

**APPLICATIONS OF STATISTICAL TECHNIQUES
IN QUALITY SYSTEMS**

by

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TABLE OF CONTENTS

	Page
ACKNOWLEDGEMENTS	ii
TABLE OF CONTENTS	iii
LIST OF TABLES	vi
LIST OF FIGURES	vii
ABSTRAK	ix
ABSTRACT	x
CHAPTER 1: INTRODUCTION	1
1.1 Introduction To Quality Systems	1
1.1.1 What is ISO 9000?	1
1.2 Evolution of ISO 9000	3
1.3 Other Quality Management System Standards	8
1.4 Application of Statistical Techniques	10
1.5 Objectives of the Dissertation	12
1.6 Organization of the Dissertation	13
CHAPTER 2: LITERATURE REVIEW	14
CHAPTER 3: QUALITY SYSTEMS AND STATISTICAL TECHNIQUES	19
3.1 ISO 9000:1994 and ISO 9000:2000	19
3.2 TL 9000	28
3.2.1 Introduction	28
3.2.2 Structure of TL 9000	31
3.2.3 Registration scope	32

3.3	AS 9100	36
3.4	ISO13485:2003	39
3.5	21 CFR Part 820 Medical Device Quality System Regulation	42
3.6	QS-9000 / TS 16949	44
3.7	Statistical Techniques Used in Manufacturing Industry	47
	3.7.1 Statistical Process Control (SPC)	47
	3.7.2 Process Capabilities Studies	64
	3.7.3 FMEA	65
CHAPTER 4: CASE STUDY		68
4.1	Introduction	68
	4.1.1 Background information	68
	4.1.2 Problem statement	73
	4.1.3 Objective	74
4.2	Methodology	74
	4.2.1 Data	74
	4.2.2 Procedures	74
4.3	Statistical data analysis	75
4.4	Results and discussion	81
4.5	Conclusions	85
4.6	Other application of statistical techniques used in manufacturing industry	86
	4.6.1 P-chart and U-chart for on line statistical process control	86
	4.6.2 Failure Mode Effect Analysis (FMEA)	88
CHAPTER 5: CONCLUSION		90
5.1	Summary	90
5.2	Contribution of dissertation	90

5.3	Recommendations	91
	BIBLIOGRAPHY	92
	APPENDICES	
	Appendix A ISO Member Bodies	95
	Appendix B TC 176 Membership	102
	Appendix C ISO 9000:1994 Requirements	104
	Appendix D ISO 9000:2000 Additional Requirements	115
	Appendix E ISO 9001:2000 and TL9000 (Differences and additional TL9000 requirements)	119
	Appendix F ISO 9001:2000 and AS9100 (Differences and additional AS9100 requirements)	152
	Appendix G ISO 9001:2000 and ISO 13485:2003 (Differences and additional ISO 13485:2003 requirements)	176
	Appendix H ISO 9001:2000 and 21 CFR 820 (Differences and additional 21 CFR 820 requirements)	193
	Appendix I ISO 9001:2000 and TS 16949:2002 (Differences and additional TS 16949:2002 requirements)	200
	Appendix J FMEA (Sample)	236
	Appendix K Factors for Constructing Variables Control Charts	244
	Appendix L Suggested Evaluation Criteria For Severity, Occurrence and Detection	245

LIST OF TABLES

	Page
1-1 ISO 9000 Evolution: 1987-2000	5
1-2 Comparison of ISO 9001, 9002 and 9003 (version 1994)	6
3-1 ISO 9001 Cross-Reference	26
3-2 ISO 9001:2000 Elements	27
3-3 Identifier for TL 9000	32
3-4 Registration Requirements by Specialty Area	33
4-1 Metric Table	73
4-2 PDC Improvement actions for BAN Models	80
L-1 Suggested Severity Evaluation Criteria	245
L-2 Suggested Occurrence Evaluation Criteria	246
L-3 Suggested Detection Evaluation Criteria	247

LIST OF FIGURES

	Page
1-1 Production process inputs and outputs	11
3-1 Model of a Process-Based QMS	22
3-2 Plan-Do-Check- Act (PDCA) Cycle	24
3-3 The TL 9000 Model	31
3-4 Histogram for Casing Length	49
3-5 Pareto chart for wave defects in WW17 and WW18	51
3-6 Cause and Effect Diagram For Channel To Noise Failure	52
3-7 A Scatter Diagram	53
3-8 X Bar R Control Chart	55
3-9 SPC Decision Tree	56
3-10 One point beyond zone A	60
3-11 Nine points in a row one in or beyond zone C	60
3-12 Six point in a row, all increasing or all decreasing	61
3-13 Fourteen points in a row, alternating up or down	61
3-14 Two out of three points in a row in or beyond zone A	62
3-15 Four out of five points in a row in or beyond zone B	62
3-16 Fifteen points in a row in zone C (either side)	63
3-17 Eight points in row at both side of center line with no point in zone C	63
3-18 Process Capability	64
3-19 C_p and C_{pk} indices	65
3-20 FMEA Model	66
4-1 Harmonic Ban General Process Flow	69
4-2 Critical To Quality (CTQ) Tree	72
4-3 Pareto analysis for model PWL (May 2004)	76

