EFFECTIVENESS OF THE MANAGEMENT SYSTEM IN ACCREDITED LABORATORY AS A TOOL TO ENHANCE COMPETITIVENESS

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Abstract: The situation on the market of laboratory services in Poland is growing rapidly. In order to stay in this difficult market, one shall convince potential customers to his/her competences and quality of services. Testing or calibration laboratories, wishing to assert its position in the market, introduce the management system based on the PN-EN ISO/IEC 17025:2005 standard, the so-called 'General requirements for the competence of testing and calibration laboratories', and then apply for the certificate of accreditation in the Polish Centre for Accreditation (PCA) [14].

In order to maintain accreditation, as well as to maintain a competitive advantage, laboratories must prove that the management system is effective, which is the matter of this article. The first part presents the analysis of concepts on the effectiveness of the quality management systems and their improvement, in particular those set out in the standards of ISO 9000 series, as well as in the ISO/IEC 17025 standard (in the past and present). In the following part one identified and described the PN-EN ISO/IEC 17025:2005 standard on the effectiveness of the management system in the accredited laboratory (including the involvement of top management and quality policy, internal audits, corrective and preventive actions, evaluation of the effectiveness of training, quality control tests). Then one showed how to assess the effectiveness of the management system, which shall or may be used by the accredited laboratory (i.e. internal audit, self-assessment, management review, surveys and financial appraisal).

Key words: accredited laboratory, ISO/IEC 17025, quality management system, effectiveness of the management system.

1 Introduction

In the increasing competitiveness, more and more enterprises look for new ways to gain an advantage on the market and new opportunities for income generation. The management of different types of organisations is generally aware of the need to meet customer expectations, which determine the position of the company among its competitors. In order to develop a competitive advantage and efficient implementation of customer requirements, more and more organisations implement management systems [26]. This also applies to laboratories that play a significant role in the control parameters of raw materials, semi-processed and finished products. Laboratories shall ensure the quality of their work as well as reliable and accurate symbol and study results [12] and for this purpose they implement the management system on the basis of the PN-EN ISO/IEC 17025:2005 standard, specific to this type of activity. On this basis, laboratories shall be accredited to the selected test methods. However, for the system management in the accredited laboratory actually fulfilled its task, it must be, above all – effective. Issues on the effectiveness of the quality management system are discussed most often in the context of the ISO 9000 standards, but they apply equally well to professional management systems, including those implemented in laboratories. Moreover, the PN-EN ISO/IEC 17025:2005 standard itself is based on the principles adopted in the ISO 9001 standard. This means that if the accredited laboratory operates in accordance with the requirements of the EN ISO/IEC 17025 standard, then it simultaneously carries out its testing and calibrations, in accordance with the principles of the quality management system, compliant with the PN-EN ISO 9001 standard (however the accredited laboratory cannot declare that it meets the requirements of the ISO 9001 standard) [21].

Research on the effectiveness and efficiency of the management system in accredited laboratories are becoming more important, because one observes more intense competition in the market for accredited services. Currently, the list of accredited testing laboratories in the Polish Centre for Accreditation, according to the PN-EN ISO/IEC 17025:2005 standard contains over 1160 active laboratories, which shall take improvement actions, aimed at increasing the competitiveness on the market.

The quality management system is particularly useful in business activities, where the motives of the implementation of this system are internal, and the implementation

of the system is treated as a part of the strategy of the company [4]. Furthermore, the very effectiveness of the quality management system is defined as its ability to achieve the objectives contained in the strategy of the organization. Therefore, the objective of this article is to analyse the literature and standards for the interpretation of the effectiveness of the management system and the methods of assessment of the effectiveness of the system in accredited laboratories.

