

# Quality Management Audit: Problems, Decisions, and Perspectives

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## Abstract

This study addresses the pervasive issue of distrust in audit results, a concern frequently observed in professional practice and corroborated by existing literature. The immediate objective of this research is to identify the underlying causes of this distrust and to propose practical solutions. Ultimately, our goal is to foster an environment where stakeholders can make informed management decisions based on objective and reliable audit outcomes. The methodology employed in this study integrates systems thinking, statistical analysis, and Deming's theory of profound knowledge, utilizing various tools of statistical process control. Our findings indicate that the primary cause of distrust in audit results is the imprecise formulation of requirements for audited entities. Additionally, auditors typically lack accountability for poor-quality work, despite the significant potential consequences of their errors for organizations and stakeholders. We propose the implementation of a novel evidence-based audit approach aimed at enhancing the credibility of audits and, consequently, the quality of management decisions derived from them. The cornerstone of this new procedure is the Shewhart control chart, which serves as the primary tool for ensuring the reliability and objectivity of audit results.

**Keywords:** evidence-based audit; quality management system; management decisions; profound knowledge; Deming; Shewhart control charts

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## Introduction

Modern organisations are subjected to various types of audits throughout their activities. In general, an audit is a compliance assessment procedure to determine the extent and quality of conformance to the requirements used. The main purpose of our work is to audit quality management systems (QMS). In its most general form, the requirements for QMS are established in the standard ISO 9001:2015. This standard has a universal character and contains the requirements for the QMS of organisations, regardless of their sectoral affiliation and number of personnel. However, for many areas of activity, the requirements of ISO 9001:2015 were not enough, and numerous industry standards with additional requirements appeared. Here is their certainly incomplete list:

- ISO 22000 Food safety management systems.
- ISO/TS 29001 Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organisations.
- ISO/TS 22163 Railway applications — Quality management system — Business management system requirements for rail organisations: ISO 9001:2015 and requirements for application in the rail sector.
- AS 9100 Quality Management Systems — Requirements for Aviation, Space and Defense Organizations.
- IATF 16949 Quality management system requirements for automotive production and relevant service parts organisation.
- ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes.
- IWA 2 Quality management systems — Guidelines for the application of ISO 9001:2000 in education.

In addition, there are many standards for other management systems close to quality management, which contain the requirements to conduct regular audits to improve organisational performance.

It has long since been well-known that the ultimate purpose of a quality management audit is to verify the effectiveness and efficiency of QMS (Arter, 2002). Very often, organisations try to achieve this goal by using the services of the so-called certification bodies, which carry out third-party or certification audits. It was assumed that the credibility of the QMS certificate would be high, and the number of numerous second-party audits would decrease drastically. Unfortunately, this idea turned out to be accomplished only partly. The reason for many failures while conducting QMS certification. A great number of works from different countries have discussed the problems of QMS auditing. Here are some of them (to name a few). Kaziliūnous (2008, p. 67) writes that the main problem is a too narrow view of quality management of auditors who “concentrate on what is easy and accessible, spending too much valuable time on details rather than on strategy and a large picture.”

A group of authors in their paper “Effectiveness of quality management system audit to improve quality performance - A conceptual framework” (Ramly et al., 2007, 30) proclaim a similar look that “all audit failures ... can be due to auditor competence.”

As opposed to the works mentioned above in a very interesting and slightly provocative paper, a much more systemic approach is described (Kluse, 2013). The author came to conclusion that “(a) the third-party audit process is adequate to assess an organisation’s quality management system against the ISO/TS16949 standard, (b) the third-party audit process fails to add tangible value for the organisation, (c) the relationship between the auditor (registrar) and auditee

(organisation) represents a significant conflict of interest, (d) the continued audit cycle is redundant and offers diminishing value, and (e) mature organisations fail to benefit from the third-party audit process." He proposed "(a) Revise the ISO/TS standard to incorporate requirements that drive continual improvement and offer value to an organisation, (b) Develop ISO registration and audit process infrastructure whereby the organisation does not have leverage over the auditor and make the audits truly third party, (c) Remove the requirement for continued audit cycles for organisations that have periodically demonstrated compliance to requirements via surveillance audits. Eliminate the requirement for continued audit cycles, and (d) Incorporate assessment of the quality management system level of maturity as a method to determine if an organisation is in need of a third-party audit" (Kluse, 2013). We, by and large, agree with Kluse's critique of audit shortcomings but have a different view on what to do next.

