Leadership in Accordance with the Quality Management System – An Evidenced Based Audit Conducted in Ten Countries

Karri Naveen

Research Scholar,
Department of Mechanical Engineering,
Lincoln University College,
Petaling Jaya,
Selangor Darul Ehsan, Malaysia

Dr. Chitirai Pon Selan

Supervisor, Head of School – Science and Engineering, Curtin University Dubai, UAE

Prof. Dr. Amiya Bahumik

Co-Supervisor: Professor, Lincoln University College, Petaling Jaya, Selangor Darul Ehsan, Malaysia

Abstract

There are various schools of thoughts on Leadership, Leadership, Customer focus, Process approach, Employee engagement, Evidence based decisions, continual improvement and Relationship management are the seven elements on which ISO 9001 standard is established. However most of the management system standards are fundamentally framed on the Plan, Do, Check, Act cycle. ISO 9001 standard has an explicit requirement on Leadership along with other criteria which need to be fulfilled for any organization to be certified for ISO 9001. The decision makers of ISO 9001 certified organization to demonstrate adequate evidence of their commitment and leadership by owning accountability for successful implementation of ISO 9001 requirements in their organization. Leadership element of ISO 9001 significantly influence the planning of the processes, support for the operation, evaluating performance of the processes and promoting continual improvement. This research work is dependent on the evidence verified by conducting onsite audit of quality management system in 385 organizations across ten countries. Relevant literature review indicate that not much multi nation empirical study has been conducted to determine the degree of conformity on requirements of "Leadership & Commitment" as per ISO 9001; and hence this research study has been undertaken to fulfill this gap. The requirements were assessed to determine conformance on Leadership and commitment, Policy, Organizational roles, responsibilities and authorities in accordance with ISO 9001. The criteria determined in the quality management system are analyzed to determine the extent of effective implementation and the challenges at various levels within the organization.

Primary data is collected from 385 Organizations by spending 577 Mandays onsite by interviewing the top management, Reviewing records and site observations. The extent of compliance to ISO 9001 standard has direct correlation with the effective implementation of the quality management system. Research data collected from onsite visit is analyzed with statistical software called Jamovi for determining the extent of conformance to the criteria on Leadership in accordance with ISO 9001. Numerous factors contributing effective implementation of the requirement of the standard is identified along with the opportunities for improvement. This research is different from the conventional data gathering through questionnaires techniques which is not backed up with the objective evidence to support the feedback from the participants. While other researchers have gathered data

through a survey or questionnaire; this research is based on the first hand information gathered by conducting an onsite audit of the quality management system. Researcher has conducted a through onsite audit reviewing the complete management system of 385 organizations to determine the adequacy and suitability of their documented information and level of compliance on implementation of ISO 9001 standard. Various factors were identified contributing to significant level of compliance with the requirement under criteria of "Leadership". No organization yielded similar audit results despite having similar scope of work, nature, size and complexity of the processes. Variation in extent of

Introduction

ISO stands for International organization for standardization. ISO has published many standards among which the most popular standard is 9001 revised in the year 2015. The latest version of the ISO 9001:2015 standard has ten elements out of them clause four to ten are the requirements of the standard which needs to be implemented to obtain certification in an organization. ISO 9001:2015 deals with the quality management system which is again a very generic requirement applicable to most of the industries engaged in either service or products. It is the obligation of the certified organization to adopt and implement the criteria of the ISO 9001 to suit their scope of work and maintain objective evidences to demonstrate compliance. The duration for implementation of the requirements of the standard greatly depend on the intended organizations scope of work, complexity of the process, organization's size, number of sites, competency of employees associated with various processes of the organization, necessary resources and most important the commitment of the top management including leadership of the decision makers. ISO 9001 is derived from the concepts of fundamental management elements such as process approach, commitment of leadership, involvement of employee involvement in the implementation of IOS 9001, customer focus, objective evidence based decision and continual improvement.

The ten clauses of the ISO 9001:2015 standard contains following elements of the quality management system which are auditable: Organization's context, Leadership, Planning and Support, Operation, Evaluation of Performance and Improvement. ISO 9001 encourage the process approach which would enable the organization to achieve intended process performance, consistently meet requirements of customer. Risk based thinking is introduced in ISO 9001:2015 version of the standard which eliminate the requirement of Preventive action to avoid deviations or non conformances which could occur

compliance with the requirement of the standard is verified through documented information, interviewing and site observations and a careful onsite evaluation is done to determine the conformance based on the objective evidences. The outcome of the analysis details the extent of compliance by each certified organization to fulfill the requirement of the criteria on Leadership of the quality management system.

