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## **ROLE OF AUDIT IN QUALITY MANAGEMENT SYSTEMS**

### **Introduction**

The objective of companies is to secure the best possible functioning in the existing market conditions. The provision of services and products with the expected quality has a crucial impact on the assurance of company development. Thus, since the industrialization era and the development of mass production, attention has been paid to control systems. A final control of all the products that are manufactured in the conditions of mass production is frequently difficult to implement and it does not guarantee a supervision of all processes that may influence product quality.

A significant improvement of company operations should not be restricted solely to manufacturing processes. An extension of the range of activities became necessary. In order to achieve this goal, company (organization) processes have to be identified so that they can be steered. This is done by internal audits, which help identify areas where correction results in the improvement of the functioning of the whole organization. To do this, processes are monitored, quality objectives are set by the organization and the effects of its operations are analysed. Process risk analysis makes it possible to identify all areas in company operations that may generate potential problems. As a result, operation planning is possible so that threats are minimized in advance.

The implementation and application of quality systems in organizations entails expenses and some effort on the part of all people involved. The development of advanced quality management methods is usually a long-term process. However, there are basic methods that are included in the standards of quality management systems such as the planned system of internal audits.

The aim of the article is to describe the role of internal audits and to show that:

- Internal audits play a significant role in organizations and have an impact on quality enhancement;
- Management's lack of commitment to quality decreases the effectiveness of organization functioning.

## 1. Internal audit concept

In the analysis of the issues concerning quality management systems, the meaning of the term *audit* is crucial to understand the idea of quality development. The word itself is well known and commonly used but its explanation is not always easy. What is audit and what is its function? The definition of the term states that “it is a systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled”<sup>1</sup>. To understand it fully, the definition itself requires a reference to other terms that are included in the definition. It is explained in chapter 2.4.2 of the PN-EN ISO 9001:2015 standard that auditing process is closely related to the effectiveness evaluation of the quality management system which is based on material and non-material evidence. These operations are closely connected with correcting and improving<sup>2</sup> the system, which results in the increase of its effectiveness.

As practitioners, entrepreneurs are reluctant to use explanations that are based merely on definitions and they look for simpler clarification. Thus, how can the term audit be described differently? The simplest way would be to refer to the investigation of the functioning of all organization areas in order to define – on the one hand – the weak points that require improvement and – on the other – the areas whose improvement may result in further positive effects. This process of self-analysis should be conducted first of all in order to identify company’s needs rather than to meet the requirements of the standard. The management’s understanding of the basic objective of internal audits is crucial in the effective implementation of its recommendations.

- *Systematic* – which indicates a regular recurrence of activities,
- *Independent* – independence is the result of the lack of a close relation between the auditor and the audited area
- *Evidence*, which requires a presentation of written audit documents. The evidence is used in other activities that are necessary in the quality management system. On the basis of the audit conclusions, activities can be performed to improve particular areas and to plan changes and further development.

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<sup>1</sup> PN-EN ISO 9001:2015 standard.

<sup>2</sup> A. Mazur, H. Gołaś, *Zasady, metody i techniki wykorzystywane w zarządzaniu jakością*, Wydawnictwo Politechniki Poznańskiej, Poznań 2010, p 45.

- *Material or non-material objective evidence*, which clearly shows compliance or non-compliance of the audited element. Material evidence includes any document, product, facility, infrastructure element or any other that is referred to in relevance to the existing, physical element of the audited area. Non-material evidence is related to verbal information in the form of answers to auditor's questions, statements of the audited persons as well as the inspection of processes, ways of operating or other information obtained in various ways.
- *Evaluating*, which basically indicates three situations: the audit revealed compliance, non-compliance or it identified areas to be improved. If possible and necessary, the evaluation may be graded. Grading is most frequently applied to define the level of non-compliance, such as low, medium, high or critical.
- *Audit criteria* - in compliance with the EN ISO 9001:2015 standard - are a set of policies, procedures or requirements. They constitute a reference to the actual condition that is compared with the assumptions that result from the defined criteria.

As it can be concluded from the analysis of the definition of the term *audit* that is related to quality management, this is a complex activity whose objective is to investigate a particular area with the main aim to achieve constant improvement of operations. Thus, it is closely related to the process of improving organization in a given area and improving its functioning in a broader sense. This is a process of knowledge acquisition about the functioning of organization which can be connected with its long-term development<sup>3</sup>.

