



The Impact of the Pandemic of Covid-19 on Audit of Quality Management Systems.

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Abstract

The audit of the QMS is based on the ISO 19011 standard and uses techniques, the main ones being the interview, the questionnaire, the direct observation, the analysis and the analysis of the contents. The audit of the new requirements of ISO 9001: 2015 requires the auditor some diligence. The auditor is expected to become a knowledgeable, pragmatic, open and educated professional. His objective is to evaluate the effective functioning and the performances of the organization and to help it to progress. The coronavirus era meant that many Ugandan and countries manufacturers were dealing with uncertainty ranging from a sharp decrease in business to the exact opposite. Keeping employees safe and being fully facilitated while at the same time keeping product lines running which hasn't been easy. How have companies been handling Quality Management Systems (QMS) audit with everything else they had to balance? In the context of Covid-19, the conformity assessment industry is adapting its approach to certification audit globally, and should be considering how to: Protect the health and safety of staff and auditors, protect customers and consumers, Help customers with business continuity. Due to covid, most companies resorted to remote auditing since firms were closed and movements limited.

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The global conformity assessment industry business model is built on the audit day rate and heavily reliant on contract auditors. In this instance, it is possible that contract auditors suffered financially as audit assignments were cancelled. National accreditation bodies should be communicating steps to protect staff and support certification body clients.

Key words: Quality; Quality Management; Quality Management System; Audit; ISO 9001 Standard; ISO 19011 Standard; performance; requirement; covid-19.

1. Introduction

Manufacturing Companies and their Quality Management Auditors are facing unprecedented practical challenges in a number of areas as a result of the COVID-19 pandemic. As the quality regulatory bodies face a myriad of challenges to certify any products being produced during International Health Crisis given the impact of COVID-19, auditors also have practical difficulties. These difficulties range from accessing client information to the additional time needed to assess the impact of COVID-19 on quality requirements, uncertainties related to going concerned and subsequent events disclosures. In such testing times, auditors should be looking forward to develop and leverage alternative procedures to audit clients and certify goods and services that will have no impact on the health of the population. The Republic of Tanzania opted to providing of Immunity building foods such as fruits and other foods other than locking down their economy which could have probably been worse to the livelihoods of its people. But with every one rushing to bring a product on the market as observed here in Uganda and in other developing and developed countries on the globe, this can only be possible if the quality Management auditors respect the ISO 9001 standards. By harnessing available technology, auditors may be able to better fulfil their audit obligations, mandatory isolation notwithstanding. The ISO 9001 standard provides requirements for developing a coherent and effective QMS. A QMS consists of a set of processes. Each process has objectives and measurement indicators. It uses resources and is the subject of procedures, work instructions, operating procedures, etc. To ensure the conformity and effective functioning of these processes and the performance of the QMS as a whole during this Covid-19 crisis, the quality regulatory bodies should implement a number of systems, including the audit of the QMS. The QMS audit evolves with the evolution of quality management practices. From the 1950s to the year 2000, the quality audit consisted of verifying the practices of an organization meeting the requirements of a defined benchmark. Its purpose was to provide assurance that an organization is able to provide products and services that meet customer requirements and applicable to legal and regulatory requirements. With the Covid-19 pandemic, most implementors of the ISO 9001 standard, the quality audit has been neglected as auditors have no access to manufacturing plants and service providers. This goes beyond the compliance of the organization's practices with the requirements of the benchmark to assess their effectiveness, that is to say, real satisfaction of the client. This crisis has been a bleeding period of many products that do not meet the quality standards on the market as people look for survival. In Uganda, the UNBS recalled several products i.e. posho, beans, milk etc. that had been supplied as relief food for the vulnerable due to the overwhelming complaints from the public. UNBS says 30% of rice/posho donated to covid19 taskforce is bad, unfit for human consumption [13]. Hundreds of tonnes of both beans and posho were recalled back. This was generally caused by the inability of UNBS quality regulators to access premises of these companies due to the lockdown. Hence poor-quality food being supplied to the public which could be

