QUALITY ASSURANCE IMPLEMENTATION ISSUES IN CANADIAN FIRMS - A STUDY OF ISO 9001:2000

NADEEM ALAM

A Thesis

in

The Department

of

Mechanical and Industrial Engineering

Presented in Partial Fulfillment of the Requirements

for the degree of Master of Applied Science (Mechanical Engineering) at

Concordia University

Montreal, Quebec, Canada

November 2003

Your file Votre référence
ISBN: 0-612-90988-3
Our file Notre référence
ISBN: 0-612-90988-3

ABSTRACT

Quality Assurance Implementation Issues in Canadian Firms – A Study of ISO 9001:2000

Nadeem Alam

This research studies implementation issues related to the emergence of the latest version of the ISO 9000 quality standard, ISO 9001:2000. This version has abandoned the structure of 20 sections and now has five comprehensive sections covering all the previous requirements, with some modifications and the introduction of new requirements. The ISO 9001:2000 standard has introduced a process-based approach that considers the quality management system as a single large process consisting of many smaller processes. The thesis focuses on the implementation of ISO 9001:2000 through an empirical study on Canadian firms. Results show that, whether external or internal reasons provided the impetus for registration, Canadian companies registered under the new ISO standards generally face the same degree of difficulty in implementation. However, internally driven companies have less difficulty for certain items. Empirical research also reveal that factors such as market share, nature of ownership, and size of the company have a significant affect on implementation, whereas companies with a different maturity level perceive a similar degree of difficulty in satisfying ISO 9000 requirements. In terms of benefits obtained due to ISO 9000 registration, externally driven companies perceived a higher degree of benefits as compared to internally driven companies for the respondent companies. In addition, a case study for a small-sized Canada-based

manufacturing company provides practical insight into the implications of ISO 9000 implementation, which satisfies practically, the findings of the present study.

Keywords: ISO 9000, quality, standards, implementation.

ACKNOWLEDGEMENTS

In the beginning of the present study conducted as a partial fulfillment of a Master degree in Mechanical and Industrial Engineering, I wish to take the opportunity to acknowledge those who have contributed directly or indirectly to the accomplishment of this thesis. After the benediction and encouragement of Almighty Allah, people from different areas include Professors, industrial and institutional gurus, family members and colleagues.

I would particularly like to express my gratitude to Dr. Nadia Bhuiyan, Research Supervisor of the present study, who not only provided guidance and support throughout the thesis but also assisted in writing-up papers at the level of international standard that have been accepted for publications. Very significantly, I express my gratitude for the provision of research funds.

I would also like to acknowledge the support of the President of a Montreal-based manufacturing company, Stephen Hamelin who gave the opportunity to implement ISO 9000 quality management system in his company, which helped a lot in comparing empirical findings with the practical implications. Furthermore, I am grateful to him for his financial assistance during the project span.

Many, many thanks go to some of the several institutional and industrial gurus under whom I have learnt the notion of various management systems in industries, especially ISO 9000 quality management system. These gurus include Dr. Inteaz Alli of McGill University, Vice Chair of American Society for Quality-Montreal Section; Dr.

Bulgak of Concordia University; Terry McKeogh of CMC Electronics Inc., Quality Assurance Manager; Ted Luszczek of ABCgroup Exterior Systems Inc., Quality Assurance Manager; Sanaul Haque of Quality International Consultants, Chief Executive of the Organization; and Kamran Moosa of Pakistan Institute of Quality Control, Chief Executive of the Organization. In addition, my acknowledgement extends to the various discussion forums on the present topic and valuable conversations with experienced colleagues in universities and industries on the same subject.

Last, but definitely not least, many thanks go to my family members and friends including parents, brothers, sisters, wife and those who were there for moral support during the time of study. Eternal thanks to my father and mother, especially my father who passed away two years ago; their love, encouragement and institution throughout my life always motivated me to learn and learn till grave. Finally, I am grateful to my wife not only for her support but also for her typing in most sections of the thesis.

TABLE OF CONTENTS

LIST OF FIGURES ..... **X**

LIST OF TABLES ..... **XI**

1.0 INTRODUCTION **1**

1.1 RESEARCH PROBLEM AND OBJECTIVES 2
1.2 RESEARCH METHODS 3
1.3 THESIS OUTLINE 4

2.0 LITERATURE REVIEW **5**

2.1 ISO 9000 IMPLEMENTATION 5
2.2 ISO 9000, TQM, AND ORGANIZATIONAL PERFORMANCE 9
2.3 ISO 9000 INTEGRATION WITH OTHER STANDARDS 11

3.0 OVERVIEW OF ISO 9000 ..... **13**

3.1 EVOLUTION OF ISO 9000 14
3.2 ISO 9000:1994 17
3.3 ISO 9001:2000 19
3.4 PROCESS APPROACH 21

4.0 EMPIRICAL STUDY **26**

4.1 DATA COLLECTION INSTRUMENT 27
4.2 HYPOTHESES 30
4.2.1 Reasons for seeking registration *30*
4.2.2 Market Share *31*
4.2.3 Nature of ownership *31*
4.2.4 Organization Size *32*
4.2.5 Maturity Level (years in operation) *33*
4.2.6 Benefits *34*
4.3 HYPOTHESIS TESTING 34

5.0 RESULTS **36**

5.1 HYPOTHESES RESULTS 42
5.1.1 Link between degree of perceived difficulty and reasons for seeking registration *42*
5.1.2 Link between degree of perceived difficulty and market share *43*
5.1.3 Link between degree of perceived difficulty and ownership *44*
5.1.4 Link between degree of perceived difficulty and organization size *45*
5.1.5 Link between degree of perceived difficulty and maturity level *46*
5.1.6 Link between degree of perceived benefits and reasons for seeking registration *47*

6.0 DISCUSSIONS AND IMPLICATIONS **49**

6.1 REASONS FOR SEEKING REGISTRATION 49
6.2 BENEFITS OF REGISTRATION 50

6.3 BARRIERS OF REGISTRATION 51
6.4 PERCEIVED DEGREE OF DIFFICULTY OF ISO 9001:2000 51
6.5 LINK BETWEEN DEGREE OF PERCEIVED DIFFICULTY AND REASONS FOR SEEKING REGISTRATION 54
6.6 LINK BETWEEN DEGREE OF PERCEIVED DIFFICULTY WITH MARKET SHARE 55
6.7 LINK BETWEEN DEGREE OF PERCEIVED DIFFICULTY WITH OWNERSHIP 55
6.8 LINK BETWEEN DEGREE OF PERCEIVED DIFFICULTY WITH COMPANY SIZE 56
6.9 LINK BETWEEN DEGREE OF PERCEIVED DIFFICULTY WITH MATURITY LEVEL 57
6.10 LINK BETWEEN DEGREE OF PERCEIVED BENEFITS WITH REASONS SEEKING REGISTRATION 57
6.11 CHAPTER DISCUSSION 59

7.0 CASE STUDY 61

7.1 ABOUT THE COMPANY 61
7.2 PRODUCTS 62
7.3 PROCESSES 63
7.4 QUALITY SYSTEM IMPLEMENTATION 66
7.5 DATA COLLECTION 67
7.6 QUALITY SYSTEM IMPLEMENTATION PLAN 67
7.6.1 Gap Analysis 68
7.6.2 Understanding the Quality System 68
7.6.3 Project Team Formation 69
7.6.4 Management Representative 69
7.6.5 Quality Policy and Objectives 70
7.6.6 Documentation Requirements 71
7.6.7 Training of Shop Floor Personnel 73
7.6.8 Internal Audit 74
7.7 BARRIERS DURING IMPLEMENTATION 75
7.7.1 Quality Perception 75
7.7.2 Top Management Commitment 75
7.7.3 Resistance to Change 77
7.7.4 Lack of Resources 78
7.7.5 Lack of Training 79
7.8 DESIGN OF EXPERIMENT (DOE) AT VORTEX 79
7.8.1 Design of Experiments 80
7.8.2 DOE Planning 80
7.8.3 Problem objectives 82
7.8.4 Response Variables 82
7.8.5 Control Factors 83
7.8.6 Results Verification and Action 83
7.8.7 Recommendations 84
7.8.8 Case Study and Empirical Findings 85

8.0 CONCLUSIONS 88

8.1 CONTRIBUTIONS TO PREVIOUS RESEARCH 89
8.2 FUTURE RESEARCH 90

REFERENCES **93**

MAJOR WEB LINKS 96

BIBLIOGRAPHY **97**

APPENDICES **99**

APPENDIX A: QUESTIONNAIRE 100
APPENDIX B : FACTORIAL DESIGN 105
APPENDIX C : GAP ANALYSIS (START OF PROJECT-APR 2002) 118
APPENDIX D : GAP ANALYSIS (END OF PROJECT-JAN 2003) 123
APPENDIX E : VORTEX'S PRODUCTS 128

LIST OF FIGURES

FIGURE 1. CONCEPTUAL FRAMEWORK FOR THE THREE COMPONENTS 10
FIGURE 2. EMERGENCE OF ISO 9000 16
FIGURE 3. MODEL OF A PROCESS-BASED QUALITY MANAGEMENT SYSTEM 22
FIGURE 4. PDCA CYCLE 24
FIGURE 5. PROCESS FLOW AT VORTEX 65
FIGURE 6. ISO 9000 DOCUMENTATION HIERARCHY 71

LIST OF TABLES

TABLE 1. ISO 9001:2000 PROCESSES WITH RELEVANT CLAUSES 23
TABLE 2. PERCENTAGE OF RESPONDENTS IN VARIOUS CATEGORIES 27
TABLE 3. REASONS FOR SEEKING ISO 9000 REGISTRATION 37
TABLE 4. BARRIERS IN PREPARING FOR REGISTRATION 37
TABLE 5. FACTORS FOR SELECTING REGISTRATION BODY 38
TABLE 6. SATISFACTION WITH THE REGISTRATION PROCESS 38
TABLE 7. ATTITUDE TOWARDS ISO 9000 39
TABLE 8. BENEFITS OF ACHIEVING ISO 9000 REGISTRATION 40
TABLE 9. DEGREE OF DIFFICULTY IN IMPLEMENTING ISO 9001:2000 PROCESSES 41
TABLE 10. T-TEST RESULTS FOR THE PERCEIVED DEGREE OF DIFFICULTY OF ISO 9001:2000 PROCESSES AND REASONS 43
TABLE 11. PERCEIVED DEGREE OF DIFFICULTY BASED ON MARKET(S) SERVED BY ORGANIZATIONS 44
TABLE 12. PERCEIVED DEGREE OF DIFFICULTY AND NATURE OF OWNERSHIP 44
TABLE 13. PERCEIVED DEGREE OF DIFFICULTY AND KRUSKAL-WALLIS TEST RESULT FOR SMALL, MEDIUM, AND LARGE COMPANIES 45
TABLE 14. PERCEIVED DEGREE OF DIFFICULTY AND KRUSKAL-WALLIS TEST RESULTS FOR COMPANIES WITH DIFFERENT MATURITY LEVEL 46
TABLE 15. T-TEST RESULTS FOR PERCEIVED DEGREE OF BENEFITS AND REASONS FOR SEEKING REGISTRATION 48

1.0 INTRODUCTION

A good rule in organizational analysis is that no meeting of the minds is really reached until we talk of specific actions or decisions. We can talk of who is responsible for budgets, or inventory, or quality, but little is settled. It is only when we get down to the action words - measure, compute, prepare, check, endorse, recommend, approve - that we can make clear who is to do what.

—Joseph M. Juran

For almost two decades, extensive research has been carried out in the area of implementing ISO 9000 standards, a quality management system. This research is an attempt to study the emergence of the latest version of ISO 9000, version ISO 9001:2000, which has abandoned the structure of 20 sections, and now has five comprehensive sections which cover all of the previous requirements, with some modifications and new requirements. A detailed analysis of the standard shows that it contains at least 21 smaller processes, as identified by a Canadian company, the Praxiom Research Group Limited (2002). There are a number of changes in the new version, and for those companies that are registered under the older standard, December 2003 marks the deadline to transition into the 9001:2000 version.

This thesis focuses on the implementation of the new version in Canadian firms through an empirical study that investigates the degree of perceived difficulty of

satisfying the requirements of the ISO 9001:2000 process-based approach, the items that are considered to be the most difficult to implement, as well as the benefits achieved. The effects of reasons for seeking registration, ownership, size of the company, market share, and maturity level of the company, on the degree of difficulty in implementing ISO 9001:2000 processes, are analyzed. The relationship between the degree of perceived benefits and reasons companies seek registration is also studied.