Key Words: ISO 9001, Quality Management System, Leadership, Customer focus, Policy.

potentially. The quality management system laid an explicit requirements for the top management which were assessed thoroughly by the researcher by visiting the sampled organizations onsite and conducting audit:

- Overall quality management system accountability lies with the top management
- Quality policy to be established by the management inline with their strategic business direction and plan.
- The top management should establish the quality objectives inline with their strategic business direction and plan.
- The top management should ensure the requirements of ISO 9001 is integrated with their processes.
- The top management should encourage adoption of process approach.
- The top management should encourage risk based thinking.
- The top management should avail necessary resources.
- The top management should ensure to communicate the significance of ISO 9001.
- The top management should ensure the effective implementation of ISO 9001 to yield intended output.
- The top management should support, engage and direct employees to contribute for effective implementation of ISO 9001.
- The top management should encourage continual improvement.
- The top management should encourage other managers to develop their leadership skills.

The criteria on the quality policy are determined as:

The quality policy should be relevant to the organization and inline with their strategic business direction.

The quality policy should initiate the quality objectives framework.

The quality policy should contain the commitment of the top management to fulfil with customer and other requirements.

Quality policy should contain management's commitment for continual improvement.

Quality policy should be documented and made available to the interested party.

Employees should understand the Quality policy and isto be communicated to all concern and implemented in the organization.

Quality policy should be made available to the interested party.

The criteria on the authority and responsibility are determined as:

The top management should delegate the authority and responsibility for ensuring the ISO 9001 requirements are complied with the criteria determined in ISO 9001.

Management should ensure that intended output is achieved by the processes.

The top management should ensure to get the update on the different process and their performance based on successful implementation of the ISO 9001.

The top management should ensure to encourage customer focus across the organization.

The top management should ensure the criteria determined in the ISO 9001 is maintained when any potential changes are planned to the requirements of ISO 9001.

Various theories are established on the "Leadership. This research study is confined to the ISO 9001:2015 which has an explicit requirement on "Leadership". Broadly this requirement of ISO 9001consist of three particular elements: Quality Policy, Commitment and Leadership of management, certified Organizational authorities, roles, responsibilities and Customer focus. The ISO 9001:2015 is an revised version of the quality management system which is based on the principles of the quality management system such as: Leadership, Process approach, Relationship management, Focus on customers, Employee engagement, Continual improvement and Decision based on Objective evidence. Researcher has interacted and interviewed with more than three hundred eighty five top management personnel including Chief Executive Officers, President, Managing Directors, Proprietors, General Managers and the key decision makers of the various organizations which include micro, small, medium

and large category. Difference in leadership style, risk taking capability, motivating and inspiring characteristics and many other attributes were associated with this subject which is proven over time and period. Hence this research study is conducted only to audit and analyse the level of fulfilment of the criteria laid in ISO 9001:2015 under Leadership and commitment across ten countries. Leadership is considered to be the most significant element of the management system which provide the strategic direction to the organization to achieve their intended outcome.

Literature Review

Research studies were carried out across the world to determine the benefits and or impacts of the ISO 9001 by various researchers. Explicitly the degree of conformity to the criteria on "Leadership" of ISO 9001 through an onsite evidence based audit is rare. Hence this research gap is identified and this research study is conducted.

Anna et al. (2020) conducted a research study in a sample size of 30 organizations of food industries. In their study the selected sample is segregated in two categories; one without adoption of ISO 9001 and another with adoption of ISO 9001. Their research methodology involve computer and paper based interview technique. Research data was analysed on various factors but the results could not be concretely determined to establish the correlation between Leadership and their role to in organizations complied with ISO 9001.

Zdravko et al. (2020), state that better implementation of the system is possible by using morphology of responsibility; where accountability exists the irresponsibility would reduce. He also states that the relationship between the quality management system and roles and responsibility is based on a holistic approach. Fahmi et al. (2020) focused on improving quality in food industry by explaining the principles of the quality management system in six sections of his work which include; introduction, rationale, explanation, sources, typical actions, proposed steps & key benefits.