hazardous to our lives. To my great surprise, most of these companies have operated for years without carrying out QMS audits thus putting lives of the consumers to great risk. Its therefore very important for regulatory bodies to enforce quality management systems audits as an obligation since our health as a population lies in the hands of those that certify quality. The Dutch health ministry announced it had recalled 600,000 face masks. The equipment had arrived from a Chinese manufacturer on 21 March, and had already been distributed to front-line medical teams [17]. Dutch officials said that the masks did not fit and that their filters did not work as intended, even though they had a quality certificate, the rest of the shipment was immediately put on hold. This happened in different countries. In 2015, the QMS audit became a strategic and efficiency audit. The requirements of ISO 9001: 2015 require the auditor to assess the performance of the organization's QMS, that is, the level of satisfaction of all relevant interested parties under the QMS. The conduct of the QMS audit, already framed by the ISO 19011 standard [1], is therefore impacted by the new requirements of the ISO 9001: 2015 standard. The ISO 19011 standard provides guidelines for the management of an QMS or environmental management system audit program, the performance of audit activities and the assessment of the skills of auditors and people responsible for managing the program audit especially during a pandemic era that we are face to.

1.2 QMS audit objectives during the Covid-19 Era

In order to maintain quality and respect of ISO 19011, the Auditor should put forward the following objectives of the QMS audit:

- Determining the degree of compliance of all or part of the management systems to be audited with the audit criteria;
- Determining the degree of compliance of activities, processes and products with the requirements and procedures of the management system;
- The assessment of the ability of the management system to ensure compliance with legal and contractual requirements, and other requirements with which the organization must meet;
- The evaluation of the effectiveness of the management system in meeting its specified objectives;
- The identification of the parts of the management system where there is room for improvement.

1.3 Limitations of The Study

- It was very hard to collect primary data since there was fear of getting infected by covid 19.
- The researchers could not visit physical libraries since there was a national wide lock down.
- The researchers faced a challenge of limited resources e.g. financial resources since organisations laid off or paid half salaries to workers because of their inability to meet employees' salaries
- The researchers faced a challenge of failure to balance family time and research time since both of these two elements were equally important.

2. Literature Review

In the following review of the literature, we will firstly define what a standard is. Secondly, this will be followed by a brief normative of quality management. Lastly, we shall be discussing the principles of a QMS Audit and

the effectiveness of a QMS Audit in regard to the impact of covid – 19, including existing opinions about the methods and approaches that are to be used when auditing.

2.1 The normative context of quality management

A standard is a document established by consensus and approved by a recognized body, which provides, for common and repeated uses, rules, guidelines or characteristics, for activities or their results guaranteeing an optimal level of order in a given context [14]. The main tasks of standardization bodies are to develop and disseminate standards. In general, each country has a standardization body. We can cite for example the Uganda National Bureau of Standards (UNBS), etc. Most national standards bodies are grouped together in the International Organization for Standardization (ISO). Established in 1947, the mission of ISO is to promote the development of standardization and related activities worldwide, with a view to facilitating the exchange of goods and services between nations and to developing cooperation in intellectual fields, scientific, technical and economic [8]. With the rapid spread of COVID-19 throughout the past few months, many locations throughout the world are experiencing shortages and/or price changes to many goods and services items. The unprecedented outbreak has led to shortages in many locations that do not regularly experience supply disruptions. Reasons for the shortages include exceptional demand for certain items such as disinfectants, medical products, and non-perishable staple foods, and disruptions to supply chains resulting from travel or operational restrictions [19]. In addition to shortages, there have also been reports of increasing prices and price gouging by some retailers. While these shortages and price increases have made headlines, there are also many items which are seeing substantially reduced demand. Additionally, as many countries across the globe have closed restaurants and non-essential retail outlets, those prices are essentially frozen for the time being. ISO's work results in international agreements, published in the form of international standards, called "ISO standards". The ISO 9000 series (or family) of quality management standards is the most famous of the standards developed by ISO (over twenty-one thousand seven hundred and ninety-six standards). This celebrity of the series of ISO 9000 standards can be associated with ISO 9001 certification. This certification offers advantages to the organization certified both externally and internally as well as to customers. Vis-à-vis the outside world, certification allows the certified body to:

- Increase customer confidence, in that its organization and / or its products and services comply with a recognized standard;
- Provide proof that its organization and its products / services are under control;
- Assure clients that they are listened to and well served;
- Obtain recognition for developing local and international markets;
- Committing suppliers to adopt the same levels of requirements;
- Enjoy a competitive advantage.