In 2015, in the paper "Amazing Audits: Evaluating an Audit Program's Performance with a Standardised Approach and the Kano Model", L.B. Coleman Sr. presented the practical tool to assess the audit program on the basis of the Kano model by taking into account the results of the previous internal and external audits (Coleman, 2015). A useful idea, but, naturally, it cannot change the whole system of auditing. A known quality author, M. Durivage, proposed a quantitative method to assess minor and major audit findings (Durivage, 2019). This method can be useful for better focusing organisational resources on areas where they are needed the most. However, the whole system stays unchanged.

E. Thaler and J. Bravo give some useful pieces of advice on how to be a good auditor and "make the difference between a value-added audit and a meaningless, bureaucratic exercise (Thaler & Bravo, 2021).

As follows from the literature survey, most of the authors, except for Kluse (2013), try to improve the current auditing system. We are sure that the most important problems of today's auditing are problems of a system. We do not think that auditors behave themselves wrong due to their insufficient knowledge or bad intentions. Following Deming's rule of 94/6, we are sure that the current auditing system needs to be changed. Why this is so and how to change it - these are the main goals of our work. The root cause of the situation should be found out and eliminated, if possible. We think that one of the most essential causes of many problems is a high level of distrust between auditors and auditees. In part, we have already discussed the problem of the relationship between the effectiveness of ISO 9001 and the level of trust (Adler & Shper, 2013), but the problem has been and remains actual. In addition, the fight against the constantly self-reproducing and growing bureaucratisation of the certification field (Seddon, 2005) has also failed. All these issues have not, obviously, lost their relevance but, on the contrary, are gaining in importance at the moment. It is these considerations that served as the driving motivation for this paper.

## Methodology

The methodology of our work is based on solid underpinnings of system thinking and the theory of profound knowledge by Dr. Deming (Deming, 1994). This theory consists of 4 constituents (Deming, 1994; Adler & Shper, 2019; Shper, 2022):

**Step 1. Understanding the system.** A system is a network of interdependent components working together toward a common goal. Each component is obliged to do its best for the well-being of the system, not to maximise its production, profits, sales, or any other competitive metric. The basis for negotiations between people, departments, management, and companies must be the best option for all

concerned. Therefore, managers at all levels must know the basic ideas of systems thinking.

**Step 2. Knowledge about variability.** All processes are subject to variability - it is the way of existence in the world we live in. Process intervention often occurs to improve results. Employees, managers, and auditors alike must be statistically minded and understand how processes are managed in the organisation. Attention should be paid to whether the causes of variability are evaluated and whether the actions taken depend on their nature. Special and common causes of variability require different management decisions from engineers and operators to the top brass. Intervening in a system without analysis can lead to the deterioration of processes and, consequently, of the system itself. The only tool that provides such an analysis is the control chart coined by W. Shewhart in 1924 (Nelson, 1984).

**Step 3. The theory of knowledge.** The theory of knowledge helps us understand that management in any form is a prediction. It teaches that any statement, if it carries knowledge, predicts a future outcome at the risk of error and that it is consistent with past observations. The application of the theory of knowledge is also based on the use of statistical thinking and the Shewhart-Deming cycle, Plan-Do-Study-Act (PDSA). Note here that, in essence, the PDSA cycle is precisely what puts the system approach into practice since it describes prediction, realisation, and the feedback between prediction and outcome. At the same time, going through the Shewhart-Deming cycle multiple times describes the process of growing organisational knowledge, as each cycle contributes to an understanding of the system and its processes.

**Step 4. Psychology.** Psychology helps to understand people, the interaction between people and circumstances, the relationship between customer and supplier, manager and people, and any management system. All people are different; they perceive information differently, learn differently, and communicate differently, but all people are born with the need to communicate with other people and respect others.

## Discussion

The operating ideology of quality management systems is based on preventing problems before they occur. Moreover, where problems already exist, special importance is given to early identification of the problem, problem complexity, and searching for the root cause of its occurrence. Thus, company management brings the QMS into compliance with ISO 9001 to prevent problems, identify problems, and prevent problem recurrences. Quality problems generate consumer dissatisfaction, a decrease in profits, and a deterioration of the moral and psychological climate among the personnel.