Agus et al. (2019) has circulated questionnaire through electronic medium among sample size of 200 employees to collect the research data from a Packaging industry. The objective was to establish the correlation between certain factors which could impact the quality performance. Agus has considered following factors Competence, Culture, Leadership, Motivation, Commitment and used structural equation model to analyze the data by use of statistical software called Lisrel. Agus concluded that the only two factors "Culture & Leadership" significantly contributed on the quality management system performance than other

factors.

Pregdrag et al. (2018) has randomly circulated the research questionnaire to eighty five ISO 9001 certified organizations in Serbia. Likert scale gauging seven levels was used to understand the research data collected through questionnaire which was analyzed by using SPSS and LISREL. Structural modeling equation is used to validated the framed model. Pregdrag concluded that leaders focus is inclined towards increment of the sales and business and less consideration is given to suppliers and customers.

Luic et al. (2017) conducted an online survey to seek feedback from management system auditors and made comparison with ISO 9001 version released in the year 2008 and the ISO 9001 version released in the year 2015 to EFQM Model for Business. Luic et al. has used SPSS software to analyze the data and concluded that feedback method yielded very less response rate and emphasized on change in top management and continual improvement tools & approach. Luc (2011) conducted an online survey on a sample size of 428 customers of online banking in Spain to investigate the perception of e-service quality. Luc concluded that inadequate data to correlate that ISO 9001 certified organizations has greater impact on perception of e-service quality.

Saleh (2018) conducted a sample survey in 340 organizations to analyze the impact of ISO 9001 on the satisfaction level of customers in industrial sector of Damascus Governorate, his research study concluded that further research in marketing is required to be carried out to determine the root cause of customer dissatisfaction and on customer retention.

Angelos (2012) obtained research data through questionnaire circulated among one hundred ISO 9001 certified service organizations in Greece. Quality managers supplemented the information through questionnaire which was analyzed using exploratory factor analysis and multiple regression analysis. Angelos has established significant correlation between performance of the service companies and the variables like customer satisfaction, continual improvement and handling non conformities by using SPSS software.

Agnieszka (2013) conducted a survey in ten small and medium organization in Poland to determine the role and impact of leadership in the quality management system. Agnieszka has considered independent variables such as styles of management, involvement of employees, employee satisfaction, handling non conformities. Agnieszka concluded that organization's leadership significantly contribute effective implementation of quality management system.

Zahra (2013) has conducted a cross country analysis of two organizations to study the connection between organization behavior development and effective implementation of the quality management system in accordance with ISO 9001. The research data was obtained through primary and secondary methods. A standard questionnaire was used to obtain the data from the two participating organizations based on which the research is conducted. Zahra concluded the significant factors influencing the effective implementation of the ISO 9001 were commitment and leadership of management, employees cooperation and organization's culture. The reliability of the questionnaire, competency of the individual participants, statistical software used for data analysis from the two sample organizations is detailed in the paper.

Esam (2012) has conducted a literature review of fifteen papers to determine the impact of top management's function in ISO 9001service sector of Malaysia. Some of the variables evolved from the literature review states that the effective top management's commitment and leadership has correlation with customer and market orientation, organization performance and overall customer satisfaction.

Research Gap

Literature review did not yield any significant information on the assessment from an management system auditor on "Leadership" criteria of ISO 9001; this research is conducted onsite to get the first hand information rather collecting feedback based solely from individuals without supporting objective evidence. Similar research is based on either secondary data or data collected through feedback and questionnaire. This type of methodology lack objective evidence on the information substantiated by the participants and despite statistical analysis the outcome would have an element of uncertainty. Hence researcher has conducted an onsite audit of the sample organizations to gather first hand information to determine the extent of conformance with the requirement of the criteria determined in ISO 9001 standard on Leadership.

Research Objective

To determine the adequacy of arrangements shown by the certified organizations on specific criteria of ISO 9001 standard; this research work is focussed on the clause on Commitment andLeadership of management, Quality Policy, Organizational authorities, roles and responsibilities. This paper aims at determine the extent of conformity particularly on the "Leadership" as per the quality management system requirements.