Within the certified organization, certification makes it possible to:

- Motivate staff and make them supportive;
- Capitalize on know-how and master internal operations;

- Improve relations between departments;
- Reduce the number of controls and the number of audits;
- Introduce a certain ethics and values;
- Benefit from a recognized external evaluation.

A QMS includes the activities by which the organization identifies its objectives and determines the processes and resources necessary to obtain the expected results (quality planning). It manages the processes and their interactions, and the resources necessary to provide value and obtain results for the relevant interested parties (quality control). It also allows management to optimize the use of resources that are currently scarce in this pandemic era, taking into account the consequences of its short-term and long-term decisions (quality assurance). Finally, the QMS provides the means to identify the actions making it possible to deal with the planned and unforeseen consequences in the realization of the product and the service (quality improvement). The development of the QMS in our companies and nations is based on the basic principles of quality management [18]. These seven principles according to the ISO 9000: 2015 version are described as follows;

2.1.1 Client orientation

The main objective of quality management is to meet customer requirements and strive to exceed their expectations. Lasting performance is achieved when an organization obtains and maintains the trust of customers and other relevant stakeholders. Every aspect of customer interaction offers an opportunity to create more value for the customer under this Covid-19 era. Understanding the present and future needs of customers and other stakeholders contributes to the organization's long-term performance and sustainability. The application of this principle essentially consists in setting up a real process of communication with customers, in a prospective analysis of their expectations, a regular assessment of their level of satisfaction as well as concrete actions on the results and complaints. This communication process with clients is complemented by an internal communication process in order to promote the exercise of leadership.

2.1.2 Leadership

At all levels, leaders must establish the purpose and directions and create conditions in which staff are involved to achieve the quality objectives of the organization. Establishing the purpose and directions and involving staff allows an organization to align its strategies, policies, processes and resources in order to achieve its objectives. To do this, management makes a careful observation of the environment of its organization and listens to the relevant interested parties. Information about the environment and relevant stakeholders is then used to establish the organization's vision, mission, strategy, policies and objectives. Finally, management should train, empower, motivate and assess staff and establish effective communication processes with all relevant interested parties. Staff are one of the relevant stakeholders in the organization. They can determine the quality of the output, therefore motivating them is paramount in maintaining quality Management systems.

2.1.3 Staff involvement

Competent, empowered and involved staff at all levels of the organization is essential to improve the

organization's ability to create and deliver value during this Covid-19 pandemic era. To manage an organization effectively and efficiently, it is important to respect and involve all staff at all levels. Recognition, empowerment and improvement of skills facilitate the involvement of staff in achieving the organization's quality objectives as we have seen some organisations like United Nations (UN). Staff involvement in this covid-19 era involves communication with staff, training, empowerment, motivation and recognition, among other things. The exercise of these activities can be facilitated by adopting a process approach.

2.1.4 Process approach

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes operating as a coherent system. The QMS consists of interrelated processes. Understanding how results are achieved by this system allows an organization to optimize the system and its performance. The practice of the process approach in quality management involves defining the quality objectives and the processes necessary to achieve them. Subsequently, responsibilities and authorities are defined, the necessary resources and information as well as the sequence and interactions of the processes. Criteria should also be established to assess the effectiveness of the processes in order to continuously improve them.

2.1.5 Improvement

The success of an organization is based on a constant desire for improvement. Improvement is essential for an organization to maintain its current performance levels, react to any variation in the internal and external context and create new opportunities. The application of this principle requires defining improvement objectives at all levels of the organization, developing and deploying improvement processes, training staff on the application of improvement tools and evaluating the effectiveness of the improvement actions implemented. Improvement actions should be decided on the basis of factual evidence especially the different companies whose products were rubbished during this pandemic era like the Chinese company whose Personal Protective Equipment's (PPEs) were rejected by Spain due to poor quality.

