

Effectiveness of quality management system audit to improve quality performance – A conceptual framework

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ABSTRACT

Quality Management System audit is one of the quality tools to assist organization to improve quality performance. They are commonly used in the effort to diagnose, maintain and improve quality management system. It is made compulsory for the organization to maintain their quality management system based on ISO9001 standard to undergo series of audit. However, similarly to any other physical or conceptual system, they may fail to achieve the objectives set forth, to assess effectiveness and at the same time fail to recognized area for improvement. Based on an extensive literature review, the issues relevant to quality management system audit and quality performance are examine, and discussed the several issues to identify the conceptual framework to ensure the quality management system audit deliver the results.

Keywords: Auditing, Quality audit effectiveness, Manufacturing industries, Performance improvement

I. INTRODUCTION

The need to improve organization performance has been a major discussion issues due to competitive pressure in manufacturing industries. In order to achieve the higher competitiveness level, these organizations must be able to identify the current quality performance and realign their strategies, operations and process to improve the quality performance.

Audit is one of the many tools that have been found useful to identify the current quality performance by diagnosing the opportunities for improvement and plan for improvement action. Series of audit is required for the organization maintain the QMS certification. QMS certification include generic QMS based on ISO9001 or specific industries QMS i.e ISO/TS16949 for automotive industry, ISO13484 for medical device, AS9100 for aerospace and many more. Many organizations are registered or certified to QMS but audit has

been regarded traditionally as “added cost” activities (Hepner, Wilcock and Aung, 2004) and fail improve the organization performance. In order to change that perception on audit, audit should focus toward improving the organization performance such as product quality, reduction of waste, improve service and delivery and cost reduction (Williamson and Rogerson, 1996) in order to be effective. Lack of available literature of standard on effectiveness of QMS audit is appalling (Berkmahagen, Berg, Karapetrovic, & Willborn, 2004). Beckmerhagen et al. argue that most of current literatures discuss more on effectiveness of QMS not the audit itself.

The objective of this research is to identify the QMS audit framework that should result quality performance improvement. The scope of this paper is focus on third party audit or certification audit for the QMS. The suggestion for future research is highlighted to validate the conceptual framework.

2. LITERATURE REVIEW

2.1 Background of QMS audit

Purpose of the audit can be divided into compliance audit and management audit (Arter, 1994). Compliance audit look for conformance to the audit criteria, while management audit look for conformance to the audit criteria and the effectiveness of the process and opportunities for improvement in achieving organization goals. ISO 19011 (2002) used the term of audit criteria which is refer to specification, guideline, and requirements. Example of conformance audit includes financial audit, tax audit, and regulatory audit. The management audits include manufacturing audit, product and process audit, and improvement audit. Both of compliance audit and management audit can be integrated but normally the organizations adapt the compliance audit based on audit criteria (i.e. compliance to ISO9001) before the auditor can suggest area for improvements which is outside the audit criteria. QMS certification audit can be consider as combination of compliance audit and management audit since the auditor for QMS certification focus on organization practice

against the audit criteria for example ISO9001 and also the effectiveness of the QMS (ISO19011, 2002)

Rationale of QMS is to assist organizations in enhancing customer satisfaction (ISO9000, 2000). If the organization is certified to QMS certification, the organization keep improving it process to enhanced customer satisfaction and the end results is the survival of the organization. QMS certification is awarded once the organization successfully undergo the certification body (CB) audit and the certification maintain if the organization is able to pass the surveillance and re-certification audit which normally conduct every 3 years. The pre-requisites of audit is the CB shall ensure the compliance on contractual requirement, management system requirements and resources requirements. The typical QMS certification audit is shown in figure 1 which adapted from ISO/IEC 17021 (2006) as shown in figure 2. For ISO/TS 16949 certification, the International Automotive Task Force (IATF) set the rule for the CB in the Rule for achieving IATF recognition (2004) and model shown in figure 3. The rule outline is almost typical with ISO/IEC 17021. The IATF rule set the detail of each audit process in IATF (2004) while ISO set the detail of audit process in ISO 19011 (2002).