2 Defining the effectiveness of the quality management system

The issue of effectiveness of actions is discussed in many different fields of science, including psychology, praxeology, science of organization and management [27]. It is most widely and most often discussed in the management, namely quality management. In the terms relating to the quality, the PN-EN ISO/IEC 17025:2005 standard refers to the standard glossary of ISO 9000. According to the existing standard of PN-EN ISO 9000:2006, the quality management means 'coordinated activities to direct and control an organization with regard to quality' [18], where the management and supervision, according to A. Hamrol, usually involves the establishment of a quality policy and objectives on the quality, quality planning, quality control, quality assurance and quality improvement [6]. In turn, A. Iwasiewicz defines the purpose, for which the quality management applies, and defines the phenomenon as a process. According to him, 'the quality management process is a series of coordinated actions to enhance, or at least stabilize, the market position of the company' [7].

An inherent element of the quality management is to improve the quality, which is '*part of quality management focused on increasing the ability to fulfil quality requirements*' [18]. The quality management system requires a continual improvement, i.e. '*recurring activity to increase the ability to fulfil requirements*' [18]. They can be described by two main factors, which are:

- effectiveness ('*extent to which planned activities are realized and planned results achieved*' [18]) and
- efficiency ('*relationship between the result achieved and the resources used*' [18]).

Continual improvement is a fundamental principle of the ISO 9001 standard, which is also reflected in the PN-EN ISO/IEC 17025:2005 standard. This concept encompasses all aspects of the organization. Striving after 'perfection' requires time and one shall be aware that this perfection is never reached. Each business, including laboratory, must change and improve all the time, because the environment changes. An excellent system is one that allows you to quickly and effectively respond to the changing environment of the organization and situations that take place within it. Excellent system is the ultimate goal, but in practice it is unattainable. Its perfection really comes from the effectiveness in improvement [27].

Considering the standards of the ISO 9000 series on the quality management system, they refer the issue of the effectiveness to the activities, processes and the quality management system in the organization. The very concept of efficiency has been discussed in previous standards from the 1990s, but only modern editions strongly emphasize the importance of creation of the efficiency in order to continuously develop and improve the quality management system.

The standard glossary in the field of the ISO 8402 standard quality from 1996 devoted very little attention to efficiency. This standard mentioned the efficiency only in the 3.8 point [23], where one defined the quality management as: '*actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organization and its customers*' [23]. Thus, the effectiveness referred to all activities and processes, and improvement of its level would be the result of the quality improvement. However, the concept of efficiency was not defined [27].

Much more attention was given to the effectiveness of the ISO 9004-1:1996 standard [24], despite the fact that the term itself was used in a very ambiguous manner. On the one hand, the standard presented the need to ensure the effectiveness of achieving the desired goals of the quality; on the other hand the effectiveness was showed as one of the objectives of the quality, for example: uniformity, aesthetics, cycle duration, cost, etc. The adoption of these two approaches of effectiveness resulted in the fact that it could be considered as a measure of itself, which was not logical [27].

The standard also proposes the determination of effectiveness of the quality management system as a result of audit performance. This proposal had its justification in the ISO 10011-1 standard that defines the quality audit as '*systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives*' [22]. K. Lisiecka explained the merits of determining the effectiveness of the quality system in the audit process in such a way that if one of the factors in-

spiring the development of the system shall be '*a systemic study of the effectiveness of the activity and accompanying documentation of the production sphere*' [11], then given that the purpose of the audit is to develop a system, the audit shall include an examination of the effectiveness of the system. According to an earlier edition of the ISO 9004 standard, the results of internal audits and the '*total effectiveness in meeting the guidelines of the ISO 9004 standard and the quality policy as well as objectives established by the organization*' [24], were the subject of the assessment at the time of review.

The most important source of information for the verification of an effective quality system was to be accurate records, both operated and maintained. In the standards from 1996, one pointed out two particular groups of activities in respect to which one said about the effectiveness, these included both corrective and preventive actions. Usually, however, these standards presented the information on the effectiveness with the reference to the quality system, and not to activities or processes, and at the same time in the ISO 9001:1996 standard one particularly rarely emphasised the concept on the effectiveness of the use of these matters.

At last in the revised standards of the ISO 9000 series from 2000, one paid more attention to the issue of effectiveness, and what is more, it became one of the key elements of the quality management system assessment. According to the current standard of PN-EN ISO 9000:2006, the effectiveness is defined as the extent to which one implemented the planned activities and achieved the planned results [18]. This standard presents also the definition of effectiveness, which eliminates the possibility of interchange ability of use of these terms.