2.1.6 Evidence-based decision making

Decisions based on the analysis and evaluation of data and information are more likely to produce the desired results. Decision making can be a complex process and there is always some uncertainty. It often involves multiple types and sources of input data, as well as their interpretation which can be subjective. It is important to understand the cause and effect relationships and the possible unintended consequences. Analysis of facts, evidence and data leads to greater objectivity and greater confidence in decision-making. To obtain this evidence and data is necessary to set up relevant indicators and dashboards and to carry out regular internal audits. The appropriate methods and skills for analysing this data must also be determined and implemented. The data used as a basis for decision-making relate to the interested parties of the organization.

2.1.7 Management of relations with interested parties

To achieve sustainable performance, organizations manage their relationships with relevant stakeholders, such as providers. Relevant stakeholders influence the performance of an organization. Sustainable performance is more likely to be achieved when the organization manages its relationships with all interested parties in a way that maximizes their impact on its performance. Managing relationships with its networks of providers and partners is of particular importance. To do this, it is necessary to determine these relevant interested parties with their needs and expectations and to define clear and fair objectives for each party. It is also necessary to establish clear, open and transparent communication, joint development and improvement activities as well as the sharing of information, resources including skills.

The principles described above allow an organization to:

- establish the quality policy and objectives and define the resources necessary to achieve them (quality planning);
- to organize to meet the requirements for quality (quality control);
- to give confidence that these requirements will be satisfied (quality assurance);
- make provisions for improving the efficiency of the management system (quality improvement).

Quality planning, quality control, quality assurance and quality improvement are, as mentioned above, the main components of quality management. To ensure the conformity and effective functioning of these processes and the performance of the QMS as a whole, the organizations must implement a number of systems, including the audit of the QMS. The QMS audit evolves with the evolution of quality management practices. From the 50s to the year 2000, the quality audit consisted of verifying the practices of an organization meeting the requirements of a defined benchmark. Its purpose was to provide assurance that an organization is able to provide products and services that meet customer requirements and applicable legal and regulatory requirements. With the appearance of the 2000 version of the ISO 9001 standard, the quality audit goes beyond the compliance of the organization's practices with the requirements of the benchmark to assess their effectiveness, i.e. actual satisfaction client. The ISO 19011 standard provides guidelines for the management of an QMS or environmental management system audit program, the performance of audit activities and the assessment of the skills of auditors and people responsible for managing the audit program.

2.2 Principles of the QMS audit

According to ISO Standard 19011: 2011 [3], the audit would be characterized by the trust placed in a certain number of principles; which make it an effective and reliable tool on which management can rely manage its policies and controls. It is a source of reliable information intended to improve the performance of the organism as a whole. In order for the audit conclusions to be relevant, sufficient and objective, it is essential to comply with these principles. Six in number, these principles are highlighted below:

2.3 Deontology

he foundation of professionalism, this principle requires auditors and the person responsible for managing the audit program for honesty, righteousness, skills and impartiality.

2.4 Impartial presentation

Auditors should avoid any conflict of interest and no one's judgment. They should produce audit findings, conclusions and reports that honestly and accurately reflect the audit activities. Their communication must be honest, precise, objective, timely, clear and complete.

2.5 Professional awareness

Auditors must carry out their tasks with professional conscience while remaining objective in all audit situations. All of their actions and behaviours must be directed toward achieving the objective assigned to them by the audit sponsor.

2.6 Confidentiality

Auditors should treat the information acquired during the audit with care. This information should not be used inappropriately for the sole benefit of the auditor or audit client or in a manner that could prejudice the legitimate interest of the auditee.

2.7 Independence

This principle is the basis of the impartiality of the audit and the objectivity of the audit conclusions. It requires that the auditors are independent of the activity audited and have no bias or conflict of interest throughout the whenever possible.