1.1 Research Problem and Objectives

Countless companies have become successfully ISO registered, either due to external pressures, such as customers demanding registration, or internal reasons, such as improving or developing a quality system to improve overall performance, or a mixture of both (Yahya and Goh, 2001). While the benefits of ISO 9000 certification are widely known and proven, much research has also been conducted on the difficulties faced by companies that embark on the ISO process. A number of reasons have been determined, for example, lack of commitment from top management, lack of training resources or understanding of the requirements and benefits of being ISO registered (Chin et al., 2000). Many companies avoid ISO implementation for fear of facing major organizational roadblocks in the registration process. However, there may come a time when these companies have little choice but to register if their customers demand it. A small Montreal-based manufacturing firm, for example, recently faced this situation: its biggest customer refused to do business with the company if it did not become ISO registered. At the time of the study, another small manufacturing company, also based in Montreal, was preparing for future ISO registration although the company was not in a

position, financially, to undertake the registration process at the time, the company was nevertheless taking the necessary steps to avoid a crisis in the future.

In this thesis, ISO 9000 implementation issues in Canadian firms have been studied with the focus on the following research problems and objectives:

- To study the relation between the degree of perceived difficulty in implementing ISO 9001:2000 processes and factors such as reasons companies seek registration, market share, type of ownership, organization size, and maturity level (in terms of operating years).
- To study the relation between the degree of perceived benefits of adopting ISO 9000 quality assurance model and the reasons companies seek registration.
- To share the experience of implementing an ISO 9000 quality assurance model in a small Canadian manufacturing company. This case study provides practical insight into the hypotheses formulated for the above two research objectives, as well as identifying and suggesting ISO 9000 implementation issues.

The results are expected to be useful for companies that expect to implement ISO standards. Early preparations can allow them to focus their efforts on those items that are most difficult to implement, whether externally or internally driven. Results should also be helpful in understanding what areas of their organization stand to benefit the most from the standards, whether externally or internally driven.

1.2 Research Methods

Both an empirical and a case study are used to investigate the research problems and objectives presented in this thesis. The first two research objectives are operationalized

through the formulation of hypotheses, whereas the third objective is analyzed by implementing an ISO 9000 system in a small manufacturing company. These methods have been described in detail in their respective sections.

1.3 Thesis Outline

This thesis is outlined in eight chapters. A review of the existing literature is presented in Chapter 2, which discusses implementation issues of ISO 9000. In Chapter 3, an overview of ISO 9000 is provided, which describes the evolution of the ISO 9000 standard, the latest version (2000) and its approach. Chapter 4 discusses the empirical methodology used to study the research objectives and the rationale for the formulation of hypotheses used to analyze the objectives empirically. Results are presented in Chapter 5. In Chapter 6, the findings of the study and its implications are discussed and Chapter 7 presents a case of a small manufacturing company that was attempting to prepare for ISO registration. The case study highlights the implementation issues and achievements of this company, and compares results to the results of the empirical study. It also discusses process improvement by using design of experiment (DOE). Chapter 8 presents conclusion of the thesis and opportunities for further exploration in the future.

2.0 LITERATURE REVIEW

The important thing about science is not so much to obtain new facts as to discover new ways of thinking about them.

—William Bragg

This chapter reviews the existing literature associated with ISO 9000 implementation issues. Numerous studies have been undertaken on the experiences of ISO 9000 implementation around the world, and show that quality improvement initiatives such as ISO 9000 are accompanied by major roadblocks.

2.1 ISO 9000 Implementation

In a survey of ISO 9000 implementation in companies in Singapore, it was found that devoting time to quality initiatives, lack of management support, and employee resistance to change were the main obstacles in establishing an ISO 9000 quality assurance model (Calingo et. al., 1995; Quazi and Padibjo, 1998). Findings of another survey for Greek companies by Lipovatz et. al. (1999) revealed that changing employee mentality was the main problem in preparing for ISO 9000 registration. Kim (1994) reported that understanding ISO 9000 and underestimating efforts for the implementation played a key role in hindering progress to quality assurance system implementation. These general roadblocks were also pointed out by Yahya and Goh (2001) in their study of ISO implementation in Malaysian companies. While all companies face obstacles, the nature

of obstacles may vary depending on the region and type of the company (size, ownership, market, maturity level, etc).

Carlsson and Carlsson (1996) have investigated the experience of implementing ISO 9000 in Swedish industries. The authors studied the importance of stated reasons for registration, reported success factors, reasons for difficulties experienced in implementing ISO 9000, reported measurable results of ISO registration, and reported factors influencing the choice of the registration body. Results showed that the dominating reasons for implementing ISO 9000 quality assurance system were found to be customer thrust and taking an initiative towards total quality management (TQM). They pointed out that the implementation of ISO 9000 is considered to be a powerful tool for competitiveness and cannot be disregarded.

Carlsson and Carlsson also studied factors that affect successful implementation. Their results reveal that companies do not like to rely on external assistance such as consultants. It was also found that management commitment had a positive influence on successful implementation of ISO 9000. They also found that the most difficult factors during implementation were the interpretation of the standard, and the time and resources required undertaking the initiative.

Jones et. al. (1997) studied ISO 9000 in Australian companies. Their research centred on investigating the relationship between the perception of the benefits companies received with the reasons they sought registration and the impact of time after registration. Their findings showed that companies seeking registration for non-developmental reasons, which are related to major customer requirements, market relations and competitiveness, perceived fewer beneficial outcomes. Furthermore, they

could not find statistical evidence to prove that companies registered for a longer period of time enjoyed more benefits as compared to recently registered companies.

Fuentes et. al. (2000) have examined the literature associated with the ISO 9000 quality assurance system in Spain. The study focused on the analysis of implementation issues by comparing practice (organization perception) versus theory (consultant perception). The authors studied the driving factors for implementing ISO 9000, the expected benefits of adopting the system, and roadblocks to successful implementation. It was observed that customer thrust or market reputation was the primary motive for achieving ISO 9000 registration. Organizational barriers such as cooperation among managers, resistance to change, and employee involvement were found to be major obstacles to successful implementation.

In another study, Heras et. al. (2002) have found no evidence that ISO 9000 registration provides any significant influence on profit or sales for Spanish companies. However, their study also found that any investment in registration had not adversely affected the profitability of firms, therefore implying that registration is not a bad investment. Santos and Escanciano (2002) have investigated the benefits of ISO 9000 through a survey of Spanish companies and found that organizations experienced a better understanding of processes and responsibilities as well as the awareness of quality among employees because of the implementation of ISO 9000. Besides internal benefits, companies also enjoyed external benefits such as improvement in market reputation.

Chin et. al. (2000) have identified critical maintenance issues of the ISO 9000 quality assurance system for manufacturing industries, specifically for the electronics market in Hong Kong. Their findings are useful for further exploration in other

industries and countries. Results of the study show that the most critical issue in maintaining the ISO 9000 system is corrective and preventive action. The top three measures that were found to be effective in maintaining ISO 9000 systems are: strengthening of internal quality audits, improving culture through teamwork, and management support and participation.

In a cost-benefit analysis conducted by Leung et. al. (1999) in Hong Kong through a survey of about 500 ISO registered companies, it had been found that more than 65 percent of the respondent companies agreed that adopting ISO 9000 is worthwhile. More than 76 percent believe that the cost associated with registration is reasonable.

Laframboise (2002) studied empirically the link between quality practices and business performance excellence in central Canada. His findings, based on the study of 280 firms, reveal that ISO 9000 registration coupled with a high-level quality initiative, such as a national quality award program, has a very significant impact on the perceived performance excellence. From the same study, it has been observed that the factors including industrial sector, organization location, the type, whether it is public or private, and organization size, do not affect significantly performance excellence.

Singels et. al. (2001) have compared the performance of ISO 9000 registered companies with companies that were not registered. Five indicators were derived from the literature to test the performance of organizations: production process, company result, customer satisfaction, personnel motivation, and investment on means. The production process defines the improvement of production activities including cycle time, employee coordination, product specification, delivery performance, etc. Company results reflect an increase in market share, an increase in sales, an increase in profit, and

cost savings. Customer satisfaction refers to complaint reduction and increase in customer satisfaction. Personnel motivation includes the increase in employee involvement and participation and the increase of personnel qualifications. The last indicator, investment on means, considers high investment cost, too much paper work, etc. These performance indicators were empirically analyzed. Based on these indicators, the analysis of the study shows that the ISO 9000 registration does not assure increased performance. It does not, however, mean that the implementation of ISO 9000 is worthless. Findings also show that internally motivated companies performed better than the externally motivated companies.

2.2 ISO 9000, TQM, and Organizational Performance

Many researches have been attempting to find a relationship between ISO 9000, total quality management (TQM), and organizational performance. Studies revealed that ISO 9000 can provide a sound foundation for the successful implementation of TQM. The literature shows that the implementation of both ISO 9000 and TQM together or individually leads to an improvement in organizational performance (Calingo et. al., 1995; Kanji, 1998; Rahman, 2001). Hill et. al. (2001) investigated the factors that could affect the successful transformation of ISO 9000 to TQM. The study shows that besides key transition factors such as executive mindset, understanding and motivation, there are some additional factors which have significant influence on the transitional process. These factors are willingness and learning capacity, visionary or transformational leadership. The study was conducted in Northern Ireland and also attempted to find the order of implementation where most companies believe that it is good to consider ISO

9000 system in the first place for organizational or cultural change. The findings of a company, which went for TQM first, reflect that the failure in implementation is probably due to the non-existence of operational infrastructure and systems. However, his finding on this area was too limited, which needs further investigation to generalize that TQM-ISO9000 transition is not appropriate. Rahman (2001) in his comparative study of TQM practice and organizational performance with and without ISO 9000 registration, has delineated a conceptual framework for the three components as shown in Figure 1.

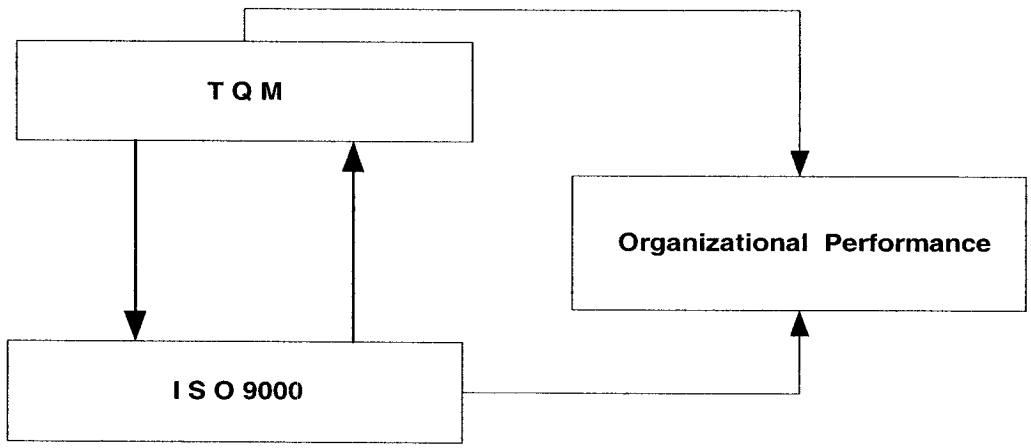

Figure 1. Conceptual Framework for the three components

This model shows that the implementation of ISO 9000 can lead to an improvement in organizational performance directly or indirectly through a TQM program. In practice, however, it is commonly perceived that implementing ISO 9000 first provides a stable foundation for a TQM program. Then the two quality programs together can provide stability in performance. Research had been carried out in Australia to find the effect of TQM on organizational performance of small to medium enterprises (SMEs) with and without ISO 9000 registration. The comparative study was undertaken on 250 SMEs. The results showed that ISO 9000 registration does not have any significant affect on the

performance of respondent TQM SMEs. However, the finding of the research supports the group of companies who prefer to implement TQM without achieving ISO 9000 registration; but it is not unreasonable to consider ISO 9000 as a solid foundation for TQM.