Amendments to the ISO/IEC 17025 standard, dedicated to laboratories, evolved towards underlining the importance of an effective management system. The ISO/IEC 17025 standard from 1999 did not significantly stressed this issue, but its amendment from 2005 was to ensure its compliance with the ISO 9001:2000 standard, including the scope of the system effectiveness. The main changes, made to the ISO/IEC 17025 standard in 2005, present amendments to the requirements for the management, particularly in order to further enhance the responsibility of top management, the need to demonstrate commitment to the continual improvement of effectiveness of the management system and taking into account an increased focus on customer satisfaction.

The effectiveness can be seen in four dimensions, including [27]:

- organization,
- quality management system,
- process,
- action.

Each of these issues has a different degree of detail. In this connection that the effectiveness itself applies to activities, by analysing the effectiveness of the organization, system or process, each of these structures is a bigger or a smaller group of operations, which cannot be identified individually. The study of the effectiveness evaluates the result of all the activities, included in the organization, system or process [27].

The standards of the ISO 9000 series state that in order for the organization to function effectively, it shall identify and manage numerous, interrelated and mutually interacting processes [18]. It shall therefore follow the recommended process approach, which is a means to achieve the desired results. Ways to continual improvement shall be looked for by the top management of the organization, which will help to achieve better results and avoid potential problems. The condition for the effective functioning of the organization is also the identification of a number of interrelated activities that occur within the processes and their management.

The PN-EN ISO/IEC 17025:2005 standard does not relate directly to the use of the process approach, however, many accredited laboratories accept them in the course of development, implementation and improvement of effectiveness of their management system. By using this approach in an implemented system, one emphasizes the importance of receipt of the results on the operation and effectiveness. The improvement of effectiveness of the management system shall be carried out by the laboratory in a continuous manner, and the top management shall provide evidence of its commitment to its systematic improvement [29].

3 The requirements of the PN-EN ISO/IEC 17025:2005 standard on the effectiveness of the management system

The PN-EN ISO/IEC 17025:2005 standard for accredited laboratories determines the requirements for the development of the system, its implementation, but also the conditions that must be met in order for the competences of the laboratory to be found due to carry out the tests [15]. This standard involves the implementation of the management system that includes quality systems, administrative systems and technical systems for the management of the lab-

Table 1. Management system in the laboratory – activities and evidence of a continuous improvement [26]

Organizational management system	Quality management system	Management system in the technical area
• refers to the top management in the laboratory • assigning the responsibility and authorities for all levels of management • identification of the resources necessary to carry out the duties • processes of communication and communication in relation to the effectiveness of the management system • commitment to continuous improvement • maintenance of the integrity of the management system in the course of the implementation of changes	• declaration of the quality policy and quality objectives • actions taken by the quality manager • use of tools arising from the quality system • obtaining information from customers – both current and future • active involvement: internal audit, management review, preventive and corrective actions • storage of records of the activities carried out	• improvement of effectiveness of the system in relation to: - Personnel, - Resources • support of these activities through other 'components of the management system'

oratory. The PN-EN ISO/IEC 17025:2005 [21] standard has been divided into two parts. The first one contains the requirements for a proper management (Chapter 4), while the second one describes the requirements for technical competence within tests and calibration (Chapter 5). The chapter on the management presents the requirements including, among others: organization, management system, documents and records control, subcontracting of tests and calibration, purchasing services and supplies, customer service and management reviews [15]. If it comes to the technical requirements, one contained those concerning factors that may affect the accuracy and reliability of tests performed, and these include [21]:

- human factors,
- accommodation and environmental conditions,
- test and calibration methods and method validation,
- equipment,
- measurement traceability,
- sampling,
- the handling of test and calibration items.

According to the PN-EN ISO/IEC 17025:2005 standard, the laboratory shall continually improve the effectiveness of its management system, using [21]:

- quality policy,
- quality objectives,
- results of audits,
- results of the analysis of data,
- results of corrective and preventive actions,
- results of the management review.