Research Methodology

First hand research data is gathered by conducting an onsite audit of the organizations to verify the conformity to ISO 9001 standard requirements. This particular research work is focussed on to the definite conformity assessment variables based on which a questionnaire is prepared. This particular research work is based on descriptive data which is supported with the objective evidence as demonstrated by the organizations audited. Primary Research data is obtained through onsite interviewing the top management including employees, verifying documented information and observation. Outcome of the audit results are quantified to arrive to a conclusion based on the degree of compliance which is measured on a Likert scale gauged five point. Conformance to requirement of ISO 9001 standard is mapped against the predetermined Likert scale.

Researcher has visited in person and conducted an impartial onsite assessment independently as per ISO 19011 in 385 companies from various countries. The sample organizations were located in Oman, New Zealand, India, Qatar, Kuwait, Bahrain, Malaysia, Kingdom of Saudi Arabia, Australia & UAE. Researcher has spent 577 Mandays onsite in 385 organizations to check the level of compliance to the criteria of ISO 9001. Sample selection is a simple random; only ISO 9001 certified organizations were selected from various industry segments as defined under European Accreditation of industry classification. Following industry sectors were part of the research sample as per EA Code classification: Wood products, Paper products, Printing companies, Publishing companies, Chemical products, Pharmaceutical, Rubber products, Concrete and Cement, Basic metal and fabricated metal products, Machinery and equipment, Engineering services, Optical equipment and Electrical equipment, Medical device, Manufacturing of Ship, Miscellaneous transportation equipment manufacturing, Miscellaneous Manufacturing not mentioned anywhere, Education, Construction, Recycling, Electrical supply, Information technology, Water supply, Retail trade and Wholesale trade, Restaurants and Hotels, Gas supply, storage and communication, Real Estate, Transportation, Financial intermediation and social services. No bias is ensured by selecting sample size of different industry sectors from ten countries as this research and the ISO 9001 standard is not industry specific. Researcher has no relatives working in the organizations audited. Researcher does not know the sample organizations and their top management prior to the audit. The research data is gathered onsite to verify adequate samples depending on the criticality of the processes and processes complexity, organization size, past performance of the processes, competence requirement of the process owners, availability of the documented information at point of use, total audit time available, confidentiality of the information, certification and accreditation body requirement and other statistical parameters were taken into consideration.

A questionnaire is established in accordance with the guideline for auditing to verify the level of conformity to the criteria on Leadership and commitment. This questionnaire is in developed in four sections to meet the criteria determined in the standard on Leadership and commitment". The questionnaire is closed ended with five options from Likert scale to demonstrate the compliance. Based on suitability and adequacy of the objective evidence. The answers were quantified using five point Likert scale. The Independent variables considered which are attributing under the criteria of "Leadership" are determined as Leadership and commitment, Customer focus and Policy.

Jamovi statistical software tool is used for the data analysis than the conventional SPSS software. Although Jamovi provides all the necessary computational instruments required for analyzing the research data such as correlation, regression, factor analysis, t-test, non parametric test, ANOVA, contingency tables and reliability.

Reliability Analysis

Reliability of the audit conformity assessment variables was derived with the Cronbach's alpha value to arrive at 0.948; which was acceptable in terms of maintaining consistency in the audit questionnaire and was maintained reliable enough to pursue the research work and make conclude logically. Although questionnaire is used as a basic structural outline of the criteria determined in ISO 9001 on the requirement of "Commitment and Leadership"; the personal interview encouraged the Top Management to express their opinion on the journey of ISO 9001 certification, challenges overcome while implementation of the quality management system within their organization, role of consultants if any, Management review meetings, consultation and participation of the employees including contract employees, customer complaints and their management, expectation of the customers and status of compliance with applicable statutory and regulatory requirements.

Results

The top management of each organization is being interviewed as per the criteria determined in the requirement of the quality management system with prior appointment. Adequate time has been spent discussing with the decision makers during the audit of their

organization. Other managers were also interviewed who are responsible for successful implementation of ISO 9001 in their organization, research work was analysed by using a new Jamovi software for its simplicity in statistical analysis. Table-1 indicate standard deviation, mean and median of variables "Leadership and commitment" (Average: 3.65, Median: 4 and standard deviation: 0.60). Analysis on the outcome of the audit resulted in only half of the audited organizations conforms to the requirement of ISO 9001, only 51.2% of the organizations audited conform to this requirement. The researcher could not

determine conformity to the requirement of the standard in almost 41.1% of the organization due to inadequate evidence to determine conformance. 162 organizations could not demonstrate sufficient objective evidences to conclude conformity. Only 6.0% meaning 26 out of sample size of 385 organizations demonstrated strong conformance to the criteria which was evidenced during the onsite audit with the effectiveness of the actions taken.