## 2. Internal auditor

The task of an internal auditor is to perform audits in areas that are independent of the auditor. The person assigned to do this should have adequate qualifications and skills. Although there are no formal requirements regarding qualifications, it is assumed that minimum indispensable conditions include the knowledge of quality management systems and the practical experience that is gained in the course of the first audits that are attended by the auditor as an observer. The knowledge of quality management systems can be gained during specialized trainings confirmed by personal certificates of attendance. Trainings conducted by specialized

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<sup>3</sup> E. Skrzypek, *Jakość wiedzy jako źródło sukcesu przedsiębiorstwa w warunkach ekonomii wiedzy*, in „Wyzwania Zarządzania Jakością”, M. Salerno-Kochan (ed.), V Ogólnopolska Sesja Naukowa Zarządzania Jakością (National Scientific Session on Quality Management – Science Club, University of Economic in Krakow), Kraków 2008, p. 189.

companies and accredited certifying bodies are also worth considering. Moreover, the knowledge acquired through postgraduate studies will be an important asset. Audit applicants frequently want to know what range of knowledge they should have as regards processes in the audited area. Should they have specialist knowledge on device designing when they conduct an audit of a design department? Although such knowledge is useful, it is not indispensable. This is because the aim of the audit is not to check the correctness of designs, circuit diagrams or software codes but to assess the compliance of processes that result in specialist documents, structures or software. The objective of the audit is to give the answer to the question whether a particular process is compliant with defined procedures, the records are kept properly and traceability is maintained at every level of operations. These are the fundamental tasks of internal audit that is related to the quality management system. Apart from this, specialist audits can be conducted or inspections that are focused for example on auditing technical documentation. In such cases, auditors should be selected with the consideration of the knowledge and skills adequate to a particular department or process. In auditing, not only are analytical and interpersonal skills useful but also the understanding of company's strategy and the direction of its development<sup>4</sup>.

Apart from the qualifications, the auditor should have some specific features. What are they? Numerous articles list them fairly precisely. However, one should look at this issue in a slightly different way. As the target of internal audits is to search areas that can be corrected and perfected, such qualities as discernment and accuracy are useful. Successful audit candidates are systematic at work, precise and can work to deadlines. Auditors should have the ability to talk, ask astute questions and – which is important – to listen to answers and make logical relations from the information gained. Thus, interpersonal qualities are useful, the ability to establish good relationships while maintaining appropriate distance is an asset. In places where employees know one another well, friendly relationships may be a disturbance rather than help. In such cases, there is a tendency to turn a blind eye to errors and diminish their significance. Good relationships should not weaken objectivity. Despite the fact that there are several other important and useful features, the most crucial qualities are accuracy, independence<sup>5</sup> from the audited area, reliability and objectivity.

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<sup>4</sup> W.J. Howard, *The cost of quality audit*, Cambridge Strategy Publication Ltd, Cambridge 2001, p. 76

<sup>5</sup> F. Mroczko, *Zarządzanie jakością*, Wałbrzyska WSZiP, Wałbrzych 2012, p. 216.

### 3. Audit operations

Company management is responsible for scheduled audit operations that comply with the standard. Internal audits are one of them. If there is a management representative, then he/she plans audits and appoints auditors. The auditors should prepare appropriately to the task assigned. Planning involves both organizational aspects, the definition of targets and the preferable methods of using the accessible sources<sup>6</sup>. In the course of the auditing process itself, the major target is to look for the evidence of compliance with the system as well as to search for the opportunities for improvement. The identification of non-compliance is not a basic objective of the process. It is important to remember that auditor's impressions are not sufficient to declare non-compliance although they may result in further actions. Impressions are not evidence and they cannot be documented; consequently their reference to the audit criteria is insufficient. Unfortunately, this happens to be the fault of auditors who represent certifying bodies. The fact is that every human has a set of experiences and is guided by his/her expectations. Consequently, it is not easy to ignore one's own expectations and to conduct the audit only with the consideration of the audit criteria and requirements that are defined in the EN ISO 9001 standard. Thus, it is extremely important to train auditors and shape their attitudes.