Table 1 describes the distribution of responsibilities and actions for the improvement of effectiveness of the management system, broken down into systems, including: organizational management, quality management and management in the technical area [26].

The development and a continual improvement of effectiveness of the management system in the laboratory is the responsibility of the top management. The requirements of the PN-EN ISO/IEC 17025:2005 results in the commitment of the top management in this regard. Therefore, the top management shall [21]:

- provide the evidence of its commitment to the development and implementation of the management system and continual improvement of effectiveness of the system,
- inform the organization about the importance of meeting customer demands as well as statutory and regulatory requirements,
- ensure that the integrity of the management system is maintained in the planning, implementation and changes to the management system.

According to the PN-EN ISO/IEC 17025:2005 standard, the laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to ensure the quality of test results. One of the main obligations that must be included in the policy statement of the quality of the accredited laboratory is the labora-

tory management statement to continuously improve the effectiveness of the management system. In addition, the top management shall ensure that appropriate processes in the laboratory will be established and that communication takes place regarding the effectiveness of the management system.

Information on the effectiveness of the management system is collected under the internal audits carried out in the laboratory. In order to confirm that the activities of the laboratory shall continue to comply with the requirements of the management system and the PN-EN ISO/IEC 17025:2005 standard, the laboratory shall periodically and in accordance with the program and procedure carry out internal audits of its activities. The internal audit program shall address the elements of the system, including the activities of the study. If the audit results raise doubts about the effectiveness, accuracy or reliability of the results, the laboratory must take corrective actions and notify customers, if it had an impact on the results. In accordance with the requirements of the standard, one shall made records for audited area, findings of the audit and subsequent actions [21].

The effectiveness of the management system implemented in the laboratory is also provided through corrective and preventive actions. In accordance with the requirements of the PN-EN ISO/IEC 17025:2005 standard, the laboratory shall establish a procedure and give the power to implement corrective actions in the case of nonconforming work or deviations from policies and procedures in the system of management or technical activities. The procedure for corrective actions shall start with determination of the root cause of the problem, and corrective actions shall be adapted to the size of the problem and the associated risk. In further activities, the laboratory shall [21]:

- monitor the results of corrective actions in order to determine their effectiveness,
- ensure that appropriate areas of activity will be subject to an additional audit if the identified non-compliances or deviations justify doubts as to whether the proceedings are compliant with the policies and laboratory procedures,
- perform additional audit in order to confirm the effectiveness of corrective actions (if it is warranted – for example, when one found a serious problem or the interest of the laboratory is in danger).

On the other hand, with regard to preventive measures, in accordance with the PN-EN ISO/IEC 17025:2005 standard, the laboratory shall [21]:

- determine the necessary improvements and potential sources of non-compliance, both technical and on the management system,
- develop, implement and monitor action plans in order to reduce the likelihood of such non-compliances and take advantage of opportunities for improvement.

Procedures for preventive actions shall include the initiation of activities and use of surveillance in order to ensure their effectiveness.

Furthermore, in order to continuously improve the effectiveness of the management system in the laboratory and meet the requirements of customers as well as their satisfaction, the laboratory shall determine and provide the necessary resources, in particular financial ones, which shall be planned, shared and monitored by the management. The issue of effectiveness is often considered in conjunction with human resources. In the PN-EN ISO/IEC 17025:2005 standard, one recommends to perform the tasks by the personnel qualified on the basis of appropriate education, training, experience and /or demonstrated skills. The laboratory management shall ensure the competence of anyone, who [21]:

- operate specific equipment,
- perform tests,
- evaluate the results,
- sign test reports.

Assurance of competences is promoted by further education and training of employees, which shall be assessed in terms of impact on the effectiveness and efficiency of laboratory activities. Therefore, the laboratory management shall formulate objectives for education, training and skills of the laboratory personnel, and training programs shall be targeted to current and anticipated tasks of the laboratory [21]. The PN-EN ISO/IEC 17025:2005 standard presents the requirements for the laboratory to evaluate the effectiveness of activities concerning training, and to determine the personnel competences, independently of the kind of employment. Emphasizing a human factor in the standard is the most understandable, because both deliberate and conscious actions of employees to the greatest extent shape the processes and quality management systems.