Table-1 Descriptives

	Leadership and commitmen
N	385
Missing	O
Mean	3.65
Median	4
Standard deviation	0.604
Minimum	3
Maximum	5

Table-2 represents the frequency for the top management's commitment towards customer focus. The compliance to the requirements of the customer focus criteria is demonstrated by 82.1% meaning 316 organizations were conforming to criteria on customer focus. 16.9% of the

organizations were neither complying nor non complying meaning researcher required further evidence to determine the conformance during the audit. The mean value for this criteria is found to be 3.84 and median being 4 with standard deviation 0.39.

Table-2 Frequencies of Customer Focus

Levels	Counts	% of Total	Cumulative %
3	65	*****	16.9□%
4	316	82.1 \(\tag{%}	99.0□%
5	4	1.0□%	100.0□%

Table-3 represent confirmation to the requirement of the criteria on policy. The frequency distribution indicate that only 39.0% of the sample size meaning 150 organizations out of 385 were conforming to the requirement of this criteria on policy. More than half of sample size meaning 57.9% of the organizations demonstrated evidence of

conformance based on which researcher could not determine the conformity or non conformity and require further objective evidence to conclude. The mean value for this criterion is 3.45, median being 3.0 and standard deviation is 0.558.

Table-3 Frequencies of Policy

Levels	Counts	% of Total	Cumulative %
3	223	57.9□%	57.9□%
4	150	39.0□%	96.9□%
5	12	3.1 □%	$100.0\square\%$

Table-4 represent the criteria on roles, responsibilities and authorities which indicate 51.2% of the sample size conforms to the requirement of the standard. 160 organizations out of 385 demonstrated inadequate evidence wherein the researcher could not determine the

conformance or non conformance. Furthermore 7.3% of the sample size demonstrated exceptional compliance of the criteria which was evidenced with the effectiveness of the actions taken. The mean value represented by the sample is 3.66, median is 4 and standard deviation is 0.61.

Table-4 Frequencies of Roles, Responsibilities and Authorities

Levels	Counts	% of Total	Cumulative %
3	160	41.6□%	41.6□%
4	197	51.2□%	92.7□%
5	28	7.3 □ %	100.0 □ %

Conclusion

The top management of any organizations knows how to run a business to enhance profits and satisfy stakeholders. Perhaps a fine tuning is required from the dimension of ISO 9001:2015 standard to demonstrate compliance against explicit criteria on Leadership and commitment". Empowering the employees at relevant functions and levels could be a possible solution; along with the top management's realization on the accountability for successful implementation of ISO 9001 is to be improved upon. Conducting a detailed management review meeting would keep the top management abreast on the process performance, status of non conforming products, customer complaints, dynamic changes in the external and internal issues, status of actions from last meetings, internal audits

results, performance of external providers, achievement of quality objectives, customer satisfaction levels, resource requirements, arrangements to address identified risks and opportunities and any other continual improvement opportunities. Successful Implementation of ISO 9001 is possible only when the management is customer focused and provide necessary resources and support the employees to achieve the intended results. The first hand information obtained through interviewing the top management of 385 organizations revealed that majority of the decision makers rely on the management representative and were unaware of the potential benefits of the successful implementation of ISO 9001. Most of the organization ISO 9001 certified completely depend on Management representative who liaise with the employees internally and

with the external service providers. To avoid this one man centred culture the revised quality management system published in 2015 has abolished this culture of Management representative though we still find traces of this practice unofficially. Another major drawback identified were inadequate and irrelevant documents being developed by an external consultant with product knowledge and complete dependency of the organizations on the consultants to support them during and after the external and or internal audits.

Top management has to unleash from the clutches of stereotyped attitude of acquiring ISO certification and should promote continual improvement through empowering every process owner and reviewing the performance of the process at frequent intervals and not just before the external audit once in a year. Frequent monitoring and reviewing mechanism through management reviews ensure proper implementation of ISO 9001 and achieve planned output. Fifty percent of the sample demonstrated the compliance with the requirements of the criteria and only seven percent of the decision makers and the top management has demonstrated effectiveness of the criteria on the management commitment and leadership in terms of effective implementation of the requirements of ISO 9001 in their organization. It was observed that those organizations which were customer driven the leadership traits of those organizations has indicated exceptional compliance to the criteria on Leadership in accordance with the ISO 9001 standard.