4-4	Pareto analysis for model PWL (June 2004)	76
4-5	Type of PDC breakdown analysis (July & August 2004)	77
4-6	Cause and Effect (Fishbone) Diagram Analysis	78
4-7	Decision Tree	79
4-8	PDC Defect Rate trend for PWL at QA02 – April 2004 (Before improvement) to December 2004 (After improvement)	81
4-9	PDC Defect Rate trend for HLD at QA02 – April 2004 (Before improvement) to December 2004 (After improvement)	82
4-10	PDC Defect Rate trend for PWL at QA03 – January 2004 (Before improvement) to September 2004 (After improvement)	82
4-11	PDC Defect Rate trend for HLD at QA03 – January 2004 (Before improvement) to September 2004 (After improvement)	83
4-12	Defect percentage for PWL in May and August 2004	84
4-13	PDC defect rate for PWL (May 2004 to May 2005)	84
4-14	Test Yield Trend for PWL/HLD (July to December 2004)	85
4-15	U-chart and P-chart for SMT 01	86
4-16	Detailed breakdown of defective and defects	87
4-17	FMEA (Programming fixture process)	89

APLIKASI TEKNIK STATISTIK DALAM SISTEM KUALITI

ABSTRAK

Untuk bersaing dan memenangi perniagaan baru dalam pasaran kini, setiap organisasi cuba mendapatkan pelbagai pengiktirafan sistem pengurusan kualiti dengan bergantung kepada keperluan pelanggan. ISO 9000 adalah sistem pengurusan kualiti yang paling dikenali dan diamali oleh kebanyakan organisasi. Sistem pengurusan kualiti lain seperti QS 9000/TS 16949, AS 9100, TL 9000, ISO 13485 dan sistem kualiti untuk alat-alat perubatan telah digubal untuk memenuhi pelbagai keperluan industri dan pelanggan. Aplikasi teknik statistik dalam pelbagai jenis sistem pengurusan kualiti telah dibanding dan dibincangkan. Setiap sistem pengurusan kualiti memerlukan aplikasi teknik statistik. Ia menjadi semakin penting terutamanya dalam industri pembuatan dalam usaha mengurangkan variasi proses dan mengelakkan kecacatan produk. Walaubagaimanapun, sebahagian teknik statistik yang digunakan dalam pelbagai sistem pengurusan kualiti adalah berbeza. Teknik statistik yang spesifik diperlukan dalam sesetengah sistem pengurusan kualiti seperti QS 9000/TS 16949. Kajian telah dijalankan untuk mengkaji teknik statistik yang digunakan dalam sebuah kilang pembuatan elektrik dan elektronik. Teknik statistik telah disahkan dapat mengurangkan variasi dan mengelakkan kecacatan produk. Kebanyakan organisasi cuba mengaplikasikan teknik statistik secara optimum disebabkan oleh keberkesanannya. Oleh sebab sistem pengurusan kualiti hanya memerlukan keperluan statistik secara umum, cadangan telah dikemukakan supaya teknik statistik yang lebih spesifik dilaksanakan untuk kemajuan pada masa hadapan.

ABSTRACT

In order to compete and gain new business in the market, every organization is trying to obtain certification of various types of quality management system (QMS) standards based on their customer needs. ISO 9000 is the most popular quality management system that are adopted by most of the organizations. Other specific industry QMS standards such as QS 9000/TS 16949, AS 9100, TL 9000, ISO 13485 and Quality System Requirements (QSR) for medical devices are developed to meet different industry and customer requirements. Application of statistical techniques in different types of QMS is compared and discussed. Every QMS standard requires application of statistical techniques. It becomes more important especially in the manufacturing industry to reduce process variation and prevent defects. However, there are some differences in the application of statistical techniques in various types of QMS. Specific statistical techniques are required in some QMS like QS 9000/TS 16949. A case study has been carried out on the statistical techniques used in a printed circuit board assembly (PCBA) manufacturing factory. It was proved that statistical techniques are effective in variation reduction and defects prevention. Most of the organizations try to apply the statistical techniques optimally due to its effectiveness. Since the QMS standard only stated the statistical requirements in general, so it is recommended that specific statistical techniques are enforced in order to obtain greater improvement in the future.

CHAPTER 1

INTRODUCTION

1.1 Introduction To Quality Systems

Badiru (1995) defines quality system as a system consisting of organization, structure, resources, responsibilities, procedures and processes that are used to manage quality. A quality system is a collection of interrelated elements with a common objective. All of these elements together constitute the synergistic system needed to achieve the objective of quality improvement (Badiru, 1995).

1.1.1 What is ISO 9000?

The short designation for ISO 9000 was actually borrowed from the Greek word *isos*, which means "equal" (Badiru, 1995). The intention of ISO 9000 is to have a common standard used by all organizations worldwide. ISO 9000 is a series of quality assurance standards that were created by the International Organization for Standardization (ISO), based in Geneva, Switzerland (Johnson, 2000). ISO was established in 1947 to promote standards in international trade, communications and manufacturing (Goetsch and Davis, 2002). ISO is a non-governmental organization but is a worldwide federation of national standards organizations from 130 nations (Goetsch and Davis, 2002).