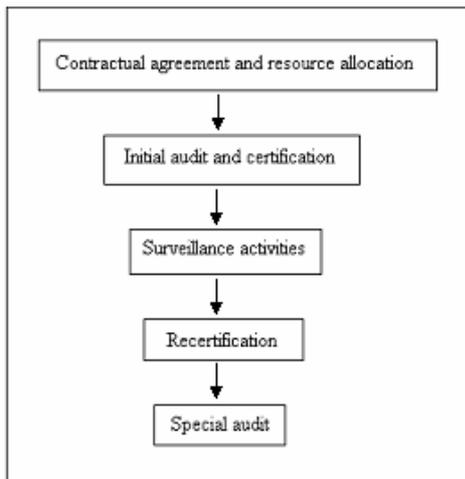


Figure 1: QMS audit process

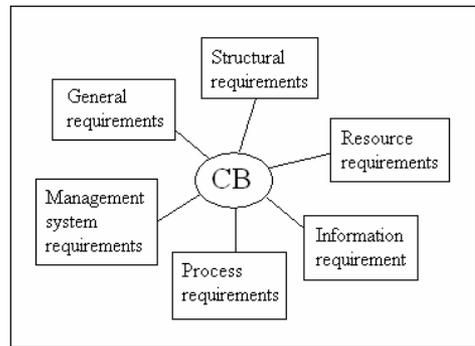


Figure 2: ISO 17021 (2006) model

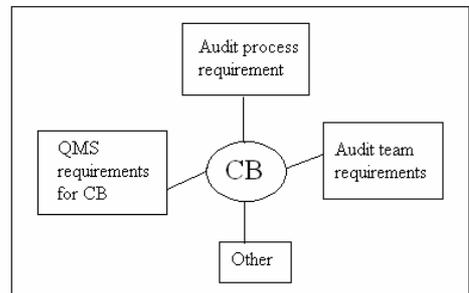


Figure 3: IATF model

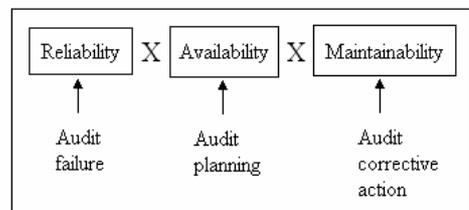


Figure 4: Karapetrovic and Willborn model

2.2 Effective audit and audit failure

Effective being defined as producing intended result (Oxford, 1989). Effective audit mean the audit will produce the intended result. What is the intended result. The intended result from certification audit included pleasing the client (Karapetrovic & Willborn, 2000) and organization able to improve their performance (Ramly, Mohd Yusof & Mohd Rohani, 2007).

In order to achieve the intended result various aspect of audit need to be considered. Karapetrovic and Willborn (2000) suggest that the audit effectiveness can be measure in order to improve the audit effectiveness. The model of measurement is based the probability calculation of audit availability, reliability and suitability as shown in figure 4. For reliability of the audit, Karapetrovic and Willborn identified the

potential audit failure as per figure 5. Beckerhagen et al., (2004) refine the model by clearly identified the principles for measuring audit effectiveness, criteria for an effective audit for measurement of the audit effectiveness. For audit failure, Beckerhagen add there is a result-related failure. Other typical audit problems or failures are due to lack of audit preparation, audit criteria elements or checklist driven, auditor skills and knowledge, commitment from the management, and bureaucratic reporting (Askey & Dale, 1994; Karapetrovic & Willborn, 2002; Barthelemy & Zairi, 1994).

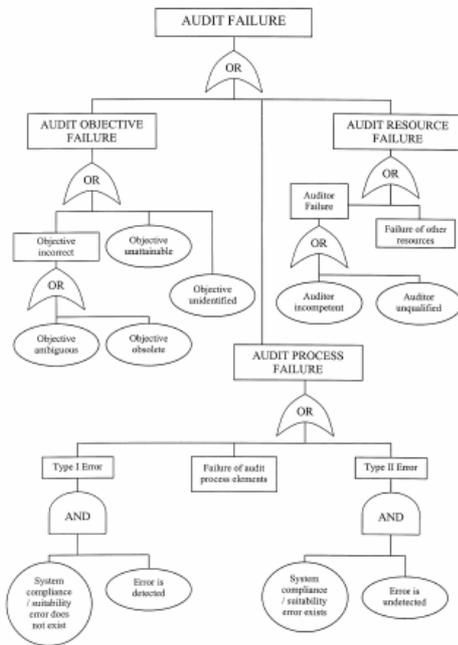


Figure 5: Audit failure tree diagram (Karapetrovic & Willborn, 2000)

Since series of research conducted by Karapetrovic and Willborn was cited and main literature was published on QA and effectiveness of the audit system, the discussion next will focus more on comparison of Karapetrovic and Willborn model with the most common QMS model which from ISO9001 and ISO/TS16949 certification audit model.