In the case of internal audits that consist in auditing one's own organization with regard to the functioning of its quality management system, the main objective is to gain information concerning the compliance level with legal regulations, standards, agreements with clients and the requirements of the organization itself. It may concern processes under completion, the functioning of particular areas or departments, company products and the services it provides.

Audits can be divided into several categories. However, from the point of view of an organization the most important division is as follows:

- internal audits (first- party audits)
- external audits (second-party audits)
- certifying body audits (third party audits)

Practically, internal audits should be considered as the basic ones. Why is that so? They play the main role in the system improvement process. The role of every audit is to audit selected elements and not the whole system. A particular small area is subject to analysis, e.g. selected documents, which is the basis for the assessment of the condition of the whole area. Thus, if non-compliance is not found in the course of an audit, it does not mean that it does not

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<sup>6</sup> R. Cascarino, *Auditor's guide to information systems auditing*, John Wiley&Sons, Inc., New Jersey 2007, p. 58.

exist. Similarly, finding a non-compliance does not negate all the operations. Nevertheless, this is an important indicator that leads to further analysis. In practice, the more sincere is the organization's attitude to internal audits and the more areas it sees to improve and when, first of all, it accomplishes corrective actions, the higher certainty that the audits that are conducted by external bodies will also show the compliance of the system with the requirements.

From this point of view, audits conducted by certifying bodies have lesser significance to the organization, particularly in the case of systems that have no connections with legal requirements as it happens for example with the quality system for manufacturers of medical devices (ISO 13485). The objective of a third-party audit is to confirm in an independent and external way that a particular organization operates in compliance with specified standard procedures. Subsequent regular annual supervision audits aim at helping the organization find areas that need improvement or enhancement. As audits conducted by certifying bodies are announced beforehand, companies frequently prepare specially to them. Then they give an impression that they are functioning better than they actually are. Due to this fact, without prejudice to the role of third-party audits, the significance of internal audits should be emphasized. It is internal audits that play the most significant role in a systematic development of organization's operations quality. During a third-party audit, a selected sample of a particular area is audited. It never happens that the object of the audit covers everything that is related to the functioning of the organization and consequently not all non-compliances can be revealed. Practitioners who use quality methods point out to the negative impact of unexpected disturbances which result in the fact that quality changes do not always align with expectation<sup>7</sup>. As the disturbances are not necessarily constant and they may appear periodically, it is easier to identify them on everyday basis, which happens in the case of a quality internal supervision system. On the basis of data obtained, many more incorrect factors can be identified by an internal auditor than by a third-party audit.

In the case of second-party audits, which are conducted by a customer, product or service recipient (this is done on their own or by a contracted entity), the scope and the objective are different. The audit is mainly focused on the processes that are crucial to the product or service recipient. In many cases, within the framework of cooperation, additional guidelines, procedures or instructions are provided that are important for the entity that orders an external

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<sup>7</sup> R. Kolman, *Kwalitologia. Wiedza o różnych dziedzinach jakości*, Placet, Warszawa 2009, p. 465.

audit. Then, they must be treated as documented and accomplished requirements, which is also the object to the audit.

In practical terms, particularly in the case of internal audits, other categories of audits can be introduced. They are closely related to the planning of auditing operations. Various approaches are possible, e.g. process audit, department audit, documentation or product audit.

When implementing a quality management system, it is important to identify correctly and understand the functioning of processes with all dependencies involved. At this stage the processes are described. Their functioning should be easy to understand. It is significant to define the input and the output of the process as well as the type of processing it involves. A good comprehension of the idea of the process makes it possible to describe the objectives and indicators used to assess the operating state. Necessary procedures are developed as well as instructions, specifications and other documents to keep the necessary records. Thus, the audit of a process will consist in the comparison of expectations regarding the whole process with the actual completion of tasks. This way it is possible to assess the effectiveness of the process, identify areas where improvement is necessary as well as all non-compliances that need corrective actions.

