THE MANAGERS' PERCEPTIONS TOWARDS THE QUALITY MANAGEMENT SYSTEM (QMS) IN ISO/CD2 9001:2000

By

W.MUHD RAHIMI BIN WAN SALLEH

Research Report submitted in partial fulfillment of the requirements for the degree of Master of Business Administration

May 2000

ACKNOWLEDGEMENT

I am grateful to Associate Professor Dr. Zainal Ariffin bin Ahmad for his guidance and advice throughout the completion of this project. His ideas, support and guidance give me essential inputs and encouragement to complete this project on time. I am indebted to him for making this project work a profound learning experience. I would like to thank the chairman of MBA Program, Associate Professor Dr. Muhammad Jantan for the invaluable statistical knowledge gained during the course.

I would also like to thank those people in the organisations surveyed especially those who helped in the distribution and collection of the questionnaires. My gratitude also extends to the respondents who have provided me the feedback to ensure the success of this project.

I would like to extend my gratitude to the management of Lembaga Kemajuan Kelantan Selatan (KESEDAR) for giving me the opportunity to further my study in University Science of Malaysia.

Last but not least, I would like to thank my dear wife, Saida, for her great support and patience, my children, Muhammad Luqman, Muhammad Yusuf and Nur A'ishah who have supported me in making my second degree a reality.

CONTENTS

Chapter 4 : ANALYSIS AND FINDINGS

Chapter 5 : DISCUSSION AND CONCLUSION

ABSTRACT

The quality management system (QMS) standard is the revised version of the 1994 quality system (QS) standard. It prescribes the minimum requirements of implementing the quality system in an organisation. In lieu with the development of modern business management philosophy and practices, the standards are periodically reviewed. The ISO/CD2 9001:2000 standard is the currently available revised version of the QMS standard. This study identifies the differences between the two quality systems (QMS version 2000 and QS version 1994) and explains the dimension of changes exist in the QMS standard requirements. The changes include the structural differences, customer focus orientation, human resource and use of information requirements. This study then, seeks initial response on the changes from the perspectives of those who currently implement the 1994 quality system - quality managers and quality committee members of the ISO 9000 certified organisations. Results from 109 managers (quality manager and quality committee members) of the ISO 9000 certified organisations in Penang shows that the managers rated customer focused orientation as the most agreeable feature of the changes, followed by the use of information requirements, human resource requirements and finally the structural changes. Further, the results also shows that job position of respondents have the most significant effects on their perceptions towards the changes.

ABSTRAK

Piawaian sistem pengurusan berkualiti (quality management system - QMS) merupakan versi semakan bagi piawaian sistem kualiti (QS) edisi 1994. Piawaian ini meyatakan keperluan yang perlu dipatuhi oleh organisasi dalam melaksanakan sistem pengurusan kualiti. Bersesuaian dengan perkembangan semasa, piawaian-piawaian sistem kualiti disemak secara berkala untuk memastikan ianya selari dengan falsafah dan amalan pengurusan terkini. ISO/CD2 9001:2000 merupakan edisi semakan terkini bagi piawaian sistem pengurusan berkualiti (QMS). Kajian ini mengenal pasti perbezaan yang wujud diantara dua edisi piawaian sistem kualiti (piawaian sistem pegurusan berkualiti edisi 2000 dan piawaian sistem kualiti edisi 1994) dan menerangkan dimensi perubahan yang wujud di dalam QMS. Antara perubahan yang diambil kira di dalam kajian ialah perubahan struktur, penumpuan terhadap pelanggan, pengurusan sumber manusia dan penggunaan maklumat. Kajian ini cuba mendapatkan tanggapan awal mereka yang melaksanakan sistem kualiti edisi 1994 terhadap perubahan-perubahan yang berlaku. Kajian terhadap 109 pengurus di organisasi yang telah menerima sijil piawaian ISO 9000 di Pulau Pinang mendapati mereka lebih bersetuju terhadap perubahan yang berlaku dalam konteks penumpuan pelanggan berbanding lain. Ini diikuti oleh perubahan dalam keperluan pengurusan sumber manusia, penggunaan maklumat dan akhir sekali perubahan struktur. Kajian juga mendapati jawatan mereka di dalam organisasi mempunyai pengaruh yang penting terhadap tanggapan mereka.