2.8 Evidence-based approach

Rational method for arriving at reliable and reproducible audit conclusions in a systematic audit process. The evidence-based approach requires auditors to base their audit findings only on verifiable audit evidence, that is, on verifiable information. Audit findings, conclusions and reports must honestly and accurately reflect the audit activities. To achieve this, auditors must respect the ethical rules of the profession. They must also maintain a positive attitude in all audit circumstances so as to collect all of the information necessary for the audit. This information should be treated with care so as to have verifiable audit evidence without prejudice to the legitimate interest of the auditee. While compliance with these principles is essential to obtain reliable information, the use of appropriate tools is no less. In summary, the QMS audit is a tool for progress, making it possible to assess the performance of organizations and thereby contribute to ensuring their sustainability. The audit mainly applies to a QMS, a process or a product. The QMS audit can be performed internally or externally. The internal audit of the QMS, also called the first part audit, is carried out by the organization for its own internal needs. The external QMS audit can be a supplier audit (or second party audit) carried out by a customer on his supplier in order to assess the latter's effectiveness. It can also be a certification audit (or third-party audit) carried out by an auditor mandated by an accredited certification body. The QMS audit is based on basic principles that guarantee the reliability of its conclusions. The QMS audit is a professional examination carried out by persons competent in the subject and using tools and techniques as well as a methodology

specified in ISO 19011: 2011. The new version of ISO 9001, published in September 2015, presents new requirements which greatly influence the QMS audit practices. These new features to which audit practices must adapt are:

- Understanding of internal and external issues;
- Identifying the needs and expectations of interested parties;
- Leadership;
- Performance;
- Organizational knowledge;
- The risk and opportunity approach; etc.

In this context, the auditors are no longer simply specialists in standards and benchmarks implemented in the organizations they audit but must be real guides to the services of managers in order to help them accomplish a difficult task which is that of permanent search for performance and efficiency.

2.3 Quality Management Systems' Audit effectiveness

At the beginning of the new century, Reference [6] were concerned that the implied effectiveness of auditing services rests only on the qualification and competence of auditors, and on the conformance of conduct of the audit to audit guidelines. According to them, the effectiveness of audits depends on pre-stated qualifications and the competence of the auditors and procedural correctness of audits. [11] refer to [6], who offer a fault tree diagram in which three sources for the ineffectiveness of QAs are identified. These are failures of the objective set for the QA, the processes conducted, and the resources provided to conduct the QA. In terms of DIN EN ISO 9001, auditing objectives as well as the auditing processes are standardized. The resources include the auditor, the time allocated for the audit, and the auditor's competencies. The time allocated for the audit will be always determined by the certification body before the audit starts. The required competence is roughly defined in ISO 17021:2011 (appendix A) [3]. Shortly after the introduction of the process-oriented Standard DIN EN ISO 9001:2000 [2,10] discussed the ineffectiveness of audits, noting the replacement of the ISO 9000 family applied before 2000 by the new standard containing the principle-like criteria to be audited were introduced. Reference [10] argue that the DIN EN ISO 19011:2002 was simply rehashed and does not provide a new or different audit model or approach. They add that "a component-based structure had been shifted to a system-based one [10]. The previous ISO 9000 family stipulated the applicant to address 20 elements. These elements or components had to be documented and utilized. Therefore, the auditing was component based. The ISO 9001:2000 [2] and its successors are process based. These processes are interrelated and do therefore establish a system. Reference [10] conclude that the old approach of auditing a quality system no longer works. While the newly introduced audit standard DIN EN ISO 17021:2011[3] does not deliver new solutions to audit methodology and subsequent approaches, it defines the competency, skill, and qualification needs for certification auditors anew. As an auditor was previously expected to be more of an engineer in the field of the customer (product orientation), the new auditor now needs to have competence in the field of entrepreneurship according to the DIN EN ISO 17021:2011 [3]. This is because the auditors are supposed to audit processes required to manage the processes necessary to produce products or serve a customer, rather than test the outcome of relevant processes. Reference