Calingo et. al. (1995) in their attempt to study the achievement of TQM through ISO 9000 in Singapore, found that a number of ISO 9000 registered companies are approaching towards TQM steadily. Kanji (1998), in his study, considered it practical to promote ISO 9000 as a basic foundation for TQM. The critical discussion of the understanding of quality systems and testing standards provides an integrated approach for achieving organizational benefits. The study proposes that ISO 9000 and TQM integration will lead to an organization with enhanced benefits such as competitive edge reduced customer audits, high quality, increased operational efficiency and productivity.

2.3 ISO 9000 Integration with Other Standards

One of the major benefits of the ISO 9001:2000 standard is its structure, which provides compatibility with other management systems including environmental, occupational, health and safety (OHS) systems. McDonald, et. al. (2003) discusses the plausibility of integrating management systems. After identifying similarities among quality, environment, and safety, he argues that an organization can achieve a high return on investment by taking the advantage of integration. Furthermore, he points out some benefits of an organization by adopting integrated management systems, which are: simplified systems (reduces confusion of documents); optimized resources (less time, money and man-hours required for single system that covers the requirements of all three

standards); improved performance (helps to identify and provide opportunity for improving risk, hazard, complaints, wastage, product nonconformity, accidents and illness).

3.0 OVERVIEW OF ISO 9000

Without a standard there is no logical basis for making a decision or taking action.

—Joseph M. Juran

An overview of ISO 9000 and its evolution into an internationally accepted standard is provided in this chapter. The structure and requirements of the previous (1994) and latest (2000) versions are also compared and contrasted.

The ISO 9000 series of standards is a non-governmental organization established to promote the development of standardization and related activities. The goal is to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activity. The work of ISO results in international agreements, which are published as International Standards. ISO 9000, the first international quality management system standard with a registration scheme, was issued in 1987. It has had a great impact on manufacturing industries, establishing the framework requirement for effective and efficient quality assurance and quality management systems. It does not refer to any specific technical specification for products, but does apply to every type of industry and service. As a result of its applicability to a variety of organizations, it has also been gaining widespread attention in service organizations, such as educational institutions. The requirements described in

these standards are in general terms only; it is up to the organization to choose how to implement them.

3.1 Evolution of ISO 9000

Seddon (1997) has delineated the evolution of ISO 9000 extensively. The story of quality begins during the Second World War (WWII). In order to control ammunitions, UK's ministry of defense asked their vendors to write down the procedures for making products to ensure that the workers followed a standard way of doing things. The whole frame of work needed to be inspected by a government inspector. These initiatives have emerged in the name of quality. In 1959, the first quality standard for military procurement was developed by the United States. This military standard (Mil-Q-9858a-Quality Program Requirements) provided a framework for suppliers in order to achieve conformance. Efforts in quality continued and moved on to the space industry. The National Aeronautics and Space Administration (NASA) had developed its quality system for vendors in 1962. In the same year, Vice Admiral Rickover of the US Navy had pointed out problems faced in the nuclear industry, such as late deliveries and rework: "Too often management is satisfied to sit in plush offices, far removed physically and mentally from the design and manufacturing areas, relying on paper reports for information about the status of design and production in the plant itself-the real center of the enterprise. This lack of first hand evaluation results in poorly designed and manufactured equipment, late delivery or both. During the past few years hundreds of major conventional components, such as pressure vessels and steam generators have been procured for naval nuclear propulsion plants. Less than ten percent have been delivered

on time. Thirty percent were delivered six months to a year or more later than promised. Even so re-inspection of these components after delivery showed that over fifty percent of them had to be further re-worked in order to meet contractual specification requirements". Despite some improvements, things were getting worse with the increase in scope of the US Naval Reactors Program.

During 1950s and 1960s, the UK was experiencing similar problems in its nuclear power and other newly established industries. These genuine concerns demanded quality initiatives. These two decades have contributed greatly to international quality. Japan established the Japan Union of Scientists and Engineers (JUSE), and had started its regular program on quality control in1951. The French quality control association was founded in 1957 for training in quality. Similar associations were formed in Europe, which founded the European Organizations for Quality Control (EOQC), in the same year. In Germany, the German Society for Quality (DGQ) was established in 1957 to promote quality at various levels in industries.

With this progress, NATO adopted the Allied Quality Assurance Procedures (AQAP), which was the standard for procurement of NATO equipment in 1968. In order to control vendors, UK's Central Electricity Generating Board and Ontario Hydro in Canada have developed standards for quality assurance. Serious efforts in quality moved on to the next step, which was the assessment of vendors' quality systems through a third party audit. The result was the publication of BS 5750 in 1979, which was the standard developed by the British Government, whose intention it was to BS 5750 have recognized on the international market. In 1987, the Geneva-based International

Organization for Standardization (ISO) introduced BS 5750 as ISO 9000, a quality assurance model which has become widespread throughout the world.

Figure 2 shows the evolution of quality standards, from the military standards of the 1950's to today's internationally renowned ISO 9000 standard.

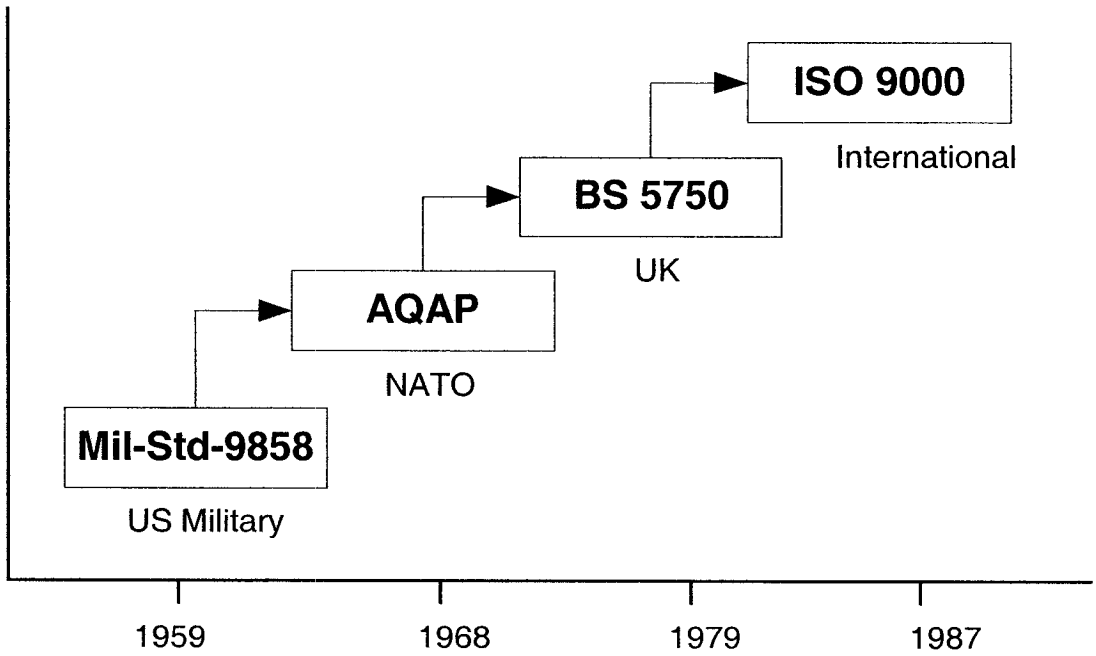

Figure 2. Emergence of ISO 9000

The evolution of the standard, ISO 9000 is an international triumph and has been accepted worldwide (Sadgrove, 1994). 'ISO' is an acronym for International Organization for Standardization, and in Greek, 'Isos' means equal or uniform. This means that ISO 9000 promotes a parallel framework for quality management systems all over the world. A manufacturer in North America can have confidence in ordering products from companies in Europe, Asia or other continents knowing that they have the

same quality management system. ISO 9000 facilitates joint-venture and export businesses as well.

3.2 ISO 9000:1994

After 1987, the ISO 9000 standard was first revised in 1994, however, the framework did not show a significant difference as it appeared in the first issue. Requirements of ISO 9000 were structured into the following twenty clauses (Appendices C and D):

4.1 Management Responsibility

4.2 Quality System

4.3 Contract Review

4.4 Design Control

4.5 Document and Data Control

4.6 Purchasing

4.7 Customer Supplied Product

4.8 Product Identification and Traceability

4.9 Process Control

4.10 Inspection and Testing

4.11 Control of Inspection, Measuring and Test Equipment

4.12 Inspection and Test Status

4.13 Control of Nonconforming Product

4.14 Corrective and Preventive Action

4.15 Handling, Storage, Preservation, Packaging and Delivery

4.16 Control of Quality Records

4.17 Internal Quality Audit

4.18 Training

4.19 Servicing

4.20 Statistical Technique

With respect to fulfilling the requirements of the above clauses, ISO 9000 had been categorized into three quality assurance models for contractual obligations between the organization and a third party (registration body), which are described in the following paragraphs.

ISO 9001:1994

This quality assurance model is for the organization that is involved in design, development, production, installation, inspection and servicing; all twenty clauses must be implemented for ISO 9001 registration.

ISO 9002:1994

This quality assurance model is for the organization that is involved in production, installation, inspection and servicing; all clauses, except design control (clause 4.4), must be implemented for ISO 9002 registration.

ISO 9003:1994

This quality assurance model is for the organization that is involved in inspection and testing; all clauses, except design control (clause 4.4), purchasing (clause 4.6), process control (clause 4.9) and servicing (clause 4.19), must be implemented for ISO 9003 registration. .

This categorization of quality assurance models has been changed into one single quality assurance model for all types of organizations in version 2000. Now, whether the

company is involved in testing only or design, development, production, inspection, installation and servicing activities, organizations will be registered as ISO 9001:2000.

3.3 ISO 9001:2000

The most recent version of the ISO 9000 standard, ISO 9001:2000, promotes a process-based approach when developing, implementing, and improving a quality management system. The ISO 8402:1994 quality management and quality assurance vocabulary defines a process as "set of inter-related resources and activities, which transforms inputs into outputs". The process approach is built on the belief that a desired result is achieved more efficiently when activities and related resources are thought of as a process. In addition, the standard promotes the application of a continuous improvement methodology. The new version offers opportunities to reduce or eliminate system redundancies, such as integrating the quality management system (QMS) and the environmental management system (EMS) (West, Haworth, et. al., 2002). The advantages of new version include:

- A process focus versus targeting individual elements
- Increased focus on customer satisfaction
- Measurement linked to continuous improvement
- Customer feedback, both internal and external
- Emphasis on the full system
- Clear management responsibilities

For those companies that are registered under the older standard, December 2003 marks the deadline to transition into the 9001:2000 version. In comparing the 1994 and 2000 versions, the following major changes can be noticed:

Structural Changes: Version 2000 has only one standard i.e. ISO 9001:2000 and consists of five comprehensive sections instead of a twenty-clause structure, and it is more compatible with ISO 14001, the standard for an environmental management system.

Approach: In the latest version, the quality management system is viewed as a single large process, which consists of many smaller processes. Each process needs to develop input-output relationships in order to apply the process approach in a meaningful way, and uses the plan-do-check-act cycle.

Requirements: In terms of requirements, the latest version modified some old requirements along with the introduction of some new requirements, which are presented below:

- Meet regulatory and statutory requirements (5.1)
- Identify quality management system improvements (5.1, 8.4)
- Improve quality management system (5.1, 8.5)
- Meet customer requirements (5.2)
- Identify customer requirements (5.2, 7.2.1)
- Support internal communication (5.5.3)
- Evaluate the effectiveness of training (6.2.2)
- Provide quality infrastructure (6.3)
- Provide a quality work environment (6.4)
- Communicate with customers (7.2.3)

- Monitor and measure customer satisfaction (8.2.1)
- Monitor and measure processes (8.2.3)
- Evaluate the suitability and effectiveness of quality management system (8.4)

3.4 Process Approach

The process-based model defines a quality management system as a single large process which links sub-processes in a continuous improvement cycle. Each process is built on input-output relationships. The output of one process almost always affects the input of another, as these processes are inter-related. Customer requirements and customer satisfaction play a significant role in defining input and output relationships, respectively. Some sources of inputs and outputs are: customer requirements (internal and external), business objectives, government and other regulations, policies, procedures, work instructions, reports, inspections and test results, products, machines, personnel, materials, plans, ideas, solutions, decisions, services, information, complaints, proposals and feedback. In version 2000, the structure of the standard has been converted into five major clauses instead of twenty clauses in version 1994. These five clauses (from 4.0 to 8.0) are linked together in a continuous improvement cycle for a quality management system (clause 4.0). Figure 3 shows that in this continuous improvement cycle, the following four clauses are connected systematically:

Clause 5.0: Management Responsibility

Clause 6.0: Resource Management

Clause 7.0: Product Realization

Clause 8.0: Measurement, Analysis and Improvement

The requirements of these clauses are documented in the ISO 9001:2000 standard. Thinking of a quality management system as a single large process requires the development of input-output relationships. The boxes on left and right sides of Figure 3 indicate sources of inputs and outputs, respectively. It is the responsibility of management (clause 5.0) to provide necessary resources (clause 6.0) in order to build a product by incorporating customer inputs at the product realization stage (clause 7.0), which then goes through the measurement, analysis and improvement (clause 8.0) to meet and exceed customer requirements so that customer satisfaction (output) can be achieved through the continual improvement cycle of the quality management system (clause 4.0).