Chapter 1

INTRODUCTION

1.0 Background

Today's competitive pressures demand that an organisation or enterprise searches for the most cost-effective and efficient means of getting ahead of its competitors as well as getting its products to the market. The situation leads many organisations to improve their management system through the implementation of the quality system. Some international standards, especially ISO 9000 standards employ quality system as a strategic tool to meet today's challenges in the local as well as international markets. The standards normally prescribe the minimum requirements of the quality systems which are recognised internationally (SIRIM, 1999).

The quality system requirements outlined by International Organisation for Standardisation (ISO) through the ISO 9000 family standards are revised periodically to ensure that they are current and reflect the needs of the global community of users. The revision also provides the opportunity for the organisations to add value to their activities and overcome problems faced during the implementation of the previous quality systems (TC 176, 2000, http).

At the time of the study is undertaken, the 1994 version of the ISO 9000 family standard is undergoing a revision exercise by ISO Technical Committee 176 (ISO TC 176). The available revised version of the standard at the time of this study is the ISO/CD2 9001:2000. This standard prescribes the minimum requirements for the quality management system (QMS). This study, thus, is carried out to describe the

expected changes in the 2000 version of the requirements of the quality management system (QMS) from the perspectives of the managers (as the implementers of the quality system version 1994) in ISO 9000 certified organisations.

1.1 Purpose of Study

The purpose of this study is to describe the changes in the quality system requirements as in ISO/CD2 9001:2000 from the perspective of the managers in the ISO 9000 certified organisations. The changes include the new requirements added to the ISO 9001:1994 as well as existing requirements in the ISO 9001:1994 which are given more emphasis in the ISO/CD2 9001:2000. The study also attempts to see how the implementers' perspectives on the new quality systems requirements vary according to their age, educational level, job position and length of service in the organisation.

1.2 Statement of the Problem

The publication of the quality management system (QMS) requirements version 2000 will make the three quality system (QS) standards, namely ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994 obsolete. According to the ISO Technical Committee 176 (TC 176) which is responsible for the revisions, all ISO 9000 certified organisations are expected to switch to the new quality system after its publication (TC 176, 2000, http). The switching may be required by their holding organisations as well as the customers through certification to the ISO 9001:2000.

This change will affect the currently ISO 9000 certified organisations in various aspects particularly the managers as the implementers of the existing quality system -

the 1994 version. At the time of this study is undertaken, the available version of the revised quality system requirements is the ISO/CD2 9001:2000. Thus, this study attempts to describe the changes in the quality system from the perspective of the managers and how their perceptions vary according to their age, educational level, job position and length of their service in the organisations.

1.3 Research Question

This study attempts to answer the following question:

> What are the perceptions of the implementers of the 1994 quality system towards the quality management system (QMS) requirements in ISO/CD2 9001:2000?.

1.4 Scope of Study

The study is conducted on the quality managers and/or quality committee members as the individuals who implement the ISO 9000 standards in their organisations. In this study, they are referred to as the managers. Respondents are selected from those who are involved in the implementation of the 1994 quality system (or known as quality assurance - QA) as they are conversant with the requirements in either the ISO 9001: 1994 or ISO 9002:1994 or ISO 9003:1994 standards. This is to ensure that they understand the statements relating to the quality management system (QMS) used in the questionnaire in this study.

1.5 Significance of the Study

One challenge or question faced by Malaysian organisations (which are already fulfilled the quality system requirements of either the ISO 9001 or ISO 9002 or ISO 9003 standards) is that how does the switching over to the QMS ensure their survival in the local and international markets? The success of the transitional process will depend on some factors including monetary resources, physical facilities, organisational environment and above all the people who implement the QMS in the organisations.

The information about the managers' perceptions towards the QMS may provide early indicators about acceptance of the requirements of the ISO 9001:2000 standard. Furthermore, the information can also be used in enhancing the organisations' training programmes to suit the needs of the QMS. This study will also gives explanation on how the implementers of the quality system differ in their perceptions towards the QMS with regards to their age, educational level, job position and length of their service.