The confirmation of effectiveness of the management system in the accredited laboratory is mostly determined by the results of monitoring the validity of tests and calibrations undertaken. In accordance with the PN-EN ISO/IEC 17025:2005 standard, the laboratory shall have quality control procedures just in order to be able to monitor the validity of the study. In addition, the data obtained in the

monitoring process shall be saved so that it is possible to track their changes. One of the key elements of monitoring of the quality of laboratory operations are proficiency testing. They are fundamental tools for external quality control tests performed in the laboratory as well as an objective and independent verification of the results. Proficiency testing is defined as '*evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons*' [3]. The main feature of proficiency testing is that they include a comparison of the results obtained by one laboratory, with the results obtained by other laboratories involved in the program [12]. The results can be used for self-assessment of the laboratory, presentation to customers or other interested parties, i.e.: accredited bodies, as an independent proof of the quality of the results obtained in the laboratory, which can also be translated into the management system effectiveness. Participation in proficiency testing programs and analysis of the results perfectly complements internal quality control procedures in the laboratory, by providing an external, competent assessment of laboratory testing opportunities [12].

The statement whether the management system implemented in the laboratory is appropriate, adequate and effective is the goal of management reviews. The PN-EN ISO/IEC 17025:2005 standard presents the requirements concerning the top management to carry out their view of the management system and testing activities [21]:

- periodically (usually every 12 months),
- according to a predetermined schedule and procedure,
- in order to ensure a continued responsibility and effectiveness of activities,

And the input data to the management review shall include [21]:

- the suitability of policies and procedures,
- reports of managerial and supervisory personnel,
- the outcome of recent internal audits,
- corrective and preventive actions,
- assessments by external bodied,
- the results of inter-laboratory comparisons or proficiency tests,
- changes in the volume and type of the work,
- customer feedback,
- complaints,
- recommendations for improvement,
- other relevant factors, such as quality control activities, resources and staff training.

In addition, the PN-EN ISO/IEC 17025:2005 standard contains the requirement for storing and maintaining the records of the reviews and subsequent actions and assurance by the management that those actions were carried out in appropriate and agreed terms [21].

4 Methods for assessing the effectiveness of the management system

The effectiveness that is created in the process of continual improvement of the management system shall be evaluated on a regular basis, which is one of the tasks of the top management of the laboratory. Basing on the standards of ISO 9000 series and the ISO/IEC 17025 standard, one may determine the following methods to assess the effectiveness of an implemented quality management system [27]:

- internal audit,
- self-assessment,
- management review,
- surveys,
- financial appraisal.

Internal audit is considered essential and best way to carry out the study and evaluate the effectiveness of the quality management system. The current term for audit, included in the PN-EN ISO 19011:2012 standard, is defined as '*systematic, independent and documented process for obtaining audit evidences and evaluating it objectively to determine the extent to which the audit criteria are fulfilled*' [17]. The standard defines an audit as a process. Its main objective is to obtain audit evidence (records), and thus the confirmation of existing facts or other information, as suggested by the point 3.3. of the ISO 19011, concerning the evidence of conducted audit. Only after the assessment of the evidence, the definition suggests the fulfilment of the quality criteria, which are in accordance with the point 3.2 – i.e. procedures, quality policy and requirements. They provide information about the effectiveness and condition of the implemented quality management system [27].

Auditing enables the identification of the effectiveness of the actions taken in the laboratory, but just like any other method it has some drawbacks that can affect the image of the implemented system. In this case, one shall also look for other alternative methods for testing and evaluating the effectiveness of the management system, which will be both – objective and independent in the course of auditing.