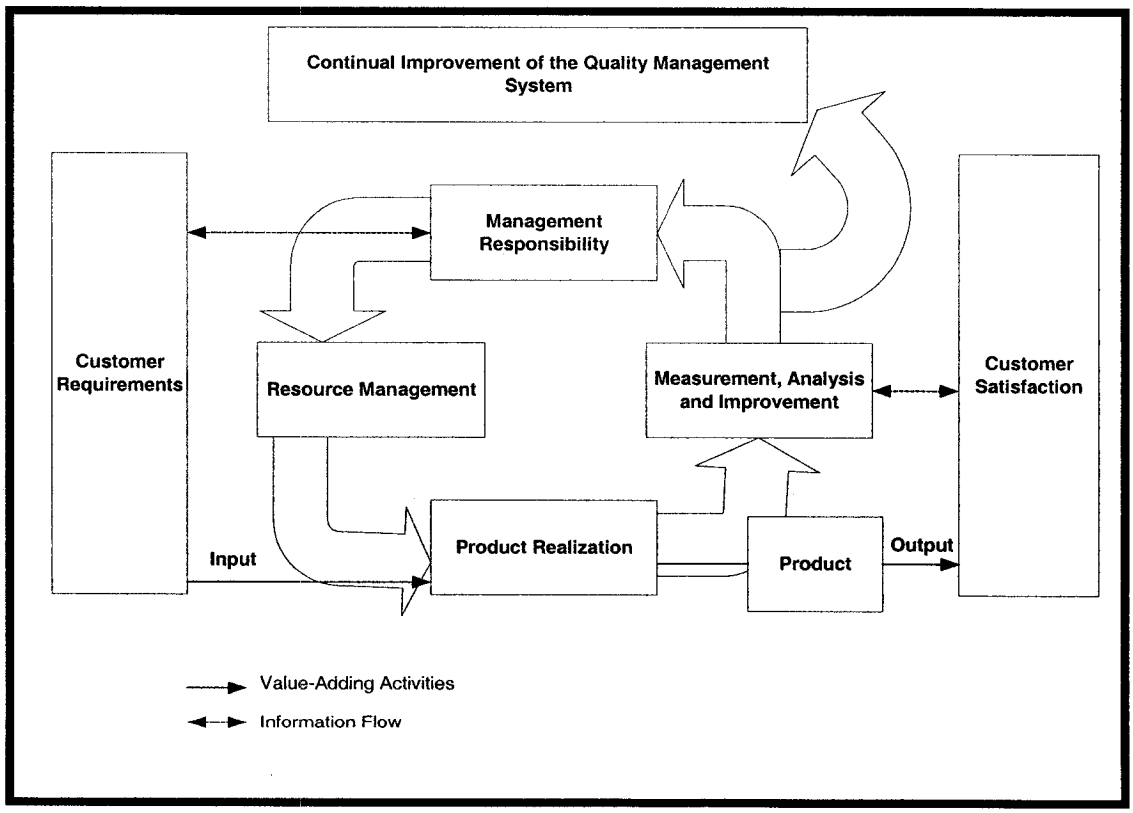

Figure 3. Model of a process-based quality management system

The model shown in Figure 3 covers the requirements of the standard in a broader spectrum but does not show processes at a detailed level. Table 1 shows the larger process as a set of 21 subprocesses and the associated clauses to which they refer from the 2000 version of the standard, as identified by the Praxiom Research Group Limited (2002):

Table 1. ISO 9001:2000 processes with relevant clauses

No.	ISO 9000 Process	Clause
1.	Quality Management Process	4.0
2.	Document Control Process	4.2.3
3.	Record Keeping Process	4.2.4
4.	Regulatory Research Process	5.1 (a), 7.2.1 (c)
5.	Market Research Process	5.2, 7.2.1, 7.2.2, 8.2.1
6.	Planning Process	5.4, 7.1, 7.3.1
7.	Internal Communication Process	5.5.3
8.	Management Review Process	5.6
9.	Resource Management Process	6.0
10.	Training Process	6.2.2
11.	Customer Needs Assessment Process	7.2.1, 7.2.2
12.	Customer Communication Process	7.2.3
13.	Product design process	7.3
14.	Purchasing Process	7.4.1
15.	Production Process	7.5
16.	Service provision process	7.5
17.	Product protection process	7.5.4, 7.5.5
18.	Monitoring and Measuring process	8.2
19.	Internal audit process	8.2.2
20.	Nonconformance management process	8.3, 8.5.2, 8.5.3
21.	Continual improvement process	8.5.1

As mentioned earlier, the standard promotes the application of a continuous improvement methodology. The PDCA cycle (Plan-Do-Check-Act) is therefore applied to all the processes of ISO 9000 as shown in the Figure 4. Walter Shewhart, the pioneering statistician who developed statistical process control, originated the idea of PDCA in 1930's. Later on in 1950's, it was taken up and promoted effectively by another quality guru, W. Edward Deming, and is consequently known by many as the 'Deming Wheel'. In order to apply the PDCA cycle to each of the above processes, the following steps must be considered:

- Plan (P): Define, develop and document each process
- Do (D): Implement documented procedure
- Check (C): Monitoring of implemented procedure
- Act (A): Improve the methodology or procedure

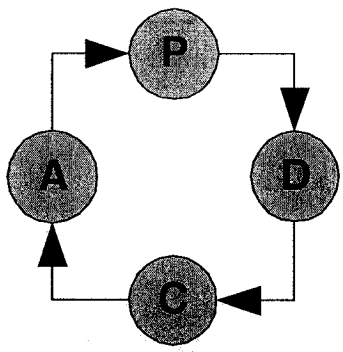

Figure 4. PDCA Cycle

In addition, since these ISO 9001:2000 processes are built on input-output relationships in which the output of the one process can affect another's input, in order to

apply the PDCA cycle to each process, consideration must be given to the input-output relationships of these processes.

This chapter provided an overview of ISO 9000 by highlighting its origin, contrasting the last two versions (1994 and 2000), and the approach of the present quality management system.

4.0 EMPIRICAL STUDY

Measurement is the first step that leads to control and eventually to improvement. If you can't measure something, you can't understand it. If you can't understand it, you can't control it. If you can't control it, you can't improve it.

—H. James Harrington

This chapter discusses the empirical study that was conducted to study the research problems presented in this thesis.

The study covers topics such as issues faced by companies during the implementation of the standard, barriers, selection of registrar, satisfaction with registration process, benefits and personnel views on ISO 9000 system. The effects of factors such as motivation towards ISO 9000, ownership of the company, markets served by the company, the size and maturity level of the company, on the degree of perceived difficulty faced during implementation, are all investigated. The effects of reasons seeking registration on the degree of perceived benefits in adopting ISO 9000 system are also studied. The research was conducted in the Canadian industries, specifically in the provinces of Quebec and Ontario. A mail survey instrument was used to collect data. One hundred and thirty-eight companies were randomly selected from the Quality Assessment Program's List of CGSB ISO 9000 Registered Companies, provided by the Canadian General Standards Board. These companies were listed as having successfully

been ISO 9000 registered, either under the 1994 version, in which case they were in the process of updating to the 2000 version, or under the 2000 version. Out of the 138 surveys that were mailed out, a total of 30 questionnaires were returned and successfully completed, yielding a response rate of 21.74 percent.

Table 2 shows the profile of the companies according to the version of ISO 9000 for which they were registered, the reasons they chose for registration (internal or external), the number of employees, and the number of years that were in operation at the time of study.

Table 2. Percentage of respondents in various categories

Version	*%*
1994	70.00
2000	30.00
Dominant reason for implementing ISO 9000 quality system	
Internal	36.67
External	63.33
Employees	
1-100 employees (Small)	70.00
101-500 employees (Medium)	26.67
501 or more employees (Large)	3.33
Years of operation	
Below 10 yrs. (Young)	10.00
11-20 yrs. (Mature)	26.67
21-30 yrs. (Very Mature)	20.00
more than 30 yrs.(Old)	43.33

4.1 Data Collection Instrument

A questionnaire survey was used to collect data from small, medium and large firms. The survey questionnaire has been designed to investigate various categories such as reasons for seeking registration, barriers to implementation, factors that affect the choice of registration body, satisfaction with the registration process, attitude towards ISO 9000,

and benefits and difficulties faced, as well as to obtain the data required to operationalize the empirical study. Items for all sections of the questionnaire have been gathered from the literature, including items from surveys conducted by the Standards Council of Canada and the International Organization for Standardization. The answers to the questions were measured using 1 to 5 Likert-types scales. Open-ended questions were also asked. The survey with both the scale items and the open-ended questions are provided in Appendix A. The unit of analysis is a company. The questionnaire was sent out to quality and operations managers or those who were responsible for managing quality issues in operations, manufacturing or purchasing.

The questionnaire consists of eight sections. The first section of the questionnaire, Section A, solicits information on the company's background. This section covers seventeen items including the company's industrial sector, the company's major product(s) and process(es), the current version of ISO 9000 under which they were registered, the dominating reason for registration, the number of employees, the total years of operation, the major market the company serves, and the type of ownership. Section B of the questionnaire addresses the reasons for which companies seek ISO 9000 registration. In this section, respondents were asked to answer each item using a Likert-type scale of 1 to 5, where 1 corresponds to the answer "Strongly Disagree" and 5 corresponds to "Strongly Agree". The same scale was used for sections C, D, F, and G. Section 'C' of the questionnaire lists the items that were potential barriers during the implementation of ISO 9000. For Sections 'D' and 'E' of the questionnaire, consideration has been given to the registration process as this is the last step of the ISO 9000 quality assurance system, and very crucial from the registration point of view since,

at the end of the ISO 9000 process, the organization must invite a third party, called the 'Registration Audit', to assess the system. Section 'D' is related to items that are considered in selecting a registration body. Section 'E' investigates whether or not companies are satisfied with the registration process. In this section, respondents were asked to choose those items that they were satisfied with during registration, and were required to answer each item using a scale of 1 to 5, where 1 corresponds to the answer "Strongly Dissatisfied" and 5 corresponds to "Very Satisfied". In section 'F' of the questionnaire, respondents were asked open-ended items about the attitude the organizations had towards ISO 9000. In the next section of the questionnaire, the benefits of achieving registration were introduced to gather information about what are the most likely benefits of adopting this quality assurance model and to investigate the link between the degree of perceived benefits with the reasons for seeking registration. Finally, the last part of the questionnaire contains a section about the degree of perceived difficulty in implementing ISO 9001:2000 processes. Again, a scale of 1 to 5 was used to indicate the level of difficulty for each ISO 9001:2000 process.

This last section was used to analyze the relationship between the degree of perceived difficulty in implementing ISO 9001:2000 processes with factors such as reasons for seeking registration, size of the company, type of ownership, years of operation and market share. The last two sections of the questionnaire were reserved to collect data for testing hypotheses formulated for the research objectives. The results of the questionnaire were analyzed empirically by using the statistical software, EXCEL / MINITAB™.

4.2 Hypotheses

To study the research problems presented in this thesis, a number of hypotheses were formulated and tested. The rationales for formulating the hypotheses are described below.