Limitation and Scope for Future Work

- 1. Industry specific research study could be conducted to determine the influencing factors for determining conformance.
- 2. Competency of the top management could be analyzed to determine correlation between successful implementation of ISO 9001.
- Constraints to ineffective implementation of the criteria on Leadership and commitment could be studied.
- 4. Cross country analysis could be conducted on variation in implementation of the quality management system requirements.

Reference

Abu Al Rub, F., Shibhab, P., & Abu Al-Rub, S. (2020). Quality Management Systems (ISO 9001:2015). Published by GAVIN eBooks, ISBN: 978-1-951814-01-4 DOI: 10.29011/978-1-951814-01-4-002.

- Djordjevic, P., Panic, M., Arsic, S., & Zivkovic, Z. (2018). Impact of leadership on strategic planning of quality. Total Quality Management and Business Excellence, DOI: 10.1080/14783363.2018.1490176.
- Fonseca, L. M., & Domingues, J. P. (2017). Listen to ISO 9001:2015 for organizational competiveness: Correlation between change management and improvement. International Conference on Business Excellence, 11(1), 916-926. DOI: 10.1515/picbe-2017-0097, pp. 916-926, ISSN 2558-9652.
- Husseini, S. A., Al-Shami, S. A., & Fam, S. (2018). Impact of ISO 9001: 2008 certification on consumer satisfaction. J Adv Res Dyn Control Syst, 10, 322-331.
- International Organization for Standardization (2019). Annual Survey Report. Available online. https://www.iso.org/the-iso-survey.html
- Krivokapić, Z., & Stefanović, M. (2020). Role of responsibility in the quality management system. International Journal for Quality Research 14(3) 805–816 ISSN 1800-6450.
- Misztal, A. (2013). The impact of leadership on the quality management systems. In Poznan University of Technology, Poznan Poland 8th research/expert conference with international participations, viewed (Vol. 30).
- Mustafa, E., & Bon, A. T. (2012). Role of top management leadership and commitment in total quality management in service organization in Malaysia: A review and conceptual framework. Elixir Human Resource Management, 51, 11029-11033.
- Nargesi, Z. R., Baniani, A. M., Galankashi, M. R., Ziaei, F.,
 Zahraee, S. M., & Abdolghader, Y. (2013).
 Organization Behaviour and Development-Related
 Issues in Effective Implementation of ISO 9001.
 Jurnal Teknologi (Social Sciences), 64(3), 151–156.
- Psomas, E.L., Pantouvakis, A. & Kafetzopoulos, D.P. (2013). The impact of ISO 9001 effectiveness on the performance of service companies. Managing Service Quality: An International Journal, 23(2), 149-164. DOI: 10.1108/09604521311303426
- Purwanto, A., Asbari, M., & Santoso, P. B. (2019). Does Culture, Motivation, Competence, Leadership, Commitment Influence Quality Performance?. Inovbiz: Jurnal Inovasi Bisnis, 7(2), 201 205
- Walaszczyk, A., & Polak-Sopinska, A. (2020). The Role of

Leadership in Organizations Managed in Conformity with ISO 9001 Quality Management System Standard. Springer nature Switzerland, h t t p://link-springernature Switzerland, h t t p://link-springernature/10.1007%2F978-3-030-20154-8 37

Yaya, L. H. P., Marimon, F., & Casadesus, M. (2011). Customer's loyality and perception of ISO 9001 in online banking. Industrial Management & Data Systems, 111(8), 1194-1213 q.

Appendices

- 1. Likert Scale interpretation:
- 2. Major Non Conformance
- 3. Non Conformance
- 4. Inadequate evidence to determine conformance or non-conformance
- 5. Conformance
- 6. Strongly Conform (with effectiveness of actions taken)

A- Questionnaire on "Leadership and Commitment"

With respect to quality management system is the top management's leadership and commitment demonstrated?