As for organisations which are not ISO 9000 certified yet, but are planning or interested to be certified, they may gain benefits from this study through the identification of some factors that may have influence on the implementers' perceptions towards the QMS. They can evaluate these factors and utilise them for the purpose of successful implementation of the ISO 9001:2000 in their respective organisations.

1.6 Definition of Terms

1.6.1 Standard

Standard refer to documented agreement containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, processes and services are fit for their purposes (ISO, 1999, http).

1.6.2 ISO 9000 Standards

According to Rao and Ragu-Nathan (1997), ISO 9000 standards are the basis for quality management that assumes consistency in products and service quality. This ISO 9000 series consist of two types of standards (Tingey, 1997). The first set are known as guidelines and are *not auditable* standards and the second type is the *auditable* ones includes ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994. Each of these standards cover a different field of application.

1.6.3 Quality

Juran (1992) defines quality as product features which meet customer needs and freedom from deficiencies. In the ISO 9000 family standards, quality "... is used in the context of achieving sustained customer satisfaction through meeting customer needs and expectations within an organisational environment committed to continual improvement of efficiency and effectiveness." (ISO/CD1 9000:1998).

1.6.4 Quality System (QS)

According to ISO 8402, quality system (QS) is defined as "The organisational structure, responsibilities, procedures, processes and resources for implementing quality maangement".

1.6.5 Quality Assurance

ISO 8402 defines quality assurance (QA) as "All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality".

1.6.6 Quality Management

ISO 8402 defines quality management as "... that aspects of the overall management function that determines and implement the quality policy". Juran and Gryna (1993) defined quality management as "A process of identifying and administering activities needed to achieve the quality objectives of an organisation". The ISO 9001:2000 standard is moving toward the quality management system (QMS).

1.7 Organisation of this Thesis

The second chapter reviews related literature on the ISO 9000 standards as well as its implementation internationally and locally. This is followed by comparison of the two versions of the standards, ISO 9001:1994 and ISO/CD2 9001:2000. The third chapter presents the methodology used in the study. This is followed by fourth chapter on data analysis and findings of the study. Finally, the conclusion and implications of the study are given in chapter five.

Chapter 2

LITERATURE REVIEW

2.0 Introduction

The objective of this chapter is to highlight the differences between the 1994 quality system (QS) outlined by the ISO 9001:1994 and quality management system (QMS) outlined by the ISO/CD2 9001:2000. The chapter begins with a review of relevant works and literature pertaining to ISO 9000 standards. This includes ISO 9000 series, its development, benefits and problems experienced by ISO 9000 certified organisations in implementing the standards. The review also includes some study conducted in Malaysia by Standards and Industrial Research Institute of Malaysia (SIRIM). Finally, the ISO 9001:1994 and ISO/CD2 9001:2000 are compared.

2.1 ISO 9000 Series

In 1983, International Organisation for Standardisation (ISO) published and circulated the first draft of ISO 9000, ISO 9001, ISO 9002, ISO 9003 and ISO 9004 which were adapted from the British Standard Institute (BSI) BS 5750 Part 1, 2, 3 and 4. In 1987, these ISO standards were made available to various European countries in an attempt to promote standardisation for facilitating international exchange of goods and services. At the same time, the ISO developed international economic, technical and intellectual co-operation (ISO, 1999, http). Today, the International Organisation for Standardisation has more than 180 technical committees that published international standards and it has more than 90 countries as its members including Malaysia (SIRIM, 1999, http).

The ISO 9000 standards are scheduled for review every five years by the ISO Technical Committee 176 (TC 176) to ensure its relevance with the latest management philosophies and practices. The 1987 version underwent limited revisions in 1994. In February 1999, the Second Committee Draft (CD2) ISO 9001:2000 was released as the revised version of the ISO 9001:1994 standard. This study is based on the ISO/CD2 9001:2000 because the Draft International Standard of ISO 9001:2000 is not yet available.

According to the ISO/CD2 9001:2000, it would replace the ISO 9001:1994 and at the same time incorporate ISO 9002:1994 and ISO 9003:1994 in it. The three standards would be withdrawn after the publication of the ISO 9001:2000. Thus, there will be only one ISO 9000 compliance standard for all organisations in a near future.