There are three categories of ISO membership : full member, correspondent member and subscriber member. A national body

designated by its respective country as the “most representative of standardization” is considered a full member. Full members may participate in the development of standards. A list of ISO member bodies (full members) can be found in Appendix A. Correspondent members are represented by a nation that does not have a standardization body. A small nation with a very small economy may become a subscriber member at a reduced membership rate. Correspondent and subscriber members are kept informed about activities of interest by ISO.

ISO 9000 consists of five subdivisions. All the subdivisions contain a set of models and guidelines for quality assurance and quality management. The approach will vary for every organization based on their specific needs. The following explains each subdivision of ISO 9000 :

- a) ISO 9000 – Quality Management and Quality Assurance Standards : Guidelines for Use. This is the roadmap that provides guidelines for selecting and using 9001, 9002, 9003 and 9004.
- b) ISO 9001 – Quality Systems : Model for Quality Assurance in Design/Development, Production, Installation and Servicing. This is the most comprehensive standard. It contains 20 elements and presents a model for quality assurance for organizations involved in the design, manufacturing and installation of products and / or services.
- c) ISO 9002 – Quality Systems : Model for Quality Assurance in Production and Installation. It contains 18 elements and

presents a model for quality assurance for organizations involved in manufacturing or production of products and/or services only.

- d) ISO 9003 – Quality Systems : Model for Quality Assurance in Final Inspection and Test. It contains 12 elements and is for firms involved in the distribution, inspection and testing of manufactured products or services only, without any production or installation activities. It presents a model for quality assurance in final inspection and test.
- e) ISO 9004 – Quality Management and Quality System Elements : Guidelines. It provides guidance for a supplier to use in developing and implementing a quality system and to determine the extent to which each quality system element is applicable. It contains guidelines for users in the process of developing in-house quality systems.

2 Evolution of ISO 9000

ISO has formed the Technical Committee 176 (TC 176), which is an international team representing 75 nations (Refer to Appendix B). The purpose of TC 176 was to develop a universally accepted set of quality standards which was needed to harmonize various types of national and international quality standards throughout the world. The ISO 9000 series of standards was first version released in 1987 and second version releases in 1994 after a mild update by TC 176. The third version, ISO 9001:2000 replaced the 1994 version from the year 2000 onwards. The older version,

ISO 9000:1994 certification remains valid until their next certification date but no later than December 2003 since the re-certification period is three years (Goetsch and Davis, 2002). For example, if a organization was certified ISO 9000:1994 in the year 1998, it will be recertified in the year 2001 although the new standard ISO 9001:2000 was introduced in the year 2000. This means starting from the year 2000, all organizations that were newly certified ISO 9000 must follow the latest ISO9001:2000 standard. Goetsch and Davis (2002) focus more on ISO 9001:2000 as this is the latest revision. There was a major change in ISO 9001:2000 compared to the two earlier versions. Now, there is only one standard (ISO 9001:2000) instead of three, and one document (ISO 9004:2000) instead of eight (See Table 1-1).

Table 1-1 shows the evolution of ISO 9000 from 1987 to 2000. In the 1987 version, two guidelines are available, ISO 9000 :1987 (Guidelines for Selection and Use) and ISO 9004 : 1987 (Guidelines for Quality System Elements and Management). There are three standards available for the 1987 version : ISO 9001 : 1987 (Model for Design/Development, Production, Installation and Servicing), ISO 9002 : 1987 (Model for Production, Installation and Servicing) and ISO 9003 : 1987 (Model for Final Inspection and Test). For the 1994 version, six additional guidelines are introduced to make eight total guidelines. The additional guidelines are ISO 9000-2 : 1993 (Guidelines for Application of the Standards), ISO 9000-3 : 1991 (Guidelines for Application of ISO 9001 to software producers), ISO 9000-4 : 1993 (Guide to "Dependability" Program Management, ISO 9004-2 : 1991 (Guidelines for Services), ISO 9004-3 : 1993 (Guidelines for Processed Materials) and ISO

9004-4 : 1993 (Guidelines for Quality Improvement). In the 2000 version, there is a great reduction in the number of guidelines and standards. Only one standard, ISO 9001 : 2000 (Quality Management Systems – Requirement) instead of three in the previous version and one guideline, ISO 9004 : 2000 (Guidelines for Organizational Performance Improvement) instead of eight guidelines for 1994 version are used. In the 2000 version, there is a document providing the fundamental and vocabulary requirements in the ISO 9001 implementation, which is ISO 9000 : 2000.

