performed within the process.

4. The concept of ‘conformity assessment’

After analysing the opinions about the concepts of ‘conformity’ and ‘assessment’ expressed in literature (dictionaries, etc.) and by different authors (Chase, Jacobs, & Aquilano, 2004; Evans & Lindsay, 1996; Sprancmanis & *et al.*, 2007; etc.), the authors concluded that the term ‘compliance’ means comparison of two objects, e.g. when the product is compared with the requirements initially specified for this product. The feature that shows conformity may manifest itself as harmony or similarity between the product and the requirements or performance meeting the requirements. The objective of conformity is to determine whether the end result (the manufactured product) corresponds to the initial requirements. It does not show the degree of compliance. After evaluating the definitions of the concept of ‘assessment’, the authors have concluded that assessment is actually a process that involves the following activities: identification, evaluation, calculation, measuring, etc. During these activities an object (product, process, etc.) compliance with the initial requirements is evaluated. The result of assessment is a specific value or object comparison. The authors’ evaluation of the concepts of ‘conformity’ and ‘assessment’ shows that ‘assessment’ is a process of comparison, during which the compliance of the object with the requirements is assessed, while ‘conformity’ means stating the fact that the object complies with the requirements.

In the European Union conformity assessment field, the definition given in the European Union regulatory acts is currently considered the leading definition: “Conformity assessment is the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled” (Regulation No. 765/2008, 2008: 35). This definition is based on the definition given in ISO/IEC 17000: 2005 “Conformity assessment – Vocabulary and general principles”. Also various authors have expressed their opinion about term ‘conformity assessment’ (Regulation No. 765/2008, 2008; Standard 17000, 2005, etc.). As example Redinger and Levine (1998) pointed out that in the broadest terms, ‘conformity assessment’ refers to the manner in which conformance/compliance to a given standard/regulation is determined. During the evaluation of the definitions and opinions of the authors, it was seen that they are very general and partly compliant and do not specify the means of conformity assessment.

The authors have consistently grouped the terms related to the concept of ‘conformity assessment’ denoting the same type of activity, highlighted those terms that most accurately and appropriately describe the concept, and displayed the links between the related terms (see Fig. 3).

The interrelations shown in the scheme in Fig. 3 confirms that conformity assessment is essentially a process that evaluates (compares) a product and its requirements. Conformity assessment process is adapted to a certain product or group of products, taking into account their specifics. In order to perform conformity assessment, there must be certain specific requirements for the product and for conformity assessment. This set of requirements is called ‘conformity assessment scheme’.

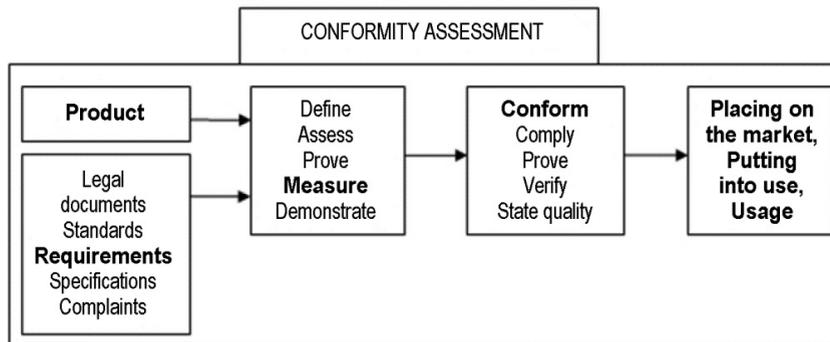


Fig. 3. The scheme of interrelations of the terminology related to the concept of ‘conformity assessment’ (Liepiņa, Lapiņa, & Mazais, 2013)

During conformity assessment process, evaluation is made using conformity assessment procedures. After conformity assessment, a decision about the product conformity or non-conformity to the requirements is taken. On the basis of a positive decision, a certificate of conformity is issued and appropriate label is attached to the products so that they can be placed on the market and delivered for use. Even if the product does not meet the requirements, a document certifying this fact is issued.

As a result, the authors conclude that conformity assessment process is complex and an important precondition for this process is the object (product, etc.) requirements. During the manufacturing of products, conformity assessment, including various quality methods, is of great importance for ensuring that only compliant and safe products are placed on the market. In addition, putting the product in use does not conclude everything; it is important that the product compliance with the requirements is ensured when it is used.

5. The relationship between ‘quality management’ and ‘conformity assessment’

One of the founders of modern quality management is Taylor who actively worked towards the development of production efficiency-enhancing techniques during the era of industrialisation. It was he who proposed to separate planning from manufacturing and manufacturing from inspection (Bergman & Klefsjö, 2010) in order to systematise and structure the activities to be done, as well as to perform their measuring. Thus, he indirectly proposed dividing quality management into smaller elements. The idea of product inspections spread throughout the world and was regarded as one of the key ways to ensure the quality of products. Nowadays it is also used as one of the conformity assessment activities. At the start of industrialization and mass production, the role of control (inspections) increased. Different types of standard measurements were often used for inspections.