3. DISCUSSIONS

The discussion of several audit models as a reference is to propose an effective QMS audit framework. The focal point was to utilize a framework that will prevent the problem of ineffectiveness of QMS audit in order to improve

audit performance, hence improve organization performance.

3.1 Models similarity

From the description listed in table 1, it is confirms that each models contains the same auditing principles which are audit policy and objective; audit process requirement and audit resources. Audit must have a feasible objective so that it is attainable and everyone aware of it. Every audit process is planned and it is a system that aimed at continuous improvement. While audit resources such as evidential material is crucial to make sure that personnel have appropriate knowledge relevant to the types of management systems in which it operates (ISO 17021,2006).

3.2 Models differences

The Karapetrovic and Willborn (2000) model express the audit system effectiveness as calculation of probability of a system reliability, availability and suitability. On the other hand the ISO 17021 did not stated any technique to evaluate the audit effectiveness and IATF model is more in describing the whole process of ensuring the audit effectiveness. Karapetrovic and Willborn recognized the audit effectiveness by the failure in fulfilling the audit generic principle. This was also stated by IATF model where the audit effectiveness is based on the audit failure through witness audit. However, the report was only used internally. Without doubt, from these differences, it indicates that these models are incomplete in viewing the effectiveness of QMS audit framework.

Table 1: Description of effective audit models

#	Effective audit model	Series of Publications
1	Karapetrovic and Willborn (2000) Comments: The model has been developed based on initial work of Willborn (1993) and through research on management system audit. The model had proposed: i. the measurement of the effectiveness of an audit system. ii. the concept of audit reliability, availability and maintainability. iii. details on prevention of audit failure. This model is generic for any audits and it clearly defined the audit failures and the root cause	Willborn (1993) Beckerhagen et al. (2004)

	<p>of the failures. Nevertheless, it is still in conceptual model and need further development. There was no real case study to validate this model. It also did not proposed the techniques in evaluating the audit system i.e. either through witness audit, self-assessment, peer-review, or any other specific quantitative method.</p> <p>This model had defined audit effectiveness as audit free of error. There was no focus attention on how the audit system might deliver the performance improvement.</p>	
2	<p>ISO 17021 model (2006) Comments: This model described:</p> <ol style="list-style-type: none"> i. the credible certification for management system. ii. the quality management system requirement for CB. iii. the audit process requirement. <p>It did not define the audit effectiveness and also not proposing the technique to evaluate the audit effectiveness i.e. witness audit, or specific quantitative method.</p> <p>There was no discussion on audit failure as proposed by Karapetrovic and Willborn (2000), i.e. audit objective failure.</p>	<p>ISO 10011 (1991) ISO 19011 (2002)</p>
3	<p>IATF model (2004) Comments: This model makes reference to the draft of ISO 17021. It describes describe the whole process to ensure audit effectiveness. Clearly define the audit effectiveness through the achievement of the goal of ISO/TS 16949 goals. It stringent the requirements on auditor qualification and study the audit effectiveness on audit failure through witness audit but the report only used internally (unpublished report) by IATF oversight body.</p>	<p>ISO/TS 16949 (2002) Rule 1st edition (2004) Rule 2nd edition (2004) IATF CB Auditor Competency Criteria (2006)</p>

4. EFFECTIVE QMS AUDIT FRAMEWORK

4.1 Proposed framework

Systematic approached to the auditing is the first elements for successful QMS audit. The audit

activities framework in figure 5 based on ISO19011 and IATF (2004) audit process is useful to provide guideline for the systematic approached to auditing. Karapetrovic and Willborn (2000 and 2002) develop the generic and self audit program framework that is useful for performance improvement related audit. The systematic audit program includes initiating the audit, preparing for on-site audit, conducting on site audit, report preparation and follow-up activities. The follow-up activities in this context are the improvements activities result from the audit finding.