Table 1-1 ISO 9000 Evolution: 1987-2000 (Goetsch and Davis, 2002)

1987 Version	1994 Version	2000 Version	Purpose
ISO 9000:1987	ISO 9000-1:1994		Guidelines for Selection and Use
None	ISO 9000-2:1993		Guidelines for Application of the Standards
None	ISO 9000-3:1991		Guidelines for Application of ISO 9001 to software producers
None	ISO 9000-4:1993		Guide to "Dependability" Program Management
		ISO 9000:2000	Fundamental ands Vocabulary
ISO 9001:1987	ISO 9000-1:1994		Standard - Model for "Full House" Producers
ISO 9002:1987	ISO 9000-2:1994		Standard - Model for Production
ISO 9003:1987	ISO 9000-3:1994		Standard - Model for Final Inspection and Test only
		ISO 9001:2000	Quality Management Systems - Requirement*
ISO 9004:1987	ISO 9004-1:1994		Guidelines for Quality System Elements and Management
None	ISO 9004-2:1991		Guidelines for Services
None	ISO 9004-3:1993		Guidelines for Processed Materials
None	ISO 9004-4:1993		Guidelines for Quality Improvement
		ISO 9004:2000	Guidelines for Organizational Performance Improvement
			*Certifications are to ISO 9001:2000 only.

The differences between the three standards of ISO 9000:1994 are given in Table 1-2.

Table 1-2 Comparison of ISO 9001, 9002 and 9003 (version 1994) (Harrington and Mathers, 1997)

Cross-Reference of ISO 9000 Quality Assurance Requirements				
ISO 9000 Clause and Title		Quality Assurance Requirement		
		ISO 9001	ISO 9002	ISO 9003
4.1	Management responsibility	√	√	0
4.2	Quality system	√	√	0
4.3	Contract review	√	√	√
4.4	Design control	√	X	X
4.5	Document and data control	√	√	√
4.6	Purchasing	√	√	X
4.7	Control of customer-supplied product	√	√	√
4.8	Product identification and traceability	√	√	0
4.9	Process control	√	√	X
4.10	Inspection and testing	√	√	0
4.11	Control of inspection, measuring, and test equipment.	√	√	√
4.12	Inspection and test status	√	√	√
4.13	Control of nonconforming product	√	√	0
4.14	Corrective and preventive action	√	√	0
4.15	Handling, storage, packing, preservation, and delivery	√	√	√
4.16	Control of quality records	√	√	0
4.17	Internal quality audits	√	√	0
4.18	Training	√	√	0
4.19	Servicing	√	√	X
4.20	Statistical techniques	√	√	0

Key:

- √ Required
- 0 Less stringent requirement than ISO 9001 and 9002
- X Not required

For ISO 9000 :1994, there is a difference between ISO 9001, 9002 and 9003 (refer to Table 1-2). ISO 9001 is the most comprehensive among three quality assurance standards. ISO 9001 is for organizations that develop unique designs for each customer's need. Since ISO 9001 contains all the 20 elements for Quality Management System, complying with all the requirements of ISO 9001 will also be complying to ISO 9002 and ISO 9003. The difference between ISO 9001 and ISO 9002 is that ISO 9002 does not address product design. It applies to organizations in which the product design is the responsibility of the customer. ISO 9003 is the least stringent among the three standards. It applies to organizations that supply less complex products whose quality can be evaluated based on inspection and test only. From Table 1-2, six of the required elements in ISO 9003 (indicated by √) are the same with ISO 9001 and ISO 9002, ten elements are less stringent than ISO 9001 or ISO 9002 (indicated by 0) and four elements do not apply (indicated by X) (Harrington and Mathers, 1997).

Goetsch and Davis (2002) highlighted ISO 9000's evolution from 1987 to 2000 which had been revised to be more aligned with the Total Quality Management (TQM) Philosophy. TC 176 has borrowed some elements of TQM for ISO 9000:1987, mostly on documentation requirements. For ISO 9000:1994, the continual improvement have been mentioned although it is not a requirement. ISO 9000:2000 has the greatest similarity to TQM if compared with the two older versions. It emphasizes on continual improvement principles from TQM. They are as follows :

- 1) **Customer focus** – understanding their needs, striving to exceed their expectations.
- 2) **Leadership** – establishing direction, unity of purpose, and a supporting work environment.
- 3) **Involvement of people** – ensuring that all employees at all levels are able to fully use their abilities for the organization's benefit.
- 4) **Process approach** – recognizing that all work is done through a process and managed accordingly.
- 5) **System approach to management** – expands on the previous principle in that achieving any objective requires a system of interrelated processes.
- 6) **Continual improvement** – as a permanent organizational objective, recognizing and acting on the fact that no process is so good that further improvement is impossible.
- 7) **Factual approach to decision making** – acknowledge that sound decisions must be based on the analysis of factual data and information.
- 8) **Mutually beneficial supplier relationships** – synergy can be found in such relationships.

As a result of the standardization of ISO 9000, any organization supplying products or services is able to develop a quality system that is recognized worldwide.

Other Quality Management System Standards

Besides ISO 9000 standard there are other specific Industry quality management system standards. They are QS 9000 / TS 16949, AS9100, TL 9000, ISO 13485 and Quality System Regulations (QSR) for medical devices. All these standards use the ISO 9000 based requirements with the addition of industry and customer specific requirements.

(a) QS 9000 / TS 16949

QS 9000 or TS 16949 are a quality management system standard applied to automotive industry.

(b) AS 9000

AS 9000 is a quality management system standard applied to aerospace industry.

(c) TL 9000

TL 9000 is a quality management system standard applied to telecommunication industry.