4.2.1 Reasons for seeking registration

Organizations choose to register for ISO 9000 for a variety of reasons. These reasons fall under two classes, internal or external, or often a combination of both. Reasons such as improving business processes, improving product quality, developing a quality culture, etc., reflecting internal motivation towards organizational improvements, are considered to be internal reasons (IR). Reasons such as customer thrust, fear of losing contracts, market competition, expectation of increased business, etc., are considered as external reasons (ER). The study first looks at the reasons for which companies seek registration in order to determine if organizations that are internally driven will perceive a different degree of difficulty than those organizations that are adopting ISO 9000 due to external pressures. It is believed that external reasons will put more pressure on the company, and therefore be more difficult, particularly because it is imposed upon them. Organizations that are motivated by internal improvements are expected to have a lower degree of perceived difficulty in fulfilling the requirements of the ISO 9000 system; internally driven reasons demonstrate a willingness to improve, and therefore should lead to a smoother implementation. Based on the above, the following hypothesis is tested:

H1: Organizations seeking registration for different reasons perceived a similar degree of difficulty in fulfilling the requirements of ISO 9001:2000 process approach.

4.2.2 Market Share

Because the ISO 9000 registration is critical for companies that serve European markets, it is likely that they have some sort of quality management system in place already. However, there is less of an onus for those companies that serve North American markets. Therefore, it is believed that those companies that have business relations (such as suppliers or buyers) outside of North America, and specifically in Europe, face fewer difficulties. This leads to the following hypothesis:

H2: Organizations that serve North American customers or not perceived a similar degree of difficulty in fulfilling the requirements of ISO 9001:2000 process approach.

4.2.3 Nature of ownership

The type of ownership, i.e., whether the organization is Canadian-owned (CA) or Foreign-owned (FR), may affect the implementation of ISO 9000 due to the presence or absence of foreign influence in terms of technology, ideas, experience or intellectual data. The sharing of knowledge, experience, and technology transfer can reduce hassles in implementing ISO 9000 quality assurance model. Thus the research question is operationalized as follows:

H3: Organizations that are majority owned by Canadians or foreigners perceived a similar degree of difficulty in fulfilling the requirements of ISO 9001:2000 process approach.

4.2.4 Organization Size

Another factor of interest in this study is the effect of the size of the company on the ease of implementation. On the one hand, it is expected that smaller-sized companies would face relatively fewer difficulties in fulfilling the requirements of the new ISO standard as compared to larger companies, since smaller companies generally have fewer products, processes, documentation requirements, and resources to run the business. On the other hand, it is also expected that it would be relatively less burdensome to make changes to conform to ISO requirements for large companies. This is because proper technologies (for example, machines, instrumentation, or testing equipment) are more available or more easily purchased by larger companies if they are needed for ISO compliance, as compared to smaller companies, who are typically more financially constrained. Furthermore, human resources are also expected to be more available to contribute to the implementation process, whereas smaller companies are relatively more resource constrained. One of the mandatory requirements of ISO 9000 is to appoint a Management Representative (MR) who leads the implementation process. This is generally more easily accomplished for larger companies. As one example, a small Canadian manufacturer was preparing for ISO registration, but could not afford to appoint an MR. Smaller companies typically resolve this problem by designating a

manager to fulfill the task of the MR, which is what the company did. Since it is believed that all companies have their share of difficulties, this leads to the next hypothesis:

H4: Organizations with different size perceived a similar degree of difficulty in fulfilling the requirements of ISO 9001:2000 process approach.

4.2.5 Maturity Level (years in operation)

The effect of the maturity level (young, mature, very mature, or old) of an organization, in terms of the total number of years it has been in operation, has also been studied. It is expected that the degree of perceived difficulty is lesser for organizations that have been in operation for a longer period of time. Younger companies typically are not as familiar with their processes, and also face difficulty in implementation as they are in the early stages of developing and expanding their business. It is not recommended that young companies implement ISO at the same as they are reengineering their processes since both require a considerable amount of resources. Mature companies, on the other hand, can implement ISO without facing as many problems since they tend to be established enough to understand their processes, and the employees are able to identify improvement opportunities and are more experienced to assist in the implementation process. Therefore, the following hypothesis is considered:

H5: Organizations with a different range of operating years perceived a similar degree of difficulty in fulfilling the requirements of the ISO 9001:2000 process approach.

4.2.6 Benefits

The study also investigates the link between the degree of perceived benefits of implementing ISO 9000 and the reasons for which registration was sought. It is believed that companies that are externally driven will enjoy greater benefits than those that are internally driven since there is more pressure to achieve compliance and therefore more effort is willingly taken to succeed. Thus the research question is operationalized as follows:

H6: Organizations seeking registration for different reasons perceived a similar degree of benefits by adopting ISO 9000 quality system.

4.3 Hypothesis Testing

The hypotheses were tested using the standard *t*-test and Kruskal-Wallis test. Except for hypotheses H4 and H5, which were tested by using Kruskal-Wallis test, all other hypotheses were tested by calculating the two mean differences and tested using the paired-samples t-test. For hypotheses H1 and H6, the mean differences between the degree of perceived difficulty and degree of perceived benefits have been calculated for internal (IR) and external (ER) reasons. For H2, organizations that ship 51% or more of the products within North America are defined as North American companies (NA). Shipping less than 51% is considered as non-North American companies (NNA). A standard t-test for the difference between two means (NA and NNA) is used to identify significant differences for ISO 9000 processes. Hypothesis H3 is calculated on the basis of ownership. The ownership is categorized into Canadian-owned (CA) and Foreign-owned (FR) and depends on the percentage of share holding. Companies in which

Canadian-owners hold 51 percent or more shares are termed as Canadian-owned (CA) companies while less than 51 percent defines Foreign-owned (FR) companies. The powerful chi-square test could not be used for hypotheses H4 and H5 because many expected frequencies of the observations were less than five, which does not satisfy one of the assumptions of the chi-square test. Therefore, a nonparametric Kruskal-Wallis test was used to investigate the significant difference in the perceived degree of difficulty in implementing ISO 9000 processes for different organization sizes and maturity level.

5.0 RESULTS

Things are hard before we know how to do them; afterwards, they are easy.

—John Woods

In this chapter, the results of the surveys and empirical study are compiled and presented. Recall that the scores obtained from the survey were based on a scale that ranges from 1 to 5. The respondents' numerical answers were normalized by converting them into weighted values by multiplying the numerical answers to pre-assigned weights, which were then added up to obtain an overall mean value for each item. The transformed mean values for each item are analyzed on the scale of 0.2 to 1.0, which corresponds, respectively, to the scale of 1 to 5 (from Strongly Disagree to Strongly Agree for sections B, C, D, F and G; from Very Dissatisfied to Very Satisfied for the section E; and from Easy to Very Difficult for section H of the questionnaire).

The results of Section 'B' show that the top three reasons that the respondent companies sought registration are:

- Customer demand/expectations
- Improved quality management practices
- Improved quality of products

Table 3 lists all the remaining reasons and their respective scores. The overall mean score for all the items in the table reveals that organizations do not disagree with any of the items as all the values are above 0.4. It is important to note that numbers in

column 'All' for the tables, which represent mean score values for the items presented are less than 1.

Table 3. Reasons for seeking ISO 9000 registration

Item	All
Customer demands/expectations	0.87
Improved quality management practices	0.85
Cultured/disciplined organization	0.81
Improved quality of products	0.79
Market advantage	0.79
Competitive Thrust	0.78
Corporate Mandate	0.73
Potential access to export market	0.63
Assistance in export	0.62
Government purchasing policy	0.61
Consultants approach to help implementation	0.49

Table 4 presents the barriers in preparing for registration, and shows that the greatest barriers were found to be:

- constraints on resources
- the implementation of set procedures
- underestimation of efforts needed for registration.

Table 4. Barriers in preparing for registration

Item	All
Constraints on resources	0.65
Implementation of set procedures	0.64
Underestimation of efforts needed for registration	0.63
Document development	0.61
High preparation cost	0.59
Training requirements	0.57
Employee resistance	0.56
Misinterpretation of standard	0.56
Document approval process	0.55
Unclear benefits of obtaining registration	0.55
Lack of management commitment	0.50
Calibration of instruments	0.40

Table 5 shows the factors that companies choose for selecting a registration body. Most organizations agreed that the "Country affiliation/accreditation" was the most critical factor to consider before selecting a registrar, followed closely by market reputation and industry experience.

Table 5. Factors for selecting registration body

Item	All
Country affiliation/accreditation	0.85
Market reputation	0.79
Industry experience	0.76
Registration cost	0.67
Geographic proximity	0.67
Corporate dictate	0.61
Consultant dictate/opinion	0.55

The satisfaction that companies have gained with the registration process is shown in Table 6. All the values are greater than 0.6, which means that organizations are generally satisfied. 'Overall attitude of the auditor' scored the highest among all the factors in the registration process. The mean score values for the other two dominating items, 'auditor's experience' and 'process understanding', fall close behind. Respondent companies do not show any dissatisfaction for any of the items dealing with the registration process.

Table 6. Satisfaction with the registration process

Item	All
Overall attitude of the auditor	0.88
Auditor's experience	0.87
Auditor's process understanding	0.86
Openness of the auditor	0.84
Registrar's availability	0.82
Assistance provided by registrar	0.77
Cost of registration	0.75

Table 7 shows the attitude that respondent companies had towards ISO 9000. Organizations responded positively and disagreed with the following statements:

- An organization that moves to ISO 9000 does not get benefit
- Implementing ISO 9000 is an unnecessary bureaucratic process
- Expected benefits of ISO 9000 is much less than investment
- ISO 9000 does not have competitive edge in Canadian market

Table 7. Attitude towards ISO 9000

Item	All
ISO 9000 registered companies can compete globally	0.81
ISO 9000 is effective for European market	0.73
ISO 9000 is suitable for large companies	0.65
ISO 9000 is for system not for the process/product	0.51
ISO 9000 does not have competitive edge in Canadian market	0.46
Expected benefits of ISO 9000 is much less than investment	0.44
Implementing ISO 9000 is an unnecessary bureaucratic process	0.39
An organization that moves to ISO 9000 does not get benefit	0.36

Table 8 shows the benefits of getting the company ISO 9000 registered, where the three most popular are:

- Improved documentation
- Improved quality perception
- Disciplined work environment

The table shows the overall mean score of each item, the values for which range from 0.71 to 0.89. As these values are greater than 0.60, this suggests that organizations registered for ISO 9000 have benefited from both internal and external gains. In other words, organizations do not disagree with any of the items presented in the table.

Table 8. Benefits of achieving ISO 9000 registration

Item	All
Improved documentation	0.89
Improved quality perception	0.87
Disciplined work environment	0.85
Consistency across the organization	0.83
Improved customer confidence	0.83
Customer satisfaction	0.82
Improved customer service	0.81
Advertising / marketing	0.76
Able to stay in business/not excluded from tenders	0.76
Improved market share	0.71

Table 9 shows the 21 processes of the new version of ISO 9001:2000. A mean value of 1 is the highest score, which represents the highest level of difficulty, while a mean value of 0.2 indicates that the item was not difficult to implement. A mean value of 0.6 therefore indicates that the responses were in between the highest and lowest scores, in other words, the response is that the degree of difficulty is neutral. Results show that, whether companies were registered for internal reasons (IR) or external reasons (ER), the perceived degree of difficulty was not significantly difficult for any of the 21 processes found under the new version of ISO 9000 as the highest score is 0.63, which is below than 0.8. As shown in Table 9, the following were viewed as being the most difficult items to implement in the ISO 9001:2000 system:

- Customer needs assessment process
- Customer communication process
- Monitoring and measuring process
- Product design process

Table 9. Degree of difficulty in implementing ISO 9001:2000 processes

Item	All
Customer needs assessment process	0.63
Customer communication process	0.61
Monitoring and measuring process	0.61
Product design process	0.61
Quality management process	0.60
Resource management process	0.59
Regulatory research process	0.59
Continual improvement process	0.58
Planning process	0.58
Market research process	0.56
Management review process	0.54
Training process	0.54
Production process	0.54
Service provision process	0.53
Document control process	0.53
Internal communication process	0.53
Product protection process	0.52
Purchasing process	0.52
Internal audit process	0.52
Record keeping process	0.49
Nonconformance management process	0.47

The processes that are perceived as being easy to implement are nonconformance management process, record keeping process, internal audit process, purchasing process and product protection process. However, since the overall mean values of each item are between 0.47 and 0.63, this shows that implementing all items are generally not very difficult.

5.1 Hypotheses Results

In this section, results for hypotheses H1 to H6 will be presented. These results will be presented in order and their interpretations will be discussed in the next chapter.