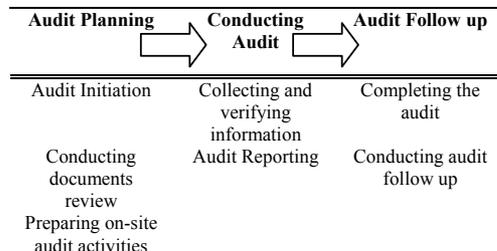


Figure 6: Audit program management

The second elements for effectiveness of audit, the audit shall cover more than the main process which shall include all supporting process in order the evaluate the organization performance. Karapetrovic and Willburn (2000) and award based model (NIST and EFQM) suggest the audit shall cover the overall system that include policy making, product design, process management and all issues related to the manufacturing. But the audit will loses it focus on performance improvement if the audit covers too much on overall management system and strategic management. The strategic management should derived based on weaknesses identified during the audit. Specific areas need to investigate in QMS audit so that the audit will focus on quality performance. The process approached auditing techniques is introduced to the ISO/TS 16949 auditor through sanction training and the process model adapt from ISO9001:2000. Process audit are highly focus, but their effective techniques not always understood (Russel, 2006). The process approached model is simplify for manufacturing process adapted from process definition, structure and interface. The focus will be on the sequence of business process and their interaction to other supporting process and others process elements. To ensure the effectiveness of the audit, the main priority in audit effectiveness is to audit the effectiveness of performance measure indicators. Without the proper

installation of quality performance indicator, the quality performance cannot be measure and manufacturing process effectiveness and efficiency will be evaluated subjectively. Tools, techniques and best practice can be shared in term of infrastructure used, locations, supplier management, logistic, human resources, procedures, occupational health and safety, social responsibilities, and financial as support either directly or indirectly toward effectiveness and efficiency of the process. All this lies on effective auditing techniques.

A third element of effective audit is auditor knowledge. In addition to auditor skill to conduct the audit according effective auditing techniques and effective audit process, the auditor should be knowledgeable in term of auditee organization process, benchmarking and best practice

4.2 Monitoring, measurement and improvement of the audit

Barthelemy and Zairi (1994) suggested the audit should evolve from compliance audit to continual improvement, thriving, ultimate and total audit. It can evolve from compliance to total audit that will cover more than quality performance.

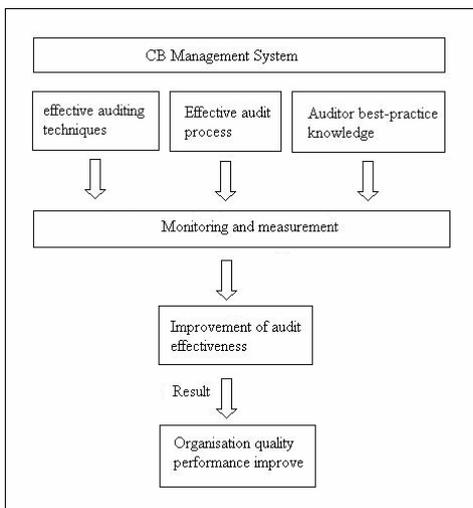


Figure 7: Proposed model for QMS audit.

Russel and Regel suggested compliance audit is conducted during infancy stage and improvement audit is conducted during steady state stage due to it required time to develop the auditor to suggest the opportunities for improvement. This can be done through series of audit and on each audit monitoring and measurement of audit is

take place. The monitoring and measurement should be conducted through:

- i. Witness audit by peers or oversight bodies to check and balance whether the audit is according to the set requirements
- ii. Check on auditee (organization audited) performance improvement during surveillance audit

These two criteria enable both CB and organization to evaluate the effectiveness of audit through conformance to the audit requirements and also deliver the positive results to the organizations.

CONCLUSIONS

This conceptual framework is the first step to ensure the effectiveness of the QMS audit that contributes toward the performance improvement. The framework focus more on auditor related criteria since the auditor is the main contribution toward effectiveness of audit. All audit failures describe by Karapetrovic and Willborn (2000) can be due to auditor competency.

The auditor main criteria are the auditor should utilized effective auditing techniques, effective auditing process and auditor knowledge level on world class practice for the organization audited. An IATF auditor qualification criterion is one of the good models to ensure auditor competency but it doesn't evaluate the auditor knowledge in best practice. Both proactive and reactive monitoring should be utilized to measure the effectiveness. The proactive monitoring can be done through monitoring of the audit process itself while reactive monitoring can be done through evaluating the audited organization performance improvement.

Action based research or case study on monitoring and measurement of audit is recommended to validate the model. The study should pay less attention on CB Management system since this area has been widely covered by ISO and IATF related literature.

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