R. Barcik draws attention to some shortcomings that accompany the auditing, i.e. [1, 27]:

- sense of observation is an essential tool for auditors,
- the whole process of auditing depends on the first impression of the auditor,
- auditor's work is largely based on feelings,
- auditor draws a lot of attention to the order which prevails in the workplace, order or its lack to a large extent shape the attitude of the auditor,
- if the auditor is an employee of downstream and audited person takes a higher or managerial position, then the audited one tries to outrun such an employee,
- rigid adherence to the content of documents is a common abnormality, the auditor who obtains answers in the form of formal quotations.

Alternative thought is introduced by the authors of another book, edited by R. Leist, who argue that '*in the course of auditing the system, the study is not subject to the person, but the effectiveness of the system*' [10], hence the '*people satisfied with the fact that well-known weak points have not been identified during the audit, prove not a weakness, but a lack of self-motivation, which threatens the future of the company, in which they work*' [10].The authors recognize the passive attitude of audited people, which is due to the caution and very limited sincerity of the personnel involved in the process [27]. The laboratory management must pay particular attention to the creation of such a working environment in order to eliminate such hazards.

Self-assessment is one of the methods of evaluating the effectiveness of the system, and the information resulting from the self-assessment on the results of the organization can be used for an efficient and effective management, as well as a systematic and continuous improvement. One of the existing models of self-assessment is a model recommended in the course of the latest edition of the ISO 9004:2009 standard (the PN-EN ISO 9004:2010 standard). The self-assessment can be a basis for any action taken by any organization, regardless of its corporate purpose, size or structure. It is the basis for planning and monitoring of strategies, policies, implementing all the tools for the use of resources [2]. It may also be used by accredited laboratories that have implemented a management system in accordance with the PN-EN ISO/IEC 17025:2005 standard. Organizations, including accredited laboratories, can use this tool to determine their strengths and weaknesses. The biggest advantage of self-assessment is both – simplicity and ease in use. Unfortunately, on the other hand, its disadvantage is determination of the effectiveness on a very general level. Although the self-assessment method is pretty much promoted in the standards of the process approach, it is not aimed at assessing the effectiveness of the processes identified in the system, but the evaluation of the effectiveness of the implementation of various points of the standard. The use of a very simple method of assessment by the employees, i.e. the five-point scale, frequently used in the assessment of all issues, can cause the formation of the risk of 'score syndrome', which is characterized by the fact that the emphasis may be placed on highlighting the strengths and hiding the weaknesses. It leads to the weakening of objectivity and accuracy assessment of the system [27, 28].

Another method to assess the effectiveness of the quality management system is a management review. The concept of review is defined as '*activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives*' [18]. The top management is responsible for conducting management reviews at planned intervals and their documentation. Management review is a secondary method in comparison with an internal audit and self-assessment, because in order to evaluate the effectiveness of the system it uses the results collected in the course of the latter [20]. Therefore, this method can be considered as the one for the verification of effectiveness of the management system in the laboratory made during the audit or self-assessment, especially since all the other input data to the review may be input data to the two methods described previously [27]. It is important that the data for the review management was credible. Traditionally, the preparation and review is the responsibility of the representative for quality (in the PN-EN ISO/IEC 17025:2005 standard, referred to as the manager for quality) in consultation with the management of the laboratory. He establishes the topics under review – all those that require the preparation by the management system, and other relevant for the laboratory. On the basis of arrangements made in the course of review, one shall draw up plans for goals and tasks for the next period [13]. Within the reviews, the management shall evaluate not only the degree of achievement of the specific objectives of quality, but also the regularity of their definition [16].

The next method that can evaluate the effectiveness of the management system is *surveying*. It allows the assessment of effectiveness of the management system in the laboratory, from the point of view of all stakeholders, including customers. According to the PN-EN ISO/IEC 17025:2005 standard, the laboratory shall obtain feedback from customers (both positive and negative) in order to [21]:

- improve its management system,
- perform testing activities,

- provide customer service.