2.2 Reasons for Implementing ISO 9000

Organisation employs quality as a strategic tool to improve its profits. Many organisations, particularly in manufacturing industry, pursue ISO 9000 certification with a hope that they can gain improvement in total earnings (FitzGibbon, 1999, http). However, this is not the sole objective of certification. Lim and Niew (1995) suggested that most companies were motivated by other reasons namely customer's pressure, competitiveness of certified competitors, enhancement of the organisation's quality image, ensuring continuous quality improvement and reduction of product's risk and service liability claims.

Some recent studies (Davis, 1993; Street and Fernie, 1993; Wenmoth and Dobbin, 1994; and Brown & Van der Wiele, 1995) found that the external forces such as

customers' demands and expectations, competitive pressures and regulatory environment drove most companies to employ ISO 9000. They also found that some internal forces include production efficiency and as a 'kick start' for further step in quality improvement contribute as the supporting reasons. These findings were supported by the Manchester Business School research (1995), as quoted by FitzGibbon (1999, http) that the main driving force behind management's decisions to pursue ISO 9000 registration was external pressure, mainly from their customers.

In a survey of on 160 respondents of small and medium sized enterprises (SMEs) in Australia, Brown et al. (1998) found five main reasons for seeking ISO certification. First was to increase market share, followed by to improve efficiency, to be considered for tenders, to improve customer service and as a basis for quality improvement.

2.3 Benefits of ISO 9000 Standards Certification

ISO 9000 certification provides a competitive edge for organisations especially in improving themselves in various aspects of business. FitzGibbon (http, 1999) reported that an empirical study by Atwater and Dicenza (1993) on technology manufacturers found that ISO registration had resulted in substantial improvements to the organisations in terms of operating efficiency, customer satisfaction, competitive position, time required to train new employees as well as reducing scrap and rework.

The improvement benefits were also supported by Brumm (1995) and Peach (1995). They found that ISO 9000 registration benefited the organisations in terms of improved communication among employees, cost savings, reduced paperwork, more

organised design and output, greater competitive advantage, access to global market, fewer customer audits, improved productivity, a better trained workforce and increased customer confidence.

The benefits of ISO 9000 registration were further examined by Brown et al. (1998) in their survey. They reported that the top seven realised benefits for the enterprises were quality awareness, improved awareness of problems, improved customer service, improved management control, improve product and service quality, greater discipline and order, and consistency across organisation. They also found that the enterprises gained minimal improvements in terms of reduction in customer audits, helped in international markets, improved staff retention, reduced costs, ability to stay in business, improved staff motivation and improved market share.

Another study by Huarng et al. (1999) in Taiwan identified several benefits that organisations can gain from ISO certification in addition to what had been mentioned above. They include increased foreign buyers' approval of the firm's product quality, improved product reliability, enhanced corporate reputation overseas, enhanced product performance and rapid new product introduction.

2.4 Problems Encountered in Implementing ISO 9000

Beside the above mentioned benefits, organisations always encounter problems that threaten the successful implementation of the ISO 9000 standards. Davis (1997) cited some problems faced by Danish companies in implementing the standards. They include lack of senior management involvement which lead to inadequate planning and *imposing not implementing quality*, increased in paperwork and time used to

prepare for certification. This finding supported his earlier statement (Davis, 1993) that many firms that went for certification focused too much on meeting the requirements of the quality assurance system, rather than pleasing the customer, the main factor that ensuring their existence in the business.

Brown et al. (1998) identified several problems faced by most small and medium enterprises in Australia. They include lack of commitment by top management, employees and also time, increased in paperwork and/or documentation, difficult in interpretation of the standards, high certification costs, inflexible standards and inflexible auditors.