Ideally, conducting a quality audit provides the audit customer with fact-based feedback, enabling them to make informed management decisions (Arter, 2002).

On the one hand, quality management audits are sufficiently formalised, systematic, and independent. Their results should be based on facts. At the same time, the effectiveness and completeness of the audit obviously strongly depend on the qualifications and experience of the auditor. Therefore, special requirements have to be imposed on the qualifications of the auditors.

The auditor must have basic education, experience, audit training, and an audit internship under the supervision of an experienced working auditor. In addition, the auditor must have general skills and understanding of audit principles, procedures and methods, as well as specific knowledge of both management system requirements and organisational structure, business processes, cultural and social aspects of the audited organisation, as well as legal requirements in the audited area (ISO 19011: 2018).

On the other hand, although many requirements are formulated for both the audit and the auditors, very often, the auditees are faced with the formally conducted audit and with the auditor who very superficially evaluates the QMS, subjectively deciding on the compliance of the management system. As a result, the real level of nonconforming products does not reduce; consumers continue to make claims, and supervisory authorities prescribe fines. Consequently, the level of distrust in audits is growing, the number of audits is increasing, and a negative attitude towards the audit procedure is becoming an obvious fact.

What are the root causes of all this we see? There are, of course, many of them, but from the system approach viewpoint, we would like to highlight a few of the most important:

- Requirements for the audit object, audit procedure, and the auditors are formulated non-operationally, which during the construction of management systems and in their verification often leads to contradictions and to the desire of the organisation to meet formally the minimum set of requirements. Thus, the goal of building an effective system automatically and often imperceptibly for all participants of the process is substituted for the satisfaction of the auditor's subjunctive demands.
- the objective of the audit is to improve the organisation, and the auditor's objectives in the audit obviously do not coincide because they operate within different systems. The auditors' activity is under control, which, because of its formal nature, leads to an understandable goal: a properly drafted report with sufficient evidence of the audit. In order to compile such a report, the auditor focuses his attention on compliance with formal requirements (this means the emphasis on the fact of availability and form of documents, not on their content, on the formal execution of the required procedures, on having records, and others.)
- The auditors' qualifications are not always sufficient for an objective assessment of the management system. A possible root cause of this situation may be the auditor's lack of understanding of the basics of system-statistical thinking and the theory of profound knowledge.

Unfortunately, practice shows that the attitude of the top management of many organisations to audits only contributes to the deterioration of the situation we described. Managers, as a rule, do not pay proper attention to the results of audits and underestimate the role of information obtained because of both internal and external audits. More often than not, the CEOs are focused on a formal goal - to obtain a certificate, opening the way to tenders, state contracts, and others. The presence of nonconformities hinders the achievement of this goal. After receiving a report with inconsistencies, due to the lack of time, the search for and analysis of root causes, as well as work on their elimination, is not performed as necessary. Instead, the activity is usually limited to carrying out corrections, i.e. symptomatic treatment of the disease, very often accompanied by the search for and punishment of the culprits, who are most often not responsible for the problem at all but mere victims of the system. In this case, fear of punishment naturally generates lies, concealment of problems, and, consequently, deterioration of the management system. On the other hand, if there are problems, but the auditor has not identified them, the result is the same: the system deteriorates, which can ultimately lead to significant losses.

Thus, the present and future situation with QMS audits is clearly ambiguous and complex and requires change on many fronts. If we do not try to change it, the audit will remain an annoying procedure that takes time and resources, does not add value to the organisation, and sometimes even harms it.



## Practical implications

The solution to the above problems, in our opinion, lies in the plane of changing the whole system of audits. If we look at the first cause of distrust - non-operational requirements, as noted above, this leads to a substitution of the purpose of the audit. In other words, we fall into the realm of the classic "Purpose Substitution" system diagram (Meadows, 2008; O'Connor et al., 1997). The way out of this situation: "Use indicators and goals that reflect the real well-being of the system" (Meadows, 2008, ch.5). So, in a nutshell, everything is very simple: you have to make sure that the goal of the audit is the real improvement of the organisation, and that the auditor's goal is the same (which immediately eliminates the second root cause of the problems we mentioned above).