(d) ISO 13485

ISO 13485 is a quality management system standard applied to medical industry (applicable to medical devices sold in the European Union (EU) only).

(e) 21 CFR Part 820 Medical Devices Quality System

21 CFR Parts 820 is a quality system regulation applied to all finished medical devices that are distributed or sold in the United States only.

Application of Statistical Techniques

Statistical techniques play an important role in quality improvement efforts since variability can only be described in statistical terms. Quality characteristics are classified into variable or attribute data in the application of statistical techniques to quality engineering. Quality characteristics are often evaluated as specifications. Variable data are continuous measurements such as thickness, length or height whereas attribute data are discrete data which take the form of counts (Montgomery, 1996).

Statistical techniques are mostly applied in three major areas which are statistical process control, design of experiments and acceptance sampling. Statistical process control (SPC) is a powerful collection of problem solving tools useful in achieving process stability and improving process capability through reduction of variability. It can be applied to any process either in manufacturing or services (Montgomery, 1996).

The seven tools of SPC are :

- 1) Histogram
- 2) Check Sheet
- 3) Pareto chart
- 4) Cause and effect diagram
- 5) Defect concentration diagram
- 6) Scatter diagram
- 7) Control chart

The use of these SPC tools will lead to great improvement of the organizations.

A process consists of inputs and output. The inputs x_1, x_2, \dots, x_p are controllable factors, such as temperature and speed. The inputs p_1, p_2, \dots, p_q are uncontrollable inputs, such as environmental factors. The process transforms all these inputs into the finished goods. The output variable y is a measure of the finished good's quality (refer to Figure 1-1).

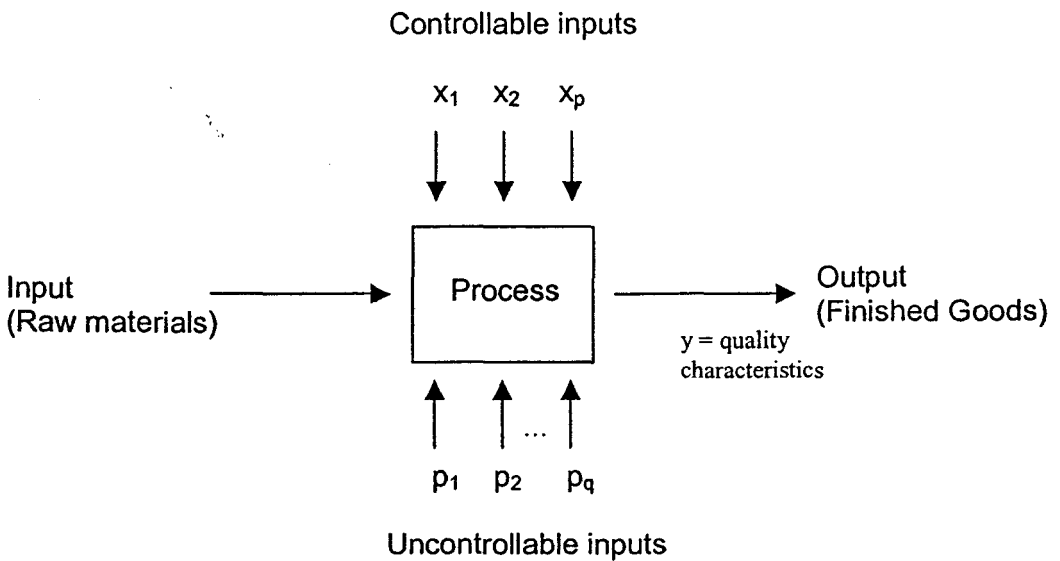


Figure 1-1 Production process inputs and outputs (Montgomery, 1996).

The last area of the quality control and improvement which involve the use of statistical techniques is acceptance sampling. Acceptance sampling defined as the inspection and classification of a sample of units selected randomly from a larger lot and the ultimate decision about disposition of the lot, usually occurs at two points : incoming raw materials or final production. Incoming and outgoing inspection normally use this method. Modern quality assurance systems usually place less emphasis on acceptance sampling compared to

SPC and DOE because it is more on detection and not prevention concepts (Montgomery, 1996).

1.5 Objectives of the dissertation

To be more competitive and to survive in the business world, every organization is trying to excel in their business by ensuring their products or services meet or exceed customer satisfaction. Most of the organizations are registered and certified to ISO 9001 quality management system (QMS) standard which is audited by third party auditors from accredited certification body. They believe by implementing a quality management system, it will lead to the organization's standardization and improvement. Specific industry standards are developed to meet specific requirements and standardization among industries. Additional requirements are added to the basic ISO 9001 requirements for individual specific industry standard. So, it would be interesting to compare the differences between all these standards in order to differentiate their strengths and weaknesses.

In all QMS standards, statistical techniques are essential requirements and have been practiced widely especially in the manufacturing industry. Statistical techniques are becoming more important because they bring improvement to the organization. Usage of statistical techniques requires data collection, measurement and analysis which will lead to decision making based on quantitative results obtained. Quality will not improve if it is not measured. Applications of statistical techniques in various QMS standards are considered.

The objectives of this dissertation is to review various QMS standards, compare the strengths and weaknesses of these standards and to study the application of statistical techniques in various QMS standards for manufacturing industry.