2.5 ISO 9000 in Malaysia

In Malaysia, ISO 9000 quality standards was first known to the manufacturing industries in the late 1989 (Muhd Aminullah, 1993). SIRIM, as the national certification body introduced the national standards known as MS ISO 9000 equivalent to the ISO 9000 series of the International Organisation for Standardisation in 1991. The national standards were first introduced to manufacturing companies especially those exporting their products to European countries that have to be compliant with product liability. Since then, Malaysia has had more than 1400 companies certified by SIRIM as of December 1999 (SIRIM, 1999). The increasing trend is due to Malaysian companies becoming more aware of the necessity to align themselves to comply with the requirements of the internationally accepted standards if they are to survive in the markets of the world (Liang, 1993).

A study by Raj (1993) found that most Malaysian organisations sought registration to ISO 9000 because they want to improve the quality of their products. This is followed by meeting customer requirements who are mainly from public authorities and large corporations. The other reasons include policy of the holding companies, improving the organisation's image, complying with the regulatory authorities such as the European Union and fear from being excluded from their large market.

In term of realised benefits, ISO certified Malaysian companies gained almost similar to what their international counterparts gained through ISO 9000 certification in terms of effective integration (94%), quality improvement (90%), competitive advantage (87%), market share increment (84%), reduction in customer complaints (81%), higher employee motivation (68%) and access to new market (58%) (SIRIM, 1995). They also faced some problems in implementing the quality system. The problems included increment in paperwork, difficulty in interpreting the standard, prescriptive nature of the standard and high certification cost (SIRIM, 1998).

2.6 Comparison between ISO 9001:1994 and ISO/CD2 9001:2000

The comparison between the two versions of ISO 9001 standards is necessary to identify the differences between the 1994 quality system (QS) and the quality management system (QMS) requirements. Since both standards consist of clauses which make up the requirements of both quality systems, the comparison is done based on the clauses in the ISO 9001:1994 standard.

The ISO/CD2 9001:2000 standard is the improved version of the ISO 9001, 9002 and 9003 series of standards. It is set to be a comprehensive model of the ISO 9001:1994

standard. Hence, a comparison between the ISO 9001:1994 and the ISO/CD2 9001:2000 standards shows many similarities in term of the quality system requirements. Nevertheless, there are still some differences between the two versions.

2.6.1 Similarities

2.6.1.1 Top Management Responsibility

Among the apparent similarities of the two versions include the demand for top management commitment and involvement to establish the quality management system (Honstein, 1999, http). The quality policies and objectives should be stated, publicised and implemented by the management. A management representative should be appointed, and the organisation should review the effectiveness of the quality management system periodically.

Both versions of the standards require the necessity of top management responsibility, involvement and commitment in successfully implementing the quality management system. Clause 4.1 of ISO 9001:1994 - Management responsibility which covers the necessity for stated quality (Clause 4.1.1), objectives and commitments to it; the responsibility and authority of personnel (Clause 4.1.2.1) who implement the system, resources needed (Clause 4.1.2.2) in ensuring successful implementation, appointment of management representative (Clause 4.1.2.3) as well as periodic review of the system (Clause 4.1.3) (Lim & Niew, 1995).

These requirements are spelled out in more detail in ISO/CD2 9001:2000 Clause 5 - Management responsibility. These include Clause 5.1 - General requirements that elaborate on five dimensions of demonstrating organisation's commitment. The

dimensions are awareness of importance to fulfil customer requirements, establishment of quality policy and objectives as well as quality planning, establishing quality management system, performing management review and ensuring the availability of resources. These dimensions are also explained in other subsequent Clauses including Clause 5.2 - Customer requirements, Clause 5.4 - Policy, Clause 5.6.2 - Responsibility and authority, Clause 5.6.3 - Management representative, Clause 5.6.5 - Quality manual and Clause 5.7 - Management review. The responsibility and authority of personnel involved in the implementation of the system is further explained in Clause 5.6.2 - Responsibility and authority. A detail coverage of management responsibilities on resources are apparent in Clause 6 - Resource management.