On the basis of Taylor’s idea about inspection, the idea of sampling appeared because controlling the full range of products in a large facility is very difficult, almost impossible. Sampling has its roots in England in the 12th century, when one or several samples of the particular production lot were tested. On the basis of the test results the entire production lot was declared to be appropriate or inappropriate. This type of approach is considered as the basis for one of the conformity assessment modules – F module that regulates product verification. It is believed that the founders of the idea of sampling are Dodge and Romig (1998). Whereas Wald proposed to compare the total number of defective (faulty) products with the number of products tested, and on the basis of the results obtained declare the production lot to be appropriate or inappropriate, but if necessary, conduct an additional control (Bergman & Klefsjö, 2010; Shahani, 1979). This method is also used today for conformity assessment of large-

amount production lots. These facts clearly point to relations of management science with quality management and conformity assessment issues, as well as confirm the importance of conformity assessment activities.

After evaluating the quality management classifications, the courses of action to be taken, and comparing them with the conformity assessment activities to be performed, the authors concluded that conformity assessment is closely related to quality management. This interrelation is essential to ensure that only compliant and reliable products are manufactured and placed on the market. As a novelty the authors offer the scheme of interrelations between quality management and conformity assessment (see Fig. 4).

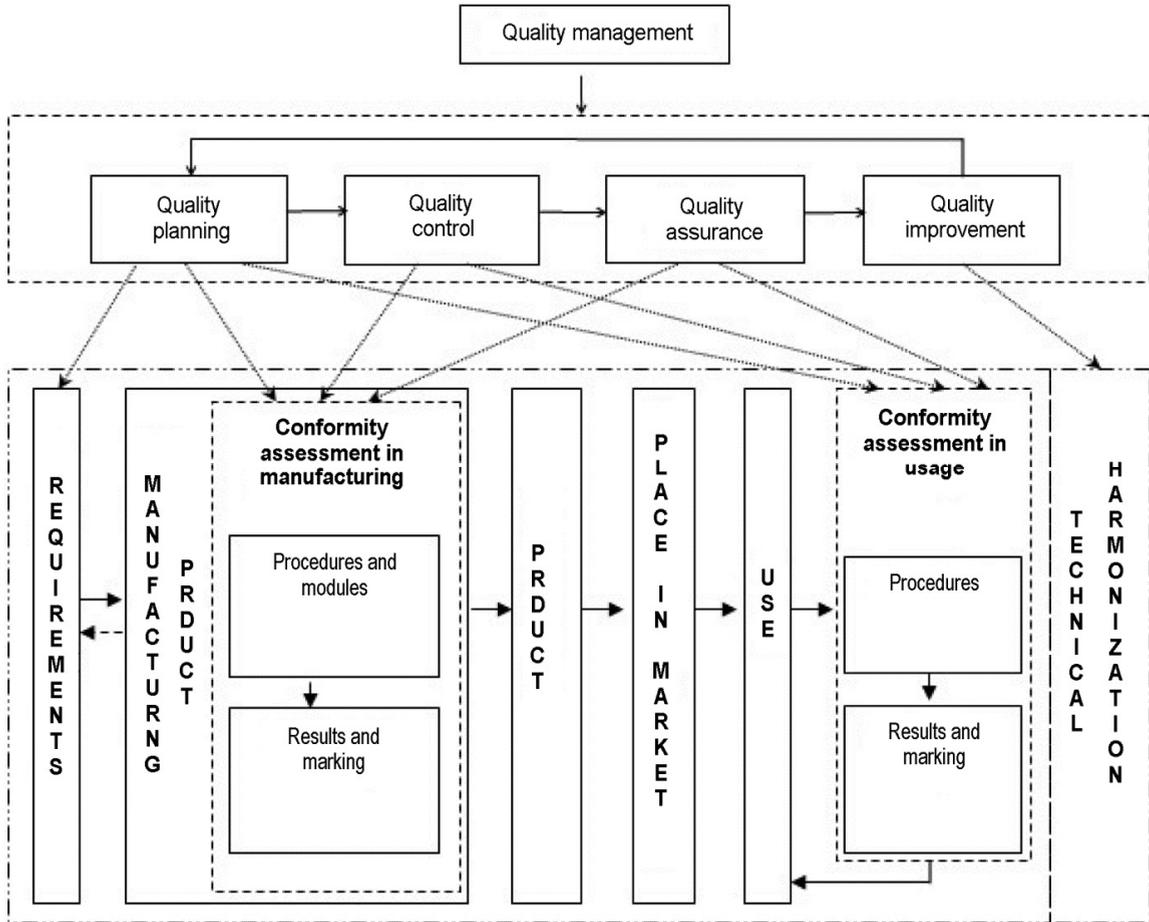


Fig. 4. The scheme of interrelations between quality management and conformity assessment

Nowadays, quality planning is often related to the standardization of activities performed (e.g., conformity assessment procedures), development and selection of procedures and methodologies. When planning quality improvement activities, the manufacturer evaluates which of the conformity assessment procedures are optimal in the particular situation. The conformity assessment body upon reception of a request to perform conformity assessment (e.g. type approval), evaluates and plans how conformity assessment will be organized, at the same time assessing the need for support procedures (calibration, testing) and attracting subcontractors for these activities. Whereas, during the quality planning stage the consumer evaluates the opportunity to continue using the product and perform its conformity assessment during its use, or to purchase another product.