5.1.1 Link between degree of perceived difficulty and reasons for seeking registration

The t-test results for hypothesis H1 is shown in Table 10. The values for the t-statistic are listed in the table using the mean difference test between internal reasons (IR) and external reasons (ER). The probability of rejecting the null hypothesis (p-values) are presented in the last column. At 5 percent significance level, the following ISO 9000 processes showed significant difference in the degree of perceived difficulty for the test, hence the null hypothesis for these processes are rejected:

- Continual improvement process
- Management review process
- Product protection process
- Record keeping process

Rejection of the null hypothesis for the above processes is also satisfied by comparing the t-values with the t* critical values for a significance level of 5 percent. Negative values of the above processes in the mean difference column (IR-ER) indicate that organizations that are implementing them for internal reasons perceived a lower degree of difficulty as compared to those who implemented them for external reasons, and that there is a significant difference for these processes. As for the remaining

processes, there was no significant difference at 5-percent significant level in the perceived degree of difficulty.

Table 10. T-test results for the perceived degree of difficulty of ISO 9001:2000 processes and reasons

ISO 9000 Process	All	Mean IR	Mean ER	Mean IR-ER	t	p
Customer needs assessment process	0.63	0.20	0.43	-0.23	-1.32	0.13
Customer communication process	0.61	0.19	0.42	-0.23	-1.48	0.11
Monitoring and measuring process	0.61	0.21	0.39	-0.18	-1.79	0.07**
Product design process	0.61	0.19	0.42	-0.23	-2.06	0.05**
Quality management process	0.60	0.19	0.41	-0.22	-1.37	0.12
Resource management process	0.59	0.19	0.39	-0.20	-1.66	0.09**
Regulatory research process	0.59	0.21	0.39	-0.18	-1.70	0.08**
Continual improvement process	0.58	0.20	0.38	-0.18	-2.35	0.04*
Planning process	0.58	0.19	0.38	-0.19	-1.96	0.06**
Market research process	0.56	0.18	0.38	-0.20	-1.81	0.07**
Management review process	0.54	0.17	0.37	-0.20	-2.48	0.03*
Training process	0.54	0.17	0.37	-0.20	-0.93	0.20
Production process	0.54	0.17	0.37	-0.20	-1.19	0.15
Service provision process	0.53	0.18	0.35	-0.17	-0.92	0.21
Document control process	0.53	0.19	0.34	-0.15	-1.40	0.12
Internal communication process	0.53	0.16	0.37	-0.21	-1.93	0.06**
Product protection process	0.52	0.19	0.33	-0.14	-2.44	0.04*
Purchasing process	0.52	0.15	0.37	-0.22	-1.32	0.13
Internal audit process	0.52	0.16	0.36	-0.20	-1.76	0.08**
Record keeping process	0.49	0.17	0.32	-0.15	-4.69	0*
Nonconformance management process	0.47	0.16	0.31	-0.15	-1.50	0.10

*Statistically significant at 5 percent.
** Statistically significant at 10 percent

5.1.2 Link between degree of perceived difficulty and market share

Table 11 presents the results for the perceived degree of difficulty based on the market(s) served by the organizations, H2. The overall mean score values for companies serving non-North American (NNA) markets are lower as compared to those serving North American (NA) markets for all of the processes of ISO 9000. Except for the regulatory

research process, all the other processes are found to be statistically significant at 10-percent level of significance and hence the null hypothesis is rejected.

Table 11. Perceived degree of difficulty based on market(s) served by organizations

ISO 9000 process	NA (Mean)	NNA (Mean)	NA-NNA (Mean)	t	p
Quality management process	0.50	0.09	0.41	2.51	0.03*
Resource management process	0.49	0.09	0.40	2.90	0.02*
Regulatory research process	0.49	0.09	0.40	1.53	0.10
Market research process	0.49	0.08	0.41	1.84	0.07**
Product design process	0.53	0.08	0.45	3.31	0.01*
Purchasing process	0.48	0.05	0.43	2.09	0.05**
Production process	0.49	0.05	0.44	2.09	0.05**
Service provision process	0.44	0.05	0.39	2.20	0.05**
Product protection process	0.47	0.05	0.42	1.75	0.08**
Customer needs assessment process	0.54	0.09	0.45	2.86	0.02*
Customer communication process	0.52	0.09	0.43	2.76	0.03*
Internal communication process	0.47	0.07	0.40	2.81	0.02*
Document control process	0.48	0.05	0.43	3.76	0.01*
Record keeping process	0.44	0.05	0.39	3.13	0.02*
Planning process	0.53	0.06	0.47	2.75	0.03*
Training process	0.47	0.06	0.41	2.24	0.04*
Internal audit process	0.45	0.06	0.39	3.28	0.02*
Management review process	0.47	0.07	0.40	4.49	0.01*
Monitoring and measuring process	0.51	0.09	0.42	2.26	0.04*
Nonconformance management process	0.43	0.05	0.38	1.91	0.06**
Continual improvement process	0.52	0.06	0.46	2.43	0.04*

* Statistically significant at 5 percent
** Statistically significant at 10 percent

5.1.3 Link between degree of perceived difficulty and ownership

Results for hypotheses H3 are presented in Table 12, which reveals that all of the ISO 9001:2000 processes, except for the regulatory research process, product protection process, and nonconformance management process, are statistically different at 10-percent level of significance. Therefore, the null hypothesis is rejected.

Table 12. Perceived degree of difficulty and nature of ownership

ISO 9000 process	CA (Mean)	FR (Mean)	CA-FR (Mean)	t	p
Quality management process	0.47	0.12	0.35	2.29	0.04*
Resource management process	0.46	0.12	0.34	2.54	0.03*

Regulatory research process	0.45	0.13	0.32	1.55	0.10
Market research process	0.45	0.13	0.32	1.59	0.09**
Product design process	0.45	0.17	0.28	1.90	0.07**
Purchasing process	0.40	0.13	0.27	2.65	0.03*
Production process	0.41	0.13	0.28	1.99	0.06**
Service provision process	0.37	0.13	0.24	2.26	0.04*
Product protection process	0.39	0.13	0.26	1.56	0.10
Customer needs assessment process	0.47	0.16	0.31	2.48	0.03*
Customer communication process	0.40	0.15	0.25	2.92	0.02*
Internal communication process	0.39	0.13	0.26	2.27	0.04*
Document control process	0.37	0.14	0.23	2.55	0.03*
Record keeping process	0.43	0.12	0.31	2.57	0.03*
Planning process	0.40	0.15	0.25	1.61	0.09**
Training process	0.42	0.13	0.29	1.61	0.09**
Internal audit process	0.42	0.09	0.33	1.58	0.09**
Management review process	0.47	0.12	0.35	2.10	0.05**
Monitoring and measuring process	0.35	0.13	0.22	2.34	0.04*
Nonconformance management process	0.35	0.12	0.23	1.36	0.12
Continual improvement process	0.43	0.15	0.28	1.79	0.07**

* Statistically significant at 5 percent
** Statistically significant at 10 percent

5.1.4 Link between degree of perceived difficulty and organization size

Results for H4 show that the perceived degree of difficulty is generally the greatest for the small companies, then medium-sized companies, followed by large companies, who generally found the 21 processes to be the least difficult. In comparing the chi-square value with the chi-square critical values at 10-percent level of significance in Table 13, it is found that except for two processes, all the other ISO 9000 processes differ significantly and therefore the null hypothesis is rejected.

Table 13. Perceived degree of difficulty and Kruskal-Wallis Test result for small, medium, and large companies

ISO 9000 Process	Small Mean	Medium Mean	Large Mean	Chi-square
Quality management process	0.39	0.17	0.03	8.54*
Resource management process	0.39	0.17	0.03	7.98*
Regulatory research process	0.41	0.14	0.03	3.70
Market research process	0.40	0.15	0.03	5.82**
Product design process	0.45	0.15	0.01	8.41*
Purchasing process	0.37	0.15	0.01	8.02*

Production process	0.39	0.14	0.01	8.14*
Service provision process	0.37	0.11	0.01	4.52
Product protection process	0.38	0.12	0.01	5.59**
Customer needs assessment process	0.43	0.17	0.03	7.62*
Customer communication process	0.42	0.17	0.03	7.98*
Internal communication process	0.37	0.14	0.03	7.42*
Document control process	0.39	0.13	0.01	9.04*
Record keeping process	0.35	0.13	0.01	8.24*
Planning process	0.42	0.15	0.01	7.62*
Training process	0.37	0.15	0.01	5.15**
Internal audit process	0.37	0.13	0.01	9.26*
Management review process	0.37	0.16	0.01	9.06*
Monitoring and measuring process	0.42	0.17	0.01	8.25*
Nonconformance management process	0.33	0.13	0.01	5.50**
Continual improvement process	0.43	0.14	0.01	6.86*

* Statistically significant at 5-percent
** Statistically significant at 10-percent

Critical Values of Chi-square at df=2:			
Level of significance	0.10	0.05	0.01
Chi-square critical	4.61	5.99	9.21

5.1.5 Link between degree of perceived difficulty and maturity level

Results for H5 are presented in Table 14. The values in columns 2 to 5 are the mean values for the responses. It is interesting to note that none of the values in the 'Chi-square' column exceeds the chi-square critical value even at the 10-percent significant level. Failure in rejecting the null hypothesis implies that the company's maturity level does not significantly affect ISO 9000 processes.

Table 14. Perceived degree of difficulty and Kruskal-Wallis test results for companies with different maturity level

ISO 9000 Process	Young (Mean)	Mature (Mean)	Very Mature (Mean)	Old (Mean)	Chi-square
Quality management process	0.05	0.17	0.12	0.24	3.70
Resource management process	0.05	0.17	0.11	0.25	4.09
Regulatory research process	0.06	0.17	0.12	0.23	3.18

Market research process	0.06	0.15	0.13	0.23	2.22
Product design process	0.07	0.19	0.13	0.23	2.47
Purchasing process	0.05	0.15	0.13	0.21	3.53
Production process	0.05	0.16	0.13	0.21	2.94
Service provision process	0.05	0.15	0.11	0.18	2.66
Product protection process	0.05	0.14	0.11	0.21	3.20
Customer needs assessment process	0.05	0.19	0.14	0.25	4.46
Customer communication process	0.05	0.18	0.13	0.25	4.42
Internal communication process	0.05	0.15	0.12	0.21	2.55
Document control process	0.05	0.16	0.14	0.19	3.43
Record keeping process	0.05	0.14	0.11	0.19	3.33
Planning process	0.05	0.17	0.13	0.23	3.35
Training process	0.05	0.21	0.11	0.22	3.44
Internal audit process	0.05	0.21	0.11	0.20	2.91
Management review process	0.05	0.19	0.12	0.23	4.52
Monitoring and measuring process	0.06	0.17	0.10	0.27	3.95
Nonconformance management process	0.05	0.13	0.10	0.20	2.55
Continual improvement process	0.05	0.17	0.14	0.22	2.83

* Statistically significant at 5-percent
** Statistically significant at 10-percent

Critical Values of Chi-square at df=3:

Level of significance	0.10	0.05	0.01
Chi-square critical	6.25	7.81	11.34

5.1.6 Link between degree of perceived benefits and reasons for seeking registration

T-test results used to analyze H6 are documented in Table 15. Values for t-statistics and the probability of rejecting the null hypothesis 'p' are computed again. By comparing the mean score for the column (IR-ER), no items were found to be positive, which indicates that organizations that implemented ISO for external reasons perceived a higher degree of benefits as compared to those who implemented it for internal reasons. At the 10 percent significance level, the null hypothesis is rejected for the item 'improved market share' since the p-value is less than the level of significance ($0.08 < 0.10$). The comparison of the t-statistic with the t* critical value at 10 percent verifies the rejection of null

hypothesis. Thus companies that seek registration for external reasons perceive this item as having significantly greater benefits than companies using internal reasons.

Table 15. T-test results for perceived degree of benefits and reasons for seeking registration

Benefit	All	Mean IR	Mean ER	Mean IR-ER	t	p
Improved documentation	0.89	0.35	0.54	-0.19	-0.88	0.21
Improved quality perception	0.87	0.34	0.53	-0.19	-0.66	0.27
Disciplined work environment	0.85	0.35	0.51	-0.16	-0.69	0.26
Consistency across the organization	0.83	0.34	0.49	-0.15	-0.57	0.30
Improved customer confidence	0.83	0.33	0.51	-0.18	-1.08	0.17
Customer satisfaction	0.82	0.33	0.49	-0.16	-0.87	0.22
Improved customer service	0.81	0.33	0.49	-0.16	-0.63	0.28
Advertising / marketing	0.76	0.25	0.51	-0.26	-1.49	0.11
Able to stay in business/not excluded from tenders	0.73	0.28	0.45	-0.17	-1.18	0.15
Improved market share	0.71	0.27	0.44	-0.17	-1.71	0.08**

* Statistically significant at 5-percent
** Statistically significant at 10-percent

6.0 DISCUSSIONS AND IMPLICATIONS

The professional's grasp of the numbers is a measure of the control he has over the events that the numbers represent.