2.6.1.2 Quality System

Clause 4.2 of ISO 9001:1994 - Quality System, requires the organisation to establish, document and maintain a quality system as a means of ensuring that a product conforms to the specified requirements. It spells out the need for documented procedures and effective implementation of the procedures (Clause 4.2.2). Clause 4.2.3 - Quality planning lays out eight activities needed to achieve the requirement. The activities are the preparation of quality plans; the identification and acquisition of any controls, processes, equipment, fixtures, resources and skills that may be needed to achieve the required quality; ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures and the applicable documentation; the updating, as necessary, of quality control, inspection and testing techniques, including the development of new instrumentation; the

identification of any measurement requirement involving capability that exceeds the known state of art in sufficient time for the needed capacity to be developed; the identification of suitable verification at appropriate stages in the realisation of product; the clarification of standards of acceptability for all features and requirements, including those which contain a subjective clause and the identification and preparation of quality records (International Organisation for Standardisation, ISO 9001:1994 standard, 1996).

The above requirements and activities are also covered under ISO/CD2 9001:2000. The requirements are explained under Clause 4 - Quality management system requirements. The other relevant Clauses are Clause 5.1 - General requirement (of management responsibility), Clause 5.5 - Planning, Clause 5.5.1 - Objectives and Clause 5.5.2 - Quality planning.

2.6.1.3 Contract Review

Clause 4.3 of ISO 9001:1994 Contract Review requires the management to establish and maintain procedures for contract review and its co-ordination. The review must ensure that all contractual requirements are adequately defined, differences are resolved and the company is capable of meeting these requirements (Clause 4.3.2). The procedure also must show that an amendment to a contract can be made and accurately conveyed to the parties concerned (Clause 4.3.3). These corresponding Clauses in ISO/CD2 9001:2000 are Clause 7.1 - General requirement (of product and/or service realisation) and Clause 7.2 - Customer related process and its sub-Clauses.

2.6.1.4 Design Control

Clause 4.4 of ISO 9001:1994 Design Control is only applicable to organisations involved in design and development activities. It requires an organisation to establish and maintain documented procedures for design control which will ensure that specified design requirements are met (Clauses 4.4.1 through 4.4.9) (Lim & Niew, 1995). This requirement is also covered by the ISO/CD2 9001:2000 under Clause 7.1 and 7.3. Clause 7.3 and its sub-Clauses include all the necessary requirements almost similar to what is explained in ISO 9001:1994 Clauses 4.41 through 4.4.9.

2.6.1.5 Document and Data Control

Clause 4.5 of ISO 9001:1994 - Document and Data Control. This clause requires the management to identify quality documents and data, and to establish a system that is capable to control the documents and data. The management must also ensure that only the correct and up-to-date documents and data are being used. This can be done through proper identification, filing, maintenance, review, approval and control. The documents and data can be in any forms of media, hard or soft copy (Lim & Niew, 1995). The requirement of this clause is covered under ISO/CD2 9001:2000 Clause 5.6 - Quality management system, and all its sub-clauses. Specifically, Clauses 5.6.6 and 5.6.7 of the new standard state the necessity for control of documents and control of records.

2.6.1.6 Purchasing

Clause 4.6 of ISO 9001:1994 - Purchasing requires the organisation to develop a documented system that will ensure the purchased products conform to specified requirements. This includes the appropriate selection of suppliers through certain evaluation (Clause 4.6.2). Purchasing also need to be done in a systematic manner i.e. the specification is documented and attached with purchase orders (Clause 4.6.3) and verification of purchased products must be practised to ensure that the products conform to the specifications (Clause 4.6.4) (Lim & Niew, 1995). These requirements are mentioned in ISO/CD2 9001:2000 under Clause 7.1 - General requirements (of product and/or service realisation) and specifically in the Clauses 7.4 - Purchasing, 7.4.1 - General requirements, 7.4.2 - Purchasing information and 7.4.3 - Verification of purchased products and/or services.

2.6.1.7 Control of Customer Supplied Products

Clause 4.7 of ISO 9001:1994 Control of customer-supplied product, requires the management to establish and document procedures for the control of verification, storage and maintenance of customer-supplied products (Lim & Niew, 1995). This requirement is specifically addressed by Clause 7.5.3 of ISO/CD2 9001:2000 - Customer property.

2.6.1.8 Identification and traceability

Clause 4.8 of ISO 9001:1994 - Product identification and traceability requires the management to establish and document procedures for identification of products to

ensure the easy trace of parts or components during all stages of production, testing, delivery and installation (Lim & Niew, 1995). This requirement is specifically addressed by Clause 7.5.2 of ISO/CD2 9001:2000 - Identification and traceablity.