1.6 Organization of the Dissertation

This dissertation discusses the similarity and differences of various types of Quality Management System (QMS) standards and the application of statistical techniques in various Quality Systems in manufacturing industry. Chapter 1 describes the definition and evolution of Quality System and ISO 9000. Chapter 2 gives an overview on the literature review for the past research done on quality systems and ISO 9000 implementation. Chapter 3 discusses the similarities and differences of various quality management system (QMS) standards and the statistical techniques used in the manufacturing industry. Chapter 4 is a case study which illustrates the applications of statistical techniques in various QMS standards for manufacturing industry. The last chapter gives the conclusion, contribution and future work of the study.

CHAPTER 2

LITERATURE REVIEW

ISO 9000 is a quality management system standard that have been recognized and accepted worldwide. The ISO 9000 series of standards have formalized systems for evaluating the ability of any firm to consistently design, produce and deliver quality products and services. Companies in over 95 countries have endorsed the ISO 9000 standards and more than 95,000 certificates are issued worldwide (Zuckerman, 1994). More than half of the medium to large-sized United States firms expressed a serious interest in pursuing certification in a 1993 survey conducted for the National Association of Manufacturers (Swamidass, 1995). ISO 9000 is rapidly becoming the internationally accepted quality standard. In Western Europe, ISO 9000 certification was an order qualifier which any organization is not being considered for future business if their manufacturing facilities were not ISO 9000 certified (Curkovic and Pagell, 1999).

Although ISO 9000 is accepted internationally, it is surrounded by controversy and criticism. It is commented that ISO 9000 is not connected directly enough to product quality (Stavros, 1997). A certified company still can have different processes and products because ISO 9000 only ensures that a quality system exists and cannot guarantee its functionality (Curkovic & Handfield, 1996). Some managers view ISO 9000 as a paper driven process due to the documentation focus in ISO 9000. The cost and

time issues have been identified as criticisms of ISO 9000 (Vloeberghs & Bellens, 1996). An organization can spend up to 18 months and 7 man years getting a single site ready for an audit (Henkoff, 1993). The cost of an audit for a small company is approximately US\$50,000 and this does not even include training costs, which may range as high as US\$100,000 – 200,000 for a medium-sized facility (Curkovic & Handfield, 1996). The process does not end after the certificate is issued. It is repeated every 3 years with compliance audits occurring every 6 months to a year (Uzumeri, 1997). ISO 9000 fails to address a company's approach to select data and information for competitive comparisons and world class benchmarks to support quality and performance planning and evaluation. Companies do not even have to include performance goals in regards to quality (Curkovic & Pagell, 1999). ISO 9000 does not argue strongly for customer-driven organizations. It makes no provision for how the company uses information gained from customers to improve customer relationship, management strategies and practices (Curkovic & Pagell, 1999).

In a study by Curkovic & Pagell (1999), it was proven that ISO 9000 did not have to be a paper-driven process and it did not guarantee outcomes. Companies who are willing to invest the time and energy into doing the process right can gain significant benefits. Although ISO is not a complete TQM program, it does contain important foundations for continuous improvement. It forces firms to measure many things they may not have measured in the past. Without paper measurement system, it is

difficult to determine what is occurring and how or if changes have affected performance. ISO 9000 requires the training of all personnel in quality and this will increase the value of the personnel which is one of the most important resources in a organizations. One of the advantages of ISO 9000 is to overcome the shortcomings of the second party audits. First, it avoids the overauditing of supplier by all the buyers from different organizations which is a waste of resources. Secondly, it eliminates difficult and expensive audits when there are foreign suppliers (Atwater and Discenza, 1993).

Atwater and Discenza (1993) have conducted a study on ISO 9000 registration costs and benefits based on the firm's size. They found that 62 percent of large (annual sales exceeding US \$100 million) and medium (annual sales between US \$25 and US \$100 million) firms were aggressively pursuing ISO 9000 registration but only 38 percent of the small firms (annual sales less than US \$25 million) were pursuing ISO 9000 registration. Ferguson (1994) comments that the overall cost of obtaining and maintaining ISO 9000 registration as a percentage of total sales is much larger for small firms than for the larger ones. This may be due to the small firms being forced to use outside management consulting firms for assistance and this caused increasing costs.

The other benefits of ISO 9000 is that it imposes the requirements that the costs and benefits of a quality assurance system to be measured and documented. The purpose of measuring the costs of the quality

system is to provide a basis for decision making because quality does not improve unless it is first measured. Reichheld and Sasser (1990) stated that “ When manufacturers unravel the costs and implications of scrap, rework or jammed machinery, they realize that ‘quality’ is the most profitable way to run a business”.

A study conducted by Korte (1999) agreed that ISO 9000 certification improves documentation, acts as a beneficial marketing tool and improves export potential. For small firm managers, they believe that ISO 9000 registration results in cost reduction and increases export potential as compared to large firm managers. On the other hand, small firm managers were generally neutral relative to benefits in the product development process whereas the large firm managers were more likely to disagree with potential benefits in product development.