—Harold Geneen

In this chapter, findings of the empirical study will be discussed and the implications of the findings for managers will be presented.

6.1 Reasons for Seeking Registration

A number of studies have shown that many companies seek registration for external reasons, such as customer pressures or market-related reasons. European companies have especially been driven by external reasons (Lipovatz et. al., 1999; Carlsson and Carlsson, 1996; Taylor, 1995). This is natural since the standard originated in this region. Companies in the USA have been found to be motivated by internal reasons (Skrabec et. al., 1997). Results of the present study show that 63% of the Canadian organizations surveyed claimed external reasons for seeking registration, with customer demand/expectations being the top reason. However, a large percentage of Canadian companies also implement ISO 9000 for internal reasons; they believe that ISO standards will lead to improvements in products, processes, and systems, and will also provide a systematic framework for quality. Thus, Canadian organizations implement ISO 9000 not only for external reasons.

6.2 Benefits of Registration

The five most popular benefits of being ISO 9000 registered for the Canadian companies surveyed are, improved documentation, improved quality perception, disciplined work environment, consistency across the organization, improved customer confidence. The first four are internal benefits, while the last one is an external benefit. These compare to the top three in Yayha and Goh's study, which are found to be: better documentation, improved customer satisfaction, and higher perceived quality. Results also suggest that organizations registered for ISO 9000 have benefited from both internal and external gains. In a survey of 400 companies based in United Kingdom, conducted by Lloyd's Register Quality Assurance Ltd., organizations had acknowledged the following three benefits as topmost, which were: improved management control, organization and planning; improved customer service; consistency across the organization. In another survey of 620 worldwide ISO 9000 registered companies, benefits that were perceived as being the most dominant were: higher quality, improved customer satisfaction and competitive edge (PIQC, 1997).

Since the recognition of ISO 9000 in international markets, many organizations, quality practitioners, and researchers have reported the internal and external benefits of obtaining the registration. However, implementation of ISO 9000 system will not necessarily lead an organization to produce a defect-free product or set up a problem-free culture. The documented procedure is expected to provide a framework to track and prevent the problems by identifying and eliminating root-cause. Internal audits, management reviews, corrective and preventive actions are the mandatory clauses of the

system whose effective implementation will result in adding value and the organization can gain benefits of the system.

6.3 Barriers of Registration

Constraints on resources and the effort needed for registration were found to be the biggest hurdles during implementation, which implies that the availability of required personnel such as a management representative, engineers, and inspectors for example, as well as the time, effort, and budget devoted to ISO 9000, play a vital role in preparing for registration and leading to smoother implementation. Companies should therefore ensure that they prepare for implementation by having adequate resources and plan for the effort required on the part of their employees.

Fuentes et. al. (2000) pointed out that a lack of resources is the greatest barrier in the implementation of ISO 9000, whether in terms of financial support and/or time allocation. Time and resource constraints were also found to be the topmost barriers in implementing ISO 9000 for Swedish companies (Carlsson and Carlsson, 1996). Similarly, Yahya and Goh (2001) in their study, pointed out that the road to ISO 9000 registration was rarely smooth due to the existence of barriers such as constraints on resources (manpower, time, finance) for companies in Singapore and Greece.

6.4 Perceived Degree of Difficulty of ISO 9001:2000

It is clear that organizations face hurdles during the implementation of the ISO 9000 quality assurance system. The nature of the obstacles varies from organization to organization. The perceived degree of difficult of implementing the new ISO 9001:2000

processes studied in this thesis shows that, whether companies were registered for internal reasons (IR) or external reasons (ER), the perceived degree of difficulty was not significantly difficult for any of the 21 processes found under the new version of ISO 9000. This is similar to the results found by Yahya and Goh for Asian firms with the ISO 9000:1994 registration.

The top five processes that are perceived as being relatively difficult in satisfying the requirements are: customer needs assessment process, customer communication process, monitoring and measuring process, product design process and quality management process. This is similar to the results found by Yahya and Goh for the Asian firms with ISO 9000:1994 registration.

The customer needs assessment process involves such tasks as identifying and reviewing customer requirements and the statutory and regulatory requirements to produce a desired product. Records for these must be kept in accordance with the record keeping process. Other processes such as the market research, document control, production and service provision, among others, are also required. Considering quality function deployment (QFD) to translate the requirements of customer into engineering and manufacturing specifications may alleviate the degree of difficulty in fulfilling the requirements of this process.

The customer communication process involves disseminating information related to product information, company or customer enquiries, customer orders or contracts or amendments related to these, or order handling and customer feedback. Companies that are not used to documenting and recording such information formally may find it difficult to organize and determine how to implement this process effectively.

Organizations are required to monitor and measure the quality processes, customer satisfaction, and product characteristics. They are also required to plan and hold regular internal audits. It is suggested that the possible difficulty associated with this process is due to reasons such as determining how to measure customer satisfaction, use customer satisfaction information, conduct internal audits effectively and regularly, use appropriate methods of measuring processes, and verify product characteristics.

The product design process involves activities such as: design and development planning, defining inputs, generating outputs, carrying out reviews, performing verifications, conducting validations, and managing amendments. Yahya and Goh (2001) have found the same result for the previous version of the standard. Lee et. al. (1999) also pointed out that the lack of effort placed on design control is the main reason as to why this process is difficult. This could be due to having to set up input-output relationships to define it as a process for items such as specifications, material details and drawings, identification of critical parameters in relation to product, process, safety and customers, tolerances and dimensions, applicable standards and regulations, sampling criteria, and acceptance limits for performance.

A poor understanding of the quality management system as a process model could be the possible reason that not only makes this process difficult, but also affects the processes associated with the quality management system. Furthermore, this process involves a large number of tasks including a process for management activities, provision of resources, product realization and measurement process.

6.5 Link between degree of perceived difficulty and reasons for seeking registration

The empirical study shows that companies that seek registration for either internal or external reasons do not find the 21 items to be very difficult, although companies that seek registration for internal reasons perceive a significantly lower degree of difficulty in only the following items: continual improvement process, management review process, product protection process and record keeping process. This is similar to the results found by Yahya and Goh.

Organizations that are motivated internally focus on having a continual improvement process, a regular improvement system through the use of a quality policy, objectives, audit results, analysis of data, corrective and preventive actions, and management reviews. This is commensurate with the findings of Fuentes et. al. (2000), Yahya and Goh (2001), and Chin et. al. (2000).

It is suggested that the management review process is less difficult for IR companies because of the internal drive to improve: management may be more likely to take an active part in the implementation process, whereas, if it is imposed on a company for external reasons, management might be less willing to participate, or may feel forced to do so. As a result, the process tends to seem onerous.

The product protection process covers both customer-supplied products and organization-owned products during internal processing and delivery. It is unclear as to why this was found to be less difficult for IR companies; however, one possibility is that because this process is a part of internal operations, IR companies may put more effort on it as compared to ER companies.

Results show that the record keeping process is comparatively easier for IR companies than ER companies, which is in line with Yahya (2001) and Chin et al. (2000) findings. A relatively better understanding coupled with executive support was found in this process for IR companies than ER.

6.6 Link between degree of perceived difficulty with market share

The t-test result for the relationship between the degree of perceived difficulty in implementing ISO 9000 processes and the market share is documented in Table 11. Results show that companies serving NNA markets perceived less difficulty than companies serving NA markets, and that of the NNA companies, 75% of them serve European markets, and 25% serve markets in Australia, Asia and South America. These findings are in parallel with Yahya and Goh (2001) for companies that serve European customers. This is not surprising since companies that do business in Europe are likely to be more rigorous with their quality management systems, and therefore face fewer roadblocks during implementation or the transition to ISO 9001:2000. Furthermore, results suggest that NNA companies place more effort on their customers, as evidenced by the customer needs assessment process, and the customer communication process, which are found to be significantly different.

6.7 Link between degree of perceived difficulty with ownership

It is believed that the involvement of foreign ownership results in sharing technology, personnel experience, methodology and intellectual property which reduces roadblocks

and difficulties in implementing ISO 9000 processes. Results show that companies with foreign-ownership perceive easier implementation than Canadian-owned companies. In support, almost all the processes show statistically significant difference. While those processes that do not show a significant difference, their t-values found very close in rejecting the null hypothesis. With this finding, it encourages foreigners to operate business in Canada, which is in contrast with Yahya and Goh (2001) to operate foreign companies in Malaysia.

6.8 Link between degree of perceived difficulty with company size

In order to study the relationship between the degree of perceived difficulty in satisfying the requirements of ISO 9000 processes with the size of the company, organizations were asked to indicate the size of the company, and were then classified into three different groups as follows: small (1-100 employees), medium (101-500 employees), and large (501 and above employees). Results of the Kruskal-Wallis test are shown in Table 13. A comparison of the chi-square values with the critical values at 10 percent shows that there is a significant difference in all processes for each classification of company size, except for the regulatory research process and the service provision process. For these two processes, there is no significant difference in the degree of difficulty, whether the company is small, medium, or large. For all other processes, results suggest that larger companies, which have more resources available to them, face fewer difficulties during implementation, as compared to smaller companies that are more resource constrained. This finding is different than Yahya and Goh's (2001) for Malaysian companies, who found no difference based on size. A case study undertaken in a small Canadian

manufacturing firm revealed that constraints on resources did in fact impede ISO 9000 implementation for that company.

6.9 Link between degree of perceived difficulty with maturity level

Organizations with different years of operation perceived a similar degree of difficulty in implementing ISO 9001:2000 processes. Yahya and Goh (2001) found the similar results in implementing ISO 9001:1994 clauses in Malaysia. Upon investigating the effect of years of operation in implementing the new standard requirements, organizations were categorized into different levels of maturity with respect to operating years, as follows: young (below 10 years), mature (11-20 years), very mature (21-30 years), and old (more than 30 years). The Kruskal-Wallis test results tabulated in Table 14 indicates that none of the chi-square values for ISO 9000 processes show a significant difference even at the 10 percent level of significance and does not reject the hypothesis. It appears that the age of the company or their experience has no significant impact on the implementation process. However, by studying the mean values of young companies, we can see that they face slightly less difficulty than others, although this is not significant. This could be due to the fact that younger companies may have greater willingness and enthusiasm in gaining market recognition, however, the difference is not significant.

6.10 Link between degree of perceived benefits with reasons seeking registration

All companies seeking registration enjoyed benefits, both internal and external to the organization, however, those that implemented ISO for external reasons perceived higher degree of benefits as compared to those who implemented it for internal reasons. This is

different from what Yahya and Goh (2001) have found. It is suggested that the external pressure to comply with the standards provides a greater drive to successfully comply, and therefore more effort is invested in the implementation process. However, companies that sought registration for external reasons perceived significantly greater benefits in improved market share. Since the main intention of these companies was to use ISO 9000 as a marketing tool, publicizing registration likely provided the intended benefits. This has also been observed by Santos and Escanciano (2002).

Irrespective of organizational motivations, it is worth pointing out that the high score found for the top four benefits are associated with internal aspects of the organization. Results show that organizations experienced better documentation, perceived better quality awareness and understanding, streamlined work processes and found consistent flow of work throughout the organization. They also reveal that organizations not only experienced internal benefits but also gained commercialization and market-oriented benefits, such as improved customer confidence and satisfaction. T-test results shown in Table 15 reflect that companies that are motivated externally perceived greater benefits in comparison with internally driven companies. This finding is in contradiction with Jones et. *al.* (1997) and Yahya and Goh (2001). Results show that organizations motivated internally or externally enjoy the benefits of implementing ISO 9000 quality assurance system which is also pointed out by Santos and Escanciano (2002). Results show that a significant difference exists for improved market share at 10 percent level of significance. It can be argued that ER companies have a major concern to get market-oriented benefits with the acquisition of ISO 9000 registration. This is also identified by Santos and Escanciano (2002), who state that ISO 9000 registration is a

powerful tool, which is able to open the door to improve the market by publicizing it to the new market. Irrespective of organization motivations, it is worth pointing out that the high score found for top three benefits are associated to internal business of the organization. Results show that organizations experienced better documentation, perceived better quality awareness and understanding, stream lined work processes and found consistent work flow throughout the organization. It also reveals that organizations not only experienced internal benefits but also gained commercialized and market oriented benefits, such as improved customer confidence and satisfaction.