2.6.1.9 Process Control

Clause 4.9 of ISO 9001:1994 - Process control requires the organisation to identify and plan the production, testing, installation and servicing processes which affect quality in order to ensure that the processes are carried out under controlled conditions (Lim & Niew, 1995). The minimum conditions that should be controlled are (ISO, 1996):

i) Documented procedures

ii) Suitable equipment operating under a suitable working environment

iii) Compliance to reference standard, quality plans and work instructions

iv) Adequate monitoring and control techniques

v) Qualification of process where appropriate

vi) Clear criteria for workmanship

vii)Effective maintenance program of equipment for continuing process capability

These requirements are mentioned in ISO/CD2 9001:2000 under Clause 6.4 - Infrastructure, Clause 7.1 - General requirements (of product and/or service realisation) and Clause 7.5.1 - General requirements (of production and service operations).

2.6.1.10 Inspection and Testing

Clause 4.10 of ISO 9001:1994 - Inspection and testing requires the organisation to establish and maintain documented procedures for inspection and testing activities. The purpose is to ensure that the products conform to specific requirements. Inspection and testing can be performed for incoming material (Clause 4.10.2), in-process (Clause 4.10.3) or final products (Clause 4.10.4) (Lim & Niew, 1995). This requirement is addressed in ISO/CD2 9001:2000 in Clause 7.1 - General requirement (of product and/or service realisation), Clause 7.5.1 - General requirement (of production and/or service operations), Clause 7.5.5 - Validation of processes, Clause 8.1 - Measurement, analysis and improvement, and Clause 8.2.3 - Measurement and monitoring of product and/or service.

2.6.1.11 Control of Inspection, Measuring and Test Equipment

Clause 4.11 of ISO 9001:1994 - Control of inspection, measuring and test equipment, requires the organisation to develop and document procedures to control, calibrate and maintain equipment used for inspection, test and measurement (Lim & Niew, 1995). This requirement is addressed in ISO/CD2 9001:2000 under Clause 7.5.1 - General requirement (of product and/or service realisation) and specifically detailed out in Clause 7.6 - Control of measuring and monitoring devices.

2.6.1.12 Inspection Test and Status

Clause 4.12 of ISO 9001:1994 - Inspection and test status, requires the organisation to develop and implement procedures to identify the inspection and test status of a

product. Thus, only parts that have passed the required inspection and tests are being processed further (Lim & Niew, 1995). This requirement is mentioned in Clause 7.5.1 - General requirement (of product and/or service realisation) and Clause 7.5.5 - Validation of processes in ISO/CD2 9001:2000.

2.6.1.13 Control of Non-conforming Products

Clause 4.13 of ISO 9001:1994 - Control of non-conforming product, requires the organisation to identify, segregate, evaluate, document and properly dispose non-conforming products. The aim is to avoid the defect product from reaching the customer. According to Clause 4.13.2, review and disposition of non-conforming product must be done by authorised personnel (Clause 4.13.2) (Lim & Niew, 1995). This requirement is addressed in ISO/CD2 9001:2000 under Clause 8.3 - Control of non-conformity, Clause 8.3.1 - General requirement and Clause 8.3.2 - Nonconformity review and disposition.

2.6.1.14 Corrective and Preventive Action

Clause 4.14 of ISO 9001:1994 - Corrective and preventive action, requires the organisation to document and maintain procedures for implementing corrective and preventive action appropriate to its needs (Lim & Niew, 1995). The procedures for corrective and preventive action are explained further in Clauses 4.14.2 and 4.14.3 . This requirement is covered by ISO/CD2 9001:2000 under Clause 8.5 - Improvement and its sub-Clauses 8.5.2 - Corrective action and 8.5.3 - Preventive action.