[4] discusses the function of internal financial auditing and notes that “effectiveness is the achievement of goals and objectives using the factor measures provided for determining such achievement” and “effective audit procedures should result in determination by the (internal) auditors of the character and quality of the effectiveness of the auditee’s control operations. This refers to the quality of conduct of the individual audit process. According to this, audit effectiveness depends on the disclosure of the quality and their strict application of procedures/processes in place. Reference [4] adds that the auditor needs to conduct the following activities in advance: the identification of the auditee’s objectives, as well as the establishment of criteria to determine the conformity to the objectives. It can be understood that [4] statement, applied to QMS auditing, suggests that to achieve an effective audit, the auditor needs to follow the system’s path by analysing set objectives and act by moving towards set objectives and measuring the objectives achieved. Additionally, the auditor needs to root the [5] approach audit effectiveness differently. They state that “performing both audit and non-audit services increases audit effectiveness and audit efficiency because it promotes a more comprehensive understanding of the client [5]. In their study, they say that the task of an audit is to transfer knowledge to the client, and this might only be managed when the non-audit and audit services are provided by the same individual. And this seems to be more than just giving recommendations for improvement; it might be the delivery of causes and measures for the recommendation given. But [5] add that the auditor exhibits a less critical position for audit customers when their company also provides non-audit services (e.g., consultation). Here, [7] agree that the quality of audits is the effectiveness of audits and note that there are two streams of literature: One stream claims that the additional provision of non-audit services to audit services does not impose a threat to audit quality; the other says it does. By referring to [9,12] postils concerning the independence, or impartiality, non-audit services cannot be applied in third-party audits that result in judgements stating conformance and/or compliance. Such an audit is dedicated to certify the *status quo* of what was audited. In the literature, audits providing additional services, like consultation are often called value-adding audits.

To sum it up, it can be said that literature states that an audit is effective, when:

- It will be conducted in conformance to guidelines.
- A clear audit objective is set and followed, and finally achieved.
- The auditee’s objective (for the objective of concern, e.g., the quality management system) are identified.
- The control operations of the auditor are of quality.
- Necessary resources for the audit are available (and applied).
- And the audit process conducted is flexible in terms of being adapted to individual and ever-changing settings of the objective under audit.

Therefore, quality management system auditing requires a more adaptive and dynamic audit approach especially during and after the Covid-19 pandemic.

3. Methodology

The researchers used secondary data due to restrictions that were put in place to curb the spread of covid-19.

4. Conclusion

Changes in how, and where, auditors are undertaking their work may necessitate quality regulatory organisations to respond to the changing environment, for example by considering quality control policies and procedures relating to direction and supervision of engagement teams and the review of their work. At the engagement level, auditors should have heightened awareness of the possibility of fraud or error, including fraudulent quality reporting, with the importance of the exercise of professional scepticism being top of mind in performing audit procedures. During this pandemic era, challenges never faced before by auditors in performing audits are emerging. In response, auditors need to be more agile and creative in performing audits and complying with the auditing and quality standards. The key is remembering that, while the auditing standards outline the performance requirements for obtaining reasonable assurance that the financial statements are free from material misstatement, the auditing and quality standards do not set specific requirements on how auditors might obtain that assurance. Auditors must therefore astutely apply their own professional judgement, maintain compliance with the ethical requirements and continue to achieve a high level of audit quality.

4.1 recommendations

- The government of Uganda should include auditing as part of essential services during the lock down due to covid 19 such that quality management among organisations is ensured so that fake and expired products do not also claim lives.
- Companies should setup strong internal quality assurance controls such that even when quality management auditors fail to turn up to certify the quality, the internal audit system is able to detect any error which might compromise the quality of goods and services produced.
- The Ugandan Government through Uganda National Bureau of Standards (UNBS) should increase its operations mostly during this covid-19 season to make sure that all companies are ensuring quality standards while producing, this will reduce on the poor quality goods in the market.
- The Ministry of health should not only encourage people to follow the standard operating procedures but also it should encourage people to only buy products which have been certified to meet quality standards as recommended by the auditors, this will reduce on the number of people who die as a result of using poor quality products.

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