- 1. Does the top management take the accountability for QMS implementation?
- 2. Does the top management ensure the quality policy is established?
- 3. Does the top management ensure the quality objectives are established?
- 4. Does the top management ensure the quality policy is suitable to the organization's context?
- 5. Does the management confirm the quality objective are suitable to the organization's context?
- 6. Does the management conform the quality policy is suitable to the strategic business plans of the organization?
- 7. Does the management confirm the quality objective are suitable to the strategic business plans of the organization?
- 8. Does the management confirm the organization's business process is integrated with the quality management system?
- 9. Does the top management encourage to apply process approach?

- 10. Does the top management encourage to adopt risk based thinking?
- 11. Does the top management ensure the necessary provisions required for the implementation of ISO 9001 are provided?
- 12. Does the top management communicate the significance of effective implementation of the quality management system?
- 13. Does the top management communicate the significance of conformance to the requirements of ISO 9001?
- 14. Does the management confirm the ISO 9001 attain its expected outcome?
- 15. Does the top management engage employees for contribution to the success of ISO 9001?
- 16. Does the top management engage employees for contribution to the success of ISO 9001?
- 17. Does the top management direct employees for contribution to the success of ISO 9001?
- 18. Does the top management support employees for contribution to the success of the ISO 9001?
- 19. Does the management promote improvement of ISO 9001?
- 20. Does the management encourage other management roles of the quality management system?

B- Questionnaire on "Customer Focus":

- 1. Does the management exhibit commitment and leadership to confirm customer requirements are determined?
- 2. Does the management exhibit commitment and leadership to confirm identification and compliance with the statutory requirements?
- 3. Does the management exhibit commitment and leadership to confirm identification and compliance with the regulatory requirements?
- 4. Does the management exhibit commitment and leadership to confirm customer requirements are understood?
- 5. Does the management exhibit commitment and leadership to confirm statutory requirements are understood?
- 6. Does the management exhibit commitment and leadership to confirm regulatory requirements are understood?

- 7. Does the management exhibit commitment and leadership to confirm customer requirements are consistently met?
- 8. Does the management exhibit commitment and leadership to confirm statutory requirements are consistently met?
- 9. Does the management exhibit commitment and leadership to confirm regulatory requirements are consistently met?
- 10. Does the management confirm the opportunities and potential risks which could effect conformance to the products and services are determined?
- 11. Does the management confirm the opportunities and potential risks which could effect conformance to the products and services are addressed?
- 12. Does the management ensure the ability to enhance satisfaction of customer are determined?
- 13. Does the management ensure the ability to enhance satisfaction of customer are addressed?
- 14. Does the management ensure the focus for enhancing satisfaction of customer is maintained?

C- Questionnaire on "Policy":

- 1. Has the top management established the quality policy?
- 2. Has the top management implemented the quality policy?
- 3. Has the top management maintained the quality policy?
- 4. Is the quality policy suitable to the organization?
- 5. Is the quality policy suitable to the organization's context?
- 6. Does the quality policy supports organizations strategic direction?
- 7. Does the quality policy provides structure for defining quality objectives?
- 8. Does the top management's demonstrate their commitment to fulfill customer requirements including regulatory and statutory requirements in quality policy?
- 9. Does the management's intention for improvement of the ISO 9001 evidenced in the quality policy?

- 10. Does the quality policy available to verify as a document?
- 11. Does the quality policy maintained as to verify as a document?
- 12. Is the quality policy communicated within the organization?
- 13. Does the quality policy understood within the organization?
- 14. Does the quality policy applied within the organization?
- 15. Does the quality policy available to interested parties?

D- Questionnaire on "Organizational authorities, responsibilities and roles:

- 1. Does the management confirm the responsibilities for various roles assigned?
- 2. Does the management confirms the authorities for various roles assigned?
- 3. Does the management confirm the authority and responsibilities are informed in their organization?
- 4. Does the management confirm the relevant authority and responsibilities are better understood within their organization?
- 5. Has the top management assigned the authority and responsibilities confirming the quality management system fulfills ISO 9001 standard requirements?
- 6. Has the management assigned the authority and responsibilities confirming the processes achieve their expected results?
- 7. Has the management designated the authority and responsibilities for reporting on the performance of the ISO 9001?
- 8. Has the management designated authority and responsibilities for reporting potential opportunities for improvement of the ISO 9001?
- 9. Does the management encourage customer focus within the organization?
- 10. Does the management confirm the coherence of the ISO 9001 whenever there are planned changes?