2.6.1.15 Handling, Storage, Packaging, Preservation and Delivery

Clause 4.15 of ISO 9001:1994 - Handling, storage, packaging, preservation and delivery, requires the organisation to establish and maintain procedures to ensure that the products are not damaged by improper handling, storage, packaging, preservation and delivery, This procedures would include incoming, in-process and finished products (Lim & Niew, 1995). This requirement is also covered by ISO/CD2 9001:2000 under Clause 6.3 - Information, Clause 7.1 - General requirement (of product and/or service realisation), and Clause 7.5.4 - Handling, storage, packaging, preservation and delivery.

2.6.1.16 Control of Quality Records

Clause 4.16 of ISO 9001:1994 - Control of quality records, requires the management to document appropriate procedures for controlling quality records. The records should be retained according to the specific needs of the individual products to provide evidence of meeting the specified requirements. The records should be legible, retrievable and stored appropriately according to the need of the organisation (Lim & Niew, 1995). This requirement is addressed by ISO/CD2 9001:2000 in Clause 5.6.7 - Control of records and partly explained by Clause 6.3 - Information.

2.6.1.17 Internal Quality Audit

Clause 4.17 of ISO 9001:1994 - Internal quality audits, requires the management to document appropriate procedures for planning and implementing internal quality audits. Internal audit reports should be reviewed periodically to ensure that the

necessary corrective action is taken (Lim & Niew, 1995). This requirement is mentioned in ISO/CD2 9001:2000 under Clause 8.1 - General requirements (of measurement, analysis and improvement) and also specifically under Clause 8.2.1.2 - Internal audit.

2.6.1.18 Training

Clause 4.18 of ISO 9001:1994 - Training, requires the organisation to continuously identify the suitable training needs of personnel whose work affects the quality of a product. The retention period of training records should be defined (Lim & Niew, 1995). Some of this requirement are addressed in Clause 6.2.2 - Competence, training, qualification and awareness.

2.6.1.19 Servicing

Clause 4.19 of ISO 9001:1994 - Servicing, requires the management to document appropriate procedures for performing, verifying and reporting that servicing meets the contractual requirements of the product's needs. The document should be established appropriately and maintained. This requirement is only applicable whenever servicing is specified in a contract (Lim & Niew, 1995). The requirement is mentioned in ISO/CD2 9001:2000 under Clause 7.1 - General requirement (of product and/or service realisation).

2.6.1.20 Statistical Techniques

Clause 4.20 of ISO 9001:1994 - Statistical techniques, requires the management to identify appropriate statistical techniques for their operation (Clause 4.20.1) and document the needed procedures for the implementation and correct application of the statistical techniques (Clause 4.20.2) (Lim & Niew, 1995). The relevant Clause that covers this requirement in ISO/CD2 9001:2000 is Clause 8.4 - Analysis for data for improvement.

The above discussion is summarised in Table 1.

Table 1 : The Similarities of Requirements of ISO 9001:1994 and ISO/CD2 9001:2000

ISO 9001: 1994	*ISO/CD2 9001: 2000*
1. Scope	1. Scope
2. Normative reference	2. Normative reference
3. Definitions	3. Terms and definitions
4. Quality system requirements	4. Quality management system requirements
4.1 Management Responsibility 4.1.1 Quality policy	5.1 - General requirements - (Management responsibility) 5.2 - Customer requirements 5.4 - Policy 5.6.5 - Quality manual
4.1.2 Organisation	
4.1.2.1 Responsibility and authority	5.6.2 - Responsibility and authority
4.1.2.2 Resources	6 - Resource management 6.2.1 - Assignment of personnel
4.1.2.3 Management representative	5.6.3 - Management representative
4.1.3 Management review	5.7 - Management review
4.2 Quality System	4 - Quality management system requirements 5.1 - General requirements - Management responsibility
4.2.1 General	4 Quality management system requirements
4.2.2 Quality system procedures	
4.2.3 Quality planning	5.5 - Planning 5.5.1 Objectives 5.5.2 Quality planning
4.3 Contract Review	
4.3.1 General	7.1 - General requirements - Products and/or service realisation
4.3.2 Review	7.2 - Customer-related processes 7.2.1 Identification of customer requirements 7.2.2 Review of customer requirements
4.3.3 Amendment of contract	7.2.2 Review of customer requirements
4.3.4 Records	7.1 - General requirements - Products and/or service realisation 7.2.2 Review of customer requirements