In the year 2000, the latest revision of quality management system, ISO 9000:2000 was introduced to replace the old standard ISO 9000:1994. The 1994 standard was a quality assurance standard that focused heavily on procedures and records whereas the new standard has less focus on procedures and the structure of the quality management system is based on the “Plan, Do, Check, Act” cycle (Merill, 2003). ISO 9000:2000 addresses a number of issues in the old standards that created widespread dissatisfaction and criticism. The new standards have a completely new structure and are based on eight principles that emphasize the core values and concepts of TQM. It emphasizes on using a process

related structure, using information from the system to facilitate quality improvement.

Although there are improvements on the latest ISO 9000:2000 standard, some weaknesses of the standard are raised. Since ISO 9000 is just a simple and general set of requirements, every auditor can have a different way of translating the requirements during auditing thus creating unnecessary arguments. Besides, some procedures or methods of process implementation are difficult to implement due to the unsuitability of the training provided which focuses more on the conceptual ideas rather than hands-on or practical training (Scott, 2005).

Although ISO 9000 has its strengths and weaknesses, if it is well implemented, ISO 9000 can result in greater efficiencies, cost reductions and productivity improvements. Many of the criticisms of ISO 9000 seem valid on the surface. Companies which take advantage of the system will gain significant rewards whereas those who view certification as a nuisance will be missing out on an opportunity to improve (Curkovic & Pagell, 1999). The true commercial value associated with ISO 9000 can only be achieved when it is made consistent with a company's strategic direction.

CHAPTER 3

QUALITY SYSTEMS AND STATISTICAL TECHNIQUES

There are various types of quality management system standards available in the market. ISO 9000 is the basic or fundamental quality management system standard. Other specific industry QMS standards such as QS9000 / TS16949, AS9100, TL9000, ISO 13485 and Quality System Requirements (QSR) for medical devices are developed to meet different industries and customer needs.

3.1 ISO 9000:1994 and ISO 9000:2000

ISO 9000:1994 is a quality management system (QMS) standard. It has three standards, which consists of ISO 9001, 9002 and 9003. ISO 9001 is the most comprehensive standards of these three standards. It covers all the basic requirements of QMS. Compliance to all the requirements of ISO 9001 will also be full compliance to ISO 9002 and 9003, therefore the 20 fundamental quality elements in ISO 9001 will be discussed. The 20 elements in ISO 9001 are described in Appendix C.

Statistical techniques have become more important in recent years with the focus on minimizing the variation within products and services. Techniques like statistical process control and lot sampling play a key role in minimizing the potential non-conformance and reducing quality costs. ISO 9001:1994 requires an organization to establish and maintain documented procedures to implement and control the application of

statistical techniques when they are applicable. It is very important to determine where statistical techniques will aid your organization in establishing, controlling and verifying process capabilities and product characteristics (Harrington & Mathers, 1997). The common statistical tools that are used are statistical process control which include seven major powerful tools used for problem solving, lot sampling plan used for incoming inspection and process capability study used to verify process capabilities.

The latest version ISO 9001:2000 has been released in the year 2000. It merged ISO 9001, 9002 and 9003:1994 into a single QMS requirement standard, ISO 9001:2000. So, all registrations will be ISO 9001:2000 since the year 2000. Besides, the terminology which is more familiar to the organization was introduced. For example, in the 1994 version, 'supplier' was referred to the entity seeking for registration whereas 'organization' was used in the 2000 release. The entity that supplies materials to the organization has changed from 'subcontractor' (1994 version) to 'supplier' in the 2000 version. This change has reduced confusion caused (Goetsch & Davis, 2002).

ISO 9001:2000 is now closely aligned with Total Quality Management and several new requirements are as follows :

- a) Continual improvement of processes and products
- b) Increased emphasis on the role of top management
- c) Consideration of legal and regulatory requirements

- d) Measurable quality objectives
- e) Monitoring of customer satisfaction
- f) Increased attention to resource availability
- g) Determination of training effectiveness
- h) Measurements covering the QMS and its processes and products
- i) Analysis of collected data on QMS performance

(Goetsch & Davis, 2002)

For ISO 9001:2000, the QMS is now viewed as a series of process (Refer to Figure 3.1):

- Quality Management System
- Management responsibility
- Resource management
- Product realization
- Measurement, analysis and improvement