In quality control, measurements are the key prerequisites for the assessment of the product compliance with the requirements and monitoring the production process. During the manufacturing process, it is possible to timely identify defective products with the help of the results of the measurements. During the product design and manufacturing phases, conformity assessment procedures are the key tools of compliance and quality control. During the use of products, quality control means conformity assessment procedures, such as repeated verification of measurement tools.

The role of quality assurance is to make the consumer believe that the operations during the manufacturing stage and the end product meet the quality requirements. When conformity assessment is performed, quality assurance does not apply to conformity assessment procedures, but to the way of organising the work of conformity assessment bodies. Conformity assessment process shall be organized so that the relevant requirements of legislation and standards are respected, the conformity assessment body has the necessary resources (staff, equipment, etc.), and the conformity assessment body's competence is confirmed upon accreditation, etc. So, creating the right environment and ensuring that conformity assessment is performed in accordance with the requirements will ensure objective and reliable results.

During quality improvement priority areas for action are identified, new goals and requirements are set. In the field of conformity assessment, quality improvement is attributable to technical harmonization, thus helping to improve the requirements for products and product compliance assessment process, making the conformity assessment more accessible to manufacturers, ensuring product reliability and safety etc.

Thus, after the evaluation of quality management classification and components, and their comparison with the product conformity assessment, the authors concluded that conformity assessment is closely related to quality management, ensuring that compliant and reliable products are placed on the market, delivered for use and used.

6. Conclusions

As that the concept of 'quality' characterizes a subjective feeling, in order to make an objective assessment a number of descriptors must be considered. Therefore, nowadays quality assessment is performed on the basis of several objective aspects. First, there must be an obvious object, which we want to assess; whether it is a product, process, person, system, or something else. Second, there have to be clearly defined object requirements, which it must comply with so that it may be found adequate and of quality. Third, to make the comparison of the object and its requirements, it is necessary to carry out conformity assessment. The reliability of assessment depends on the assessment process, its performer (personnel) and the devices/equipment used. Hence, fourth, the competence of the personnel involved in the assessment is crucial. Thus, quality is characterized by a set of four aspects and to objectively assess the quality, a link with carrying out of conformity assessment is obvious. The above statement is also confirmed by analysis of a variety of 'quality' definitions and authors' opinions. As a result, it is concluded that general conformity assessment principles are applied to quality assessment. Moreover, for its assessment specific conformity assessment procedures, such as inspection, are often used.

Quality management is the coordination of activities within the organization aiming to achieve a specific, pre-defined objective and improve the organizational performance as a whole. Quality management is divided into a number of specific actions to be carried out sequentially within the organization. Different authors' views and classifications given in the literature differ in this respect. After evaluating various quality management classifications, the authors conclude that currently the most appropriate elements are as follows: quality planning, quality control, quality assurance and quality improvement. The authors also want to emphasize that it is a cyclical process where quality improvement is always followed by quality planning, which is not always observed in organizations.

Conformity assessment is a process that evaluates whether a particular object (a product, process, etc.) complies with the requirements. This process is reliable, because the activities that are carried out are specific, previously described and validated, they are performed by competent professionals and measured using only tested devices/equipment. Thus, the stability of the process is ensured, the potential risk of errors is minimized and the result obtained in the conformity assessment process, the decision made is the same; regardless of which competent person performs it. As a result, only reliable and safe products are found to be appropriate and acceptable for placing

them on the market, delivering for use and using. The European Union requirements for conformity assessment are unified through technical harmonization.

To display the interrelations between the quality management components and the conformity assessment process, the authors examined in detail the interrelations of each component with conformity assessment elements and the procedures to be performed, as a result, specific correlations were identified. It is concluded that quality planning is related with both the requirements and the manufacturing process because planning is done in both of them and it is a decisive factor in the circumstances whether it will be possible to manufacture the product at all and whether it will be considered of good quality. Quality planning is also related to the conformity assessment of the product in use, because for this stage requirements and necessary conformity assessment procedures have to be defined in advance. Quality control is linked with carrying out the same conformity assessment activities, regardless of whether it is carried out when the product is manufactured or used. Within this framework, measurements and estimates are made on the basis of which a decision as to whether an object (i.e. a product) meets the requirements is taken. Quality assurance is also directly related to conformity assessment in order to ensure that the conformity assessment process to be carried out meets particular requirements and the decision taken within its framework is reliable. Quality improvement in the case of conformity assessment is linked with technical harmonization, because the identified weaknesses in the performance of conformity assessment have to be uniformly improved all over the EU. Therefore it is important that it is carried out through technical harmonization.

As a result, the authors conclude that quality management components are clearly related to conformity assessment during the manufacturing phase and when products are used. Each of quality management components has a link with one of the conformity assessment process stages and this link is displayed visually.

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