#### **4. Research on the quality of internal audits**

In order to carry out the research, 31 business entities were selected where certifying and supervision audits were conducted in 2009-2018. It was assumed that at least three visits should have taken place in the period under investigation. The evaluation scale of the quality of internal audits was between 1 and 5 (where 1 was the lowest grade and 5 the highest). The subjective evaluation is based on the assessment of the general condition of the system in a given organization and the assessment of processes in the company. The evaluation of audits was conducted with reference to three levels of the top management's awareness of and commitment to quality-based activities:

- organizations with a high level of management's awareness,
- organizations with a medium level of management's awareness,
- organizations with a low level of management's awareness

The results of the total of 103 audits were investigated and evaluated. Table 1 presents the results of audit assessments and the results of the system state evaluation for the three levels of quality awareness in companies and the average result for all 31 companies. The analysed

data do not reflect the dependence that could have an impact on the investigated area, i.e. the impact of third-party audits. This dependence may be treated as one that does not have an additional crucial significance as it can be concluded from the review of audit documents that there is also a dependence between presenting the companies the potential to improve internal audits and the improvement in internal audits themselves in subsequent years.

**Table 1. Average result of audit quality assessment in all companies under investigation**

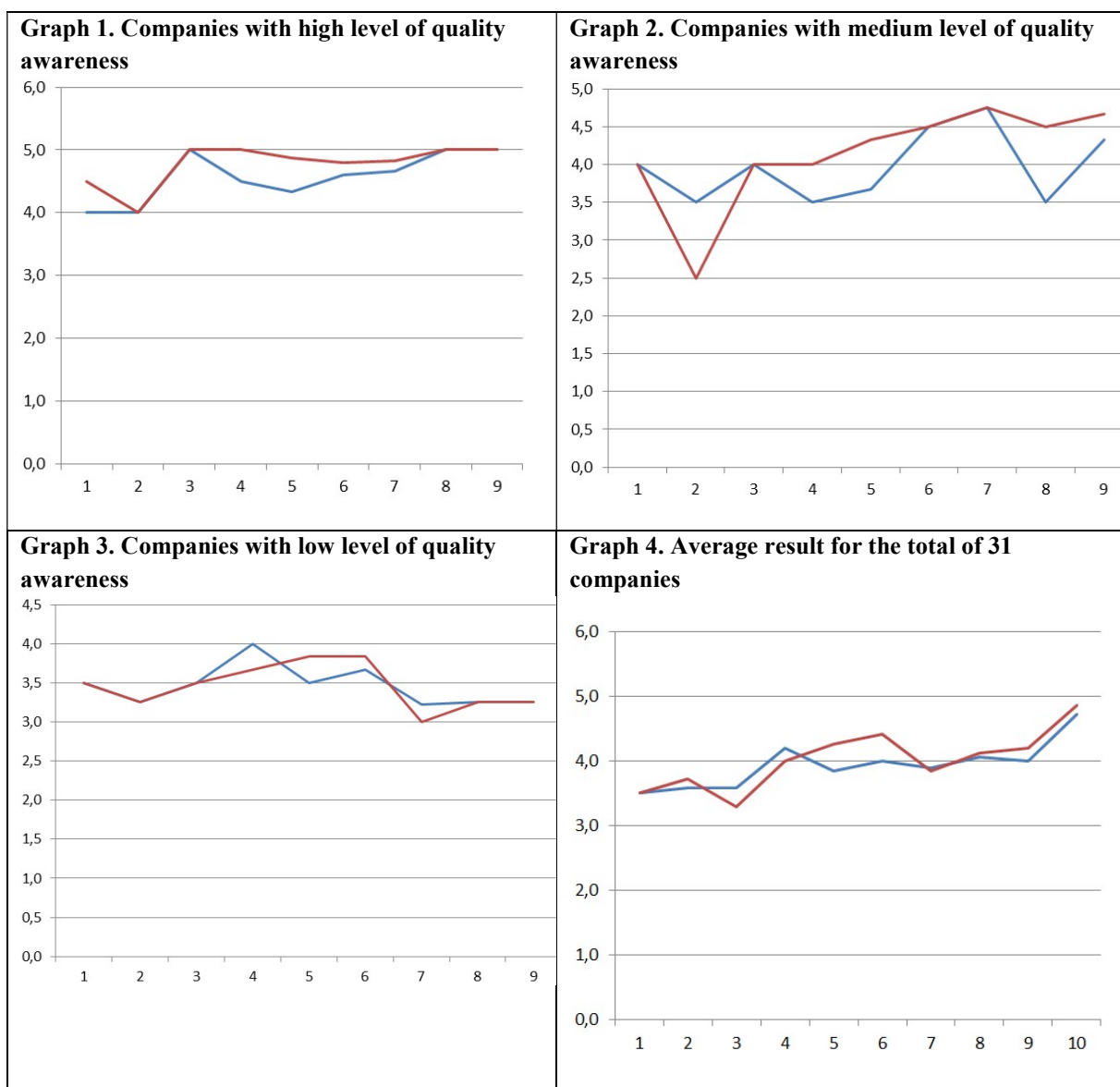
Companies by quality awareness	Year									
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
<b>High level (10 companies)</b>										
Audit quality assessment	No data	4.0	4.0	5.0	4.5	4.3	4.6	4.7	5.0	5.0
System state evaluation	No data	4.5	4.0	5.0	5.0	4.9	4.8	4.8	5.0	5.0
<b>Medium level (8 companies)</b>										
Audit quality assessment	No data	4.0	3.5	4.0	3.5	3.7	4.5	4.8	3.5	4.3
System state evaluation	No data	4.0	2.5	4.0	4.0	4.3	4.5	4.8	4.5	4.7
<b>Low level (13 companies)</b>										
Audit quality assessment	3.5	3.3	3.5	4.0	3.5	3.7	3.2	3.3	3.3	No data
System state evaluation	3.5	3.3	3.5	3.7	3.8	3.8	3.0	3.3	3.3	No data
<b>All 31 companies</b>										
Audit quality assessment	3.5	3.6	3.6	4.2	3.8	4.0	3.9	4.1	4.0	4.7
System state evaluation	3.5	3.7	3.3	4.0	4.3	4.4	3.8	4.1	4.2	4.9