Then, if the laboratory chooses the method of surveying in obtaining feedback from customers and stakeholders, it needs to narrow it to evaluate the effectiveness of actions or processes covered by the system, because none of the parties involved almost never sees directly the management system, and can only apply for its effectiveness on the basis on the performance of activities and processes implemented to this party. The customer of the laboratory may be unhappy because of improperly prepared test reports or delays in the delivery of results, while subcontractors of the laboratory may express dissatisfaction with insufficiently detailed information on the conditions of test performance, etc. The only restriction and disadvantage of this method is to obtain subjective opinions of various stakeholders. In order to obtain a more accurate assessment of effectiveness of the activities performed in the management system, and, consequently, the effectiveness of the processes and the system itself, it is possible to employ also other test methods, which are used for example in marketing research [8]. In the course of such studies, it is recommended to use the greatest possible amount of information sources [27].

The effectiveness *in financial terms* is another method that can be used in the laboratory, through the conversion of data from the processes into information on finances [20]. The financial appraisal is offered in the PN-EN ISO 9004:2010 standard, and in the PN-EN ISO/IEC 17025:2005 standard these issues are not dealt with. Implementation of the financial appraisal is important and can be justified as a result of the process of finding a comparable measure for different processes in the management system, however, it is difficult to agree with the statement that the mere fact of the implementation of such a procedure will allow not only the increase of effectiveness of the entire system, but the entire organization, which is suggested by the ISO 9004 standard [8]. The proposed method of expressing the effectiveness is quite controversial. For example, Robert Kaplan explicitly states that the application of methods to assess the performance of organizations, based solely on financial measures, is the limit. He stresses the need to use measures that relate to the time, the quality or the performance [9]. Also M. Hammer, discussing ways to measure the processes, in addition to financial measures, mentions also measures related to the time, the accuracy, the use of property, emphasizing, that they do not limit the list of possible applications. The use of only the financial measures would in effect result in the determination of efficiency of the quality management system in the enterprise [5, 27].

Each test and evaluation of the effectiveness of the management system in the laboratory must be preceded by a collection of the relevant data on its actual state. Not all of these data may be obtained through surveys or through interviews with customers or other stakeholders. A valuable source of information, and, consequently the information on effectiveness of the management system, is the system documentation and records. This opinion is confirmed by standards, where it is said that the use of documentation helps to evaluate the effectiveness and continuing suitability of the system, and the goal to establish and maintain records is to provide evidence of compliance with the requirements and proof for the effectiveness of the system operation [27]. According to the standards, both documentation and records are not only a source of data on the effectiveness of processes and activities. Their use is to support the effective operation of processes in the laboratory, including the assurance of effective planning, conduct and monitoring of its processes [19].

5 Summary

Development of the enterprise is inseparably connected with the necessity of constant changes, resulting primarily from the need to keep up with the competition, adaptation to the expectations of the market and the introduction of new technologies and methods. There is therefore a need to effectively manage these changes, while maintaining the stability of the organization's business processes [25]. The development of a laboratory depends on the proper choice of management. In recent years, a way to prove the competence of laboratories involved in testing, measurement and calibration is functioning in the management system, in accordance with the PN-EN ISO/IEC 17025:2005 standard and on this basis to obtain accreditation, being awarded by the Polish Centre for Accreditation. One of the requirements of the standard is a continual improvement of the effectiveness of the management system. Therefore, the top management and employees of the laboratory must take steps in order to ensure the effectiveness and prove it. Evidence of laboratory competence and effectiveness of the management system are primarily the results of audits, management reviews, proficiency testing, as well as the recognition and trust from customers. However, in order to improve the effectiveness of their management systems, laboratories shall go beyond the requirements of the PN-EN ISO/IEC 17025:2005 standard and make use of a wide range of

supporting standards of the quality management, as well as use various methods to improve and properly assess the effectiveness of their management system. Laboratories often focus on typically technical areas, which is understandable, but it is equally important to focus on the elements, coming typically from the management.

If the laboratory will continue to grow, and the management system will be effective, this would equate to the proper execution of tasks, obtaining reliable results and meeting customer requirements, but also to a quick response to changes in the laboratory, and thus may affect the competitiveness of the laboratory in the market of accredited laboratories.

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