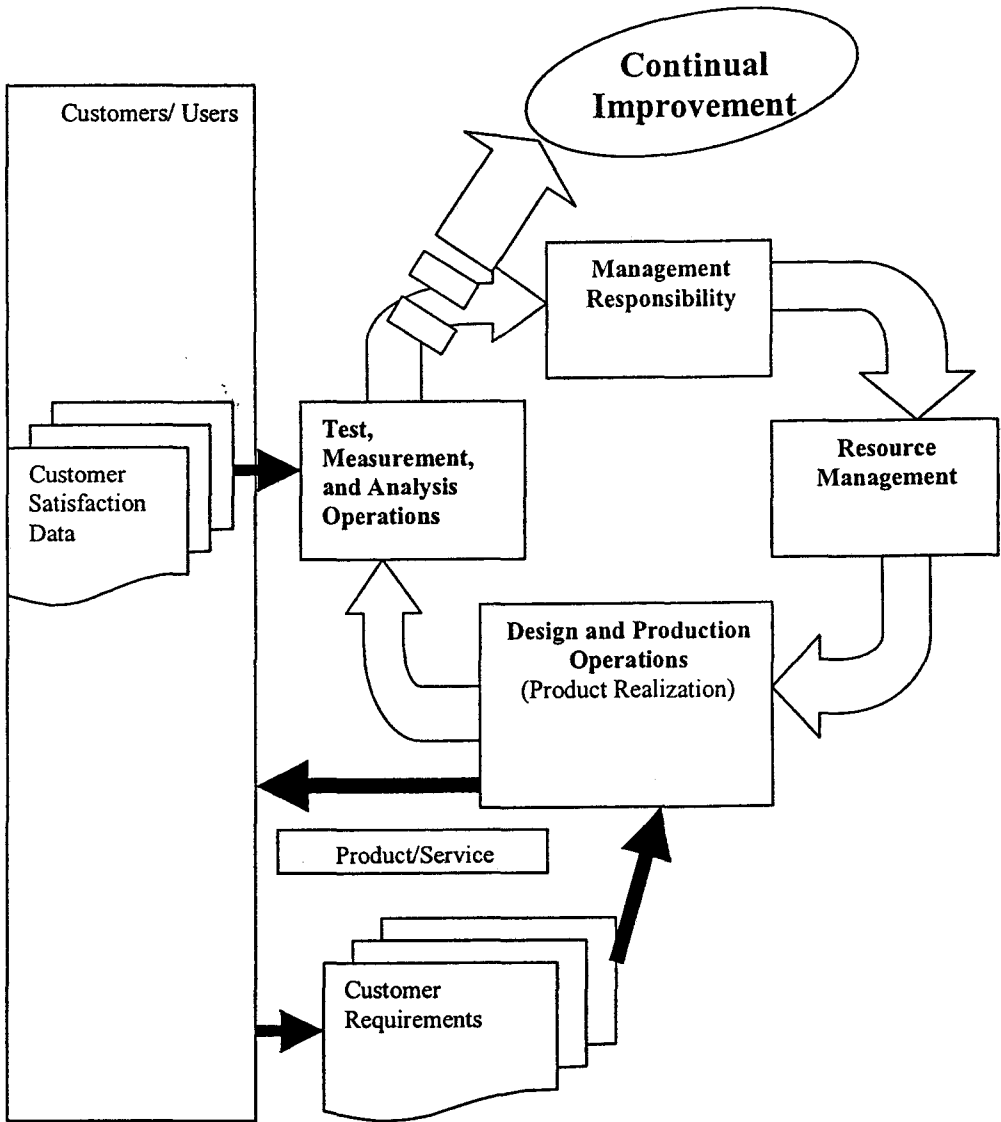


Figure 3-1 Model of a Process-Based QMS (Goetsch & Davis, 2002).

The 20 elements of ISO 9001:1994 have been replaced by five clauses containing 23 elements. The cross references of the elements in ISO 9001:1994 and ISO 9001:2000 have been presented in Table 3-1 and Table 3-2. The five clauses of ISO 9001:2000 are

a) Quality Management System (two elements)

- It sets the general framework to establish a quality management system including documentation, which defines and manages processes in order to deliver a good product or service (Johnson, 2000).

b) Management Responsibility (six elements)

- It addresses management's responsibility to establish a system that continually meets another needs and expectations. Management is responsible to define policy, objectives, planning and quality management system requirements while providing feedback through management review for initiation of improvement (Johnson, 2000).

c) Resource Management (four elements)

- Resources such as human resources, facilities and work environment are required to implement and maintain the quality management system wherever necessary (Johnson, 2000).

d) Product Realization (six elements)

- Organizations must define and describe their unique processes such as customer satisfaction, design, purchasing production and service operations that are needed to manufacture

products and/or deliver services from receipt to delivery (Johnson, 2000).

e) Measurement, Analysis and Improvement (five elements)

- Organizations are required to measure, analyze and improve product and/or service conformity, process and system performance through internal audits, nonconformity control and continual improvement (Johnson, 2000).

The 2000 revisions mostly contain elements which are already present in ISO 9001:1994 although organized differently and expanded in some cases. There are some new requirements introduced as indicated in Appendix D.

The Plan-Do-Check-Act (PDCA) cycle have been incorporated in the new standard for continual improvement of processes, products or services (Refer to Figure 3.2).

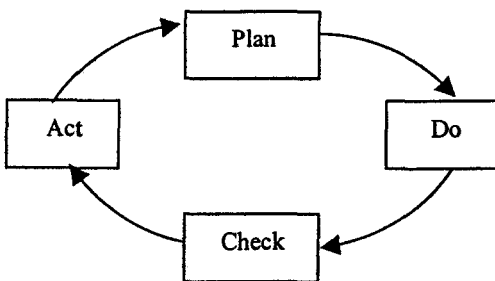


Figure 3.2 Plan-Do-Check- Act (PDCA) Cycle

1. **Plan** the improvement
2. **Do** (or implement) the planned improvement
3. **Check** the results to determine whether improvement occurred