A positive example in this area could be evidence-based medicine, the founder of which is considered to be Dr. David Sackett, who worked with colleagues at McMaster University (Canada), training young doctors to evaluate patient examinations and develop the best procedures to obtain them. To do this, his team analysed approximately 98% of the recommendations found in scientific publications. The decision about the treatment procedure was made not on the basis of the personal experience of one physician but on the basis of published results about similar cases (Patterson, 2002; Rosenberg, et al., 1995).

The authors of the concept of evidence-based management J. Pfeffer and R. Sutton (2009) showed that top managers, as well as physicians, trust their practical experience more than the results of research.

Evidence-based medicine and evidence-based management require its supporters, first, to make decisions based on facts, not on their own established beliefs and experience, and second, to continually accumulate new information and evidence to make increasingly informed and accurate decisions, not losing sight of previously unknown data and using it to improve the practice of treating people and improve management systems (Pfeffer & Sutton, 2009).

Following this global experience, we propose to begin a discussion of the concept of transitioning to evidence-based auditing as the basis for improving this area of work. The general outline of an evidence-based audit seems obvious: The goal of the audit should be the future improvement of some elements and parts of the organisation. The formulation of what and when should be improved is the prerogative of the organisation itself and its top management. In a sense, the audit should be like a visit to the doctor: the CEO comes to the auditor and asks: look, please, something is wrong (we have a pain in the side, a knock in the ear, and others). Accordingly, the auditors' work should be evaluated based on whether there has been an improvement in the work of the organisation or not. Since this improvement may come with a known or unknown delay, there should be no evaluation of the auditors' work based on the results of the reports they write. The reports are a set of tips for top managers, which they can use to varying degrees. Obviously, with this approach to audit, the need for QMS certificates disappears, and the problem of numerous industry management systems and corresponding standards disappears as well.

However, here, we must stop and point at a very important issue: such a system is not possible without a profound change in the traditional style of management. Why? Because the approach described above is entirely based on

- system thinking - the unity of purpose of the organisation and the auditors;
- real improvement of some indicators and real achievement of some goals - which one cannot do without applying the theory of variability/statistical thinking (Adler et al., 2006);

- the constant motion along the Shewhart-Deming cycle at all levels of organisation (Adler et al., 2005);
- an understanding of human psychology and consider this to be the most important component of any system (Maslow, 1987; Pink, 2009; Rosenzweig, 2007; Kahneman, 2011).

These four components lie at the core of Doctor Deming's System of Profound Knowledge, as has been already mentioned above (Adler et al., 2005).

The auditor should apply systems thinking when conducting an audit and forming conclusions. The auditor must make sure that the organisation has formulated a management system objective, that all elements of the system have goals that are consistent with that overall, one, and that each part does not create threats to the purposes of the others or losses to the overall system.

For example, a goal to reduce the cost of purchasing components may lead to the need to introduce an additional process operation and, consequently, to the failure of production to meet processing time targets.

That is, the auditor must assess not only the presence of goals and the fact that they have been achieved but also the system of internal interaction (absence of conflict) between elements of the organisation.

While assessing any processes, the auditor inevitably will encounter different forms of variability (of times, product parameters, people's actions, and others). This means that in order to assess how properly the organisation is managing processes and the system as a whole, employees, managers and auditors should be able to build and interpret Shewhart control charts because they must reveal if the processes of the organisation are stable or not. The only tool to answer this is the Shewhart control chart. However, this chart should be constructed correctly. In practice, this happens very rarely, and most often, Shewhart control charts are not used at all. In this case, the auditor's ability to build a Shewhart control chart is not enough because there will be no evidence-based data support inside the organisation.

Finally, in order for the audit to be successful, the auditor has to be attentive, trustworthy, and empathic to people, and they should be viewed as a disposable person (Green, 2021). The auditor will be able to get information not only about the management system but also about the psychological climate inside the organisation, evaluate the motivation system, and conclude on how it influences the efficacy of the management system if they have knowledge of the psychology of communication. The PDSA cycle ought to be followed by each of these actions.

## Conclusions

The audit, which is a required component of the management system, need to be a device that can acquire information that is both dependable and objective on the current state of the system. In the present moment, unfortunately, this instrument does not function efficiently, and its utilisation frequently results in merely resistance.

In this study, we propose to modernise the approach to auditing to develop a direction that, since it is analogous to evidence-based medicine and evidence-based management, may be referred to as evidence-based auditing.

The primary objective of this strategy is to enhance the quality of management choices when they are based on the findings of a credible audit that is supported by tangible evidence.

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