Source: Author's research.

Graphs 1 – 4 present the results from Table 1 in a graphical form. The red line represents the assessment of audit quality in the investigated companies while the blue one shows the evaluation of their system state. In every case a dependence is visible between the two curves. An increase in the internal audit quality results in the improvement of the overall system state.



In Graph 1, the increase in the values of the criteria is relatively insignificant, which is the result of high awareness and commitment of managements since the establishment of the quality management system. The most significant change is visible in companies with a medium quality awareness level (Graph 2). In this case an increase in the quality of the system state is visible in the course of several years, while in companies with a low level of quality awareness (Graph 3), the change is practically non-existent. However, considering all company categories of quality awareness, the improvement of audit quality influences the improvement in the state of the quality system (Graph 4).



Source: Author's research.

## Conclusions

After the analysis of the role of audits in a system of a standardized approach to quality and the analysis of how they are practically conducted, the following conclusion can be drawn that refer to theses given in the introduction.

Thesis 1 – Internal audits play a significant role in organizations and have an impact on quality improvement. The analysis of audit documentation in 31 companies showed a strong dependence between the evaluation of the system state and the assessment of the internal audit quality. Organizations with an honest attitude to internal audits showed their desire to identify non-compliances whose rectification was planned and completed. Such companies were highly assessed by the audit teams of a certifying body. Even in the cases when the starting point was unsatisfactory, the improvement of quality was visible in subsequent supervision audits. In all such cases a dependence is visible with an honest attitude to internal audits.

Thesis 2 – The lack of management's commitment to quality decreases company's effectiveness. It is typical for companies with management whose direct commitment is insignificant that the responsibility for the system is transferred to quality representatives. Internal auditors in such companies are reluctant to engage in auditing and they infrequently identify non-compliances and potentials to improve. As a result, the auditors of certifying bodies frequently find substantial drawbacks in company quality systems. The analysis of audit documentation does not show an improvement of quality over years.

In conclusion, it can be stated that company quality is significantly dependent on the management's honest commitment to quality, on the development of an experienced team of internal auditors and the support of internal audit activities.

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### ***Abstract***

Internal audits are a requirement of quality management standards. Company management is responsible for scheduled implementation of audits. Auditors must be provided with adequate working conditions, including management's commitment and support. A development of an efficient audit team is crucial in the achievement of specified quality objectives. Organizations with a committed management team have a higher compliance level with quality standards requirements than organizations with a tendency to transfer the responsibility to the representatives of management.