6.11 Chapter Discussion

Results of the study show that Canadian organizations implement ISO 9000 not only for external reasons, but also believe that ISO standards will lead to improvements in products, processes, and systems, and will also provide a systematic framework for quality. Constraints on resources and the effort needed for registration were found to be the biggest hurdles during implementation, which implies that the availability of required personnel such as a management representative, engineers, and inspectors for example, as well as the time, effort, and budget devoted to ISO 9000, play a vital role in preparing for registration and leading to smoother implementation. Companies should therefore ensure that they prepare for implementation by having adequate resources and plan for the effort required on the part of their employees.

The empirical study also shows that companies that seek registration for either internal or external reasons do not find the 21 items to be very difficult, although companies that seek registration for internal reasons perceive a significantly lower degree

of difficulty in only the following items: continual improvement process, management review process, product protection process and record keeping process. All companies seeking registration enjoyed benefits, both internal and external to the organization, however, those that implemented ISO for external reasons perceived higher degree of benefits as compared to those who implemented it for internal reasons. It is suggested that the external pressure to comply with the standards provides a greater drive to successfully comply, and therefore more effort is invested in the implementation process. However, companies that sought registration for external reasons perceived significantly greater benefits in improved market share. Since the main intention of these companies was to use ISO 9000 as a marketing tool, publicizing registration likely provided the intended benefits.

7.0 CASE STUDY

Believe one who has tried it.

—Virgil

The case study presented in this thesis documents the experience of implementing a quality system in preparation for ISO 9000 registration in a small manufacturing company. Over a nine-month period, the goal of the study was therefore to focus all efforts on changing procedures and implementing standards of quality that would not only be beneficial for the company internally, but would also prepare them for the future ISO registration process. The results of the case study highlight the challenges, lessons learned, and barriers faced during implementation, and help to identify success factors in quality systems implementation. This case study provides practical evidence by sharing the experience of implementing the ISO 9000 system in a small Canadian manufacturing company and documenting the issues faced by the company during the course of implementation. Findings of the case study are compared and contrasted with the results of the empirical analysis.

7.1 About the Company

Vortex Aquatic Structures International Inc. is a small-sized manufacturing company established in 1996 and is located in Montreal, Canada. Vortex designs and manufactures aquatic structures for recreational purposes, mainly for use in outdoor playgrounds. The company's primary market is in North America, although it also serves

markets in Europe. The company is privately owned, employing about 40 employees, and has been growing steadily, gaining a reputation among their major customers by delivering their products on time while offering high quality at competitive prices.

7.2 Products

Vortex offers a variety of products related to aquatic recreation (Appendix E). Their products use aquatic equipment such as water cannons and ground sprays, etc. to provide spray effects and to create an interactive, automated playground. All products fall under two categories: those that are above ground and those that are below ground. The above ground products have features that can be seen and are not buried underground, while the below ground products are flush mounted in the concrete and are visible when the water is rushing through them. All products are made up of a controller, an activation bollard, a distribution system, water treatment, and filtration systems. The controller is the heart of the system; it carries a microchip that allows the system to run on a predetermined sequence. The activation bollard is an above ground feature in which the users touch the surface of the product to send a signal to the controller, which then communicates with the distribution manifold to turn selected features on and off, for example. The distribution manifold is where the water comes from and then goes out to the features. The water treatment and filtration system is an option for the owners to re-circulate the water. The majority of the parts are manufactured with stainless steel while a selected few are made of fiberglass.

7.3 Processes

Because Vortex has numerous products of varying types, each has different processing requirements, and as a result, the manufacturing process is flexible. Their process flow varies between the receiving of raw materials to the delivery of the final product to customer. Figure 5 illustrates a flow chart describes the generic sequence of operations at Vortex, which begins with receiving and ends at delivery. Raw materials such as steel pipes and components (assembly accessories) are received at the receiving dock, and go through an inspection process. If they are unacceptable, a nonconformance report is generated. Raw materials that pass inspection are stored in a designated area until they are ready for the next operation, which is metal preparation. This step includes metal cutting and drilling, where the metal is prepared in the required dimension and shape before welding. Once the metal is cleaned and prepared, they are welded using two techniques: Gas Metal Arc Welding (GMAW) or Gas Tungsten Arc Welding (GTAW). This step is the most important and crucial operation at Vortex because it requires trained personnel, special equipment, right material, proper methodology and proper work environment. In some cases, Vortex sends their raw materials to subcontractors for welding due to the rush in fulfilling order requirements. Steps 14, 15 and 16 shows parallel operations in subcontractor premises. After the joining process, which could be using GMAW or GTAW, an air-test is carried out for both internal and subcontracted products to check the weld-leakage, one of the critical defects. Visual inspection is also performed to check the weld quality. Welded products are stored in a designated area after passing through inspection and test. These products are then shipped to the painting subcontractor, and once the painted structures are returned, they go through inspection

and are crated and assembled in the next operation where product accessories are pulled out from the inventories to build a final product. Finally, the product is shipped to the customer after a final check of the product. Water treatment is also a part of the Vortex business processes; it is not mentioned in the process flow because it is required for a few products only. It involves a test of water flow through automation and can be incorporated after welding in a generic process flow.

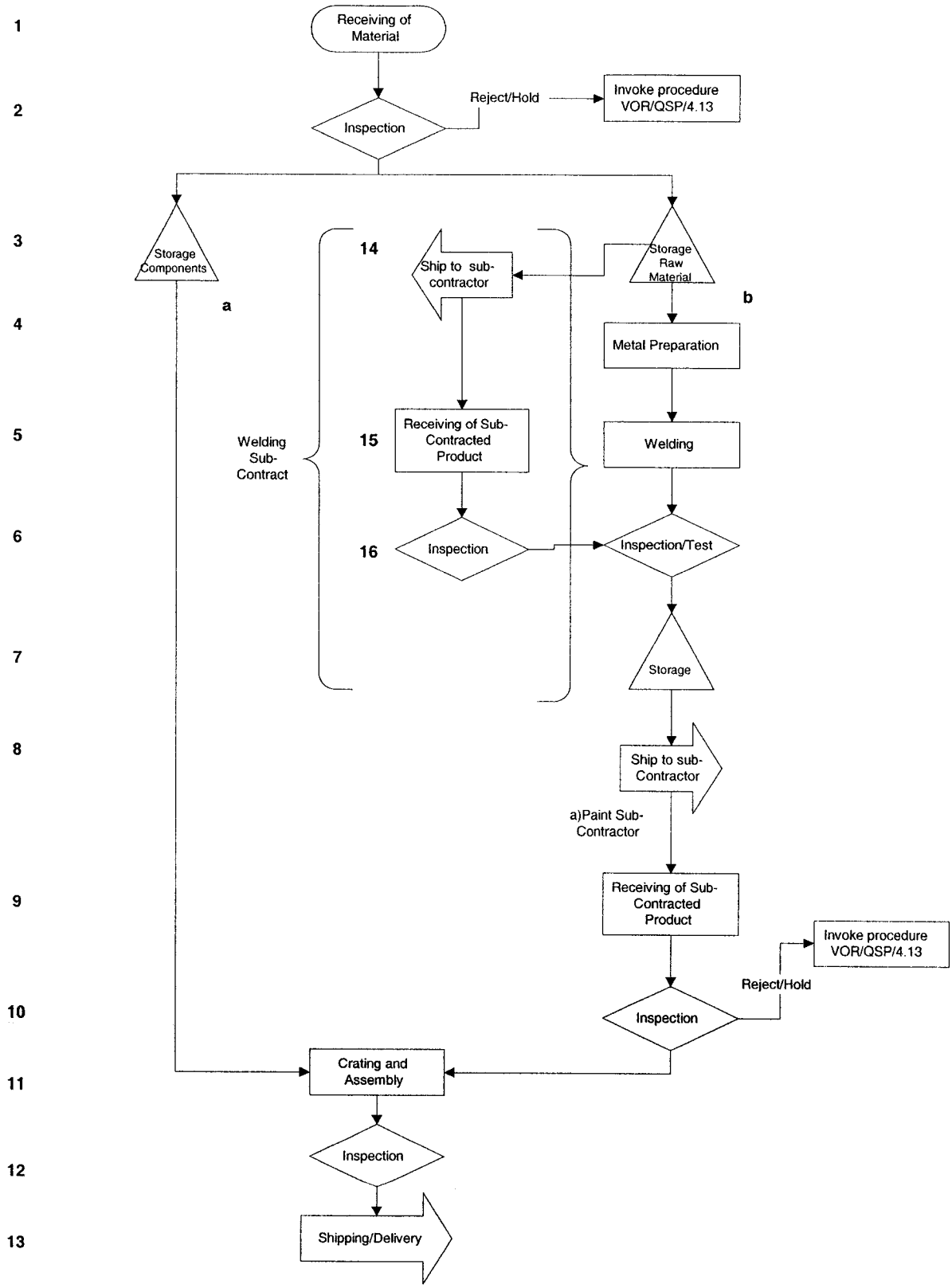

Figure 5. Process Flow at Vortex

7.4 Quality System Implementation

At the time of the study, Vortex was at a crossroads of improving their products, processes, and systems. As a young and steadily growing company, Vortex was ready to streamline their business processes, control nonconformance associated with their products, processes and systems, reduce rework, improve corporate culture, and set up an organized framework for quality. Both expansion and major reorganization of the company was being considered. The company had been thinking about registering for ISO 9000. Although the company's financial situation at the time did not allow for the registration process to be included as part of the budget, the company decided that it would be important to prepare for eventual registration nevertheless. They therefore opted to prepare for registration by hiring a quality expert to help them put in place a quality system which would comply with ISO 9000 requirements and therefore lead them to a smoother certification process when the time came. The company therefore focused its efforts on implementing what they generally called a 'quality system', a system which essentially fulfill all the requirements for ISO compliance.

Vortex was driven by three main forces to prepare for ISO 9000 registration. The first is an internal force, while the other two are external forces. First, as a young company, it was interested in putting a formal quality system in place, and expected to get benefits such as creating a disciplined work environment and more consistency in operations. Second, fulfilling customer expectations was a strong motive. Although Vortex's customers did not require the company to be ISO registered, they did expect Vortex to have a quality system in place. Finally, Vortex believed that it could gain a

strong market advantage in the future, expecting that it could earn more business, specifically in European markets, by using ISO 9000 as a marketing tool.

7.5 Data Collection

Information was collected from various data sources including interviews, attendance at project meetings, informal conversations, company documents, plant tours, and observations of the manufacturing process and product samples. The president of the company, the sales, engineering, operations, purchasing, and manufacturing manager, and technical personnel provided the information that was useful to develop an implementation plan for ISO 9000 project.

7.6 Quality System Implementation Plan

In order to initiate the case study, an implementation plan was developed to provide a systematic approach to putting in place the quality system. This roadmap was tailored specifically to ISO 9000 in order to prepare the organization for ISO compliance. Therefore, as a first step, an implementation plan was developed to provide a roadmap to prepare the company for ISO compliance. The steps are:

- Gap analysis
- Understanding the quality system
- Project team formation
- Appointing management representative
- Defining quality policy and objectives
- Identification and write-up required documents

- Training of shop-floor personnel
- Internal audit

7.6.1 Gap Analysis

The implementation of a quality system must begin with an understanding of the needs of the company as compared to fulfilling the requirements of a quality system (Appendix C). These needs are assessed through a gap analysis to determine the discrepancies between Vortex procedures and, in this case, the ISO 9000 framework. The gap analysis conducted revealed that several areas in the company needed to be considered, including: engineering, manufacturing, sales and marketing, purchasing, inventory control, and customer service. To deal with the gap analysis, a meeting was set with the President of Vortex and the Director of Operations to discuss how to initiate filling in the gaps and how the project would be developed and executed.

7.6.2 Understanding the Quality System

To get the company initiated into the new quality system implementation, a basic training was provided on quality systems, and specifically on the ISO 9000 philosophy. The training also addressed the issue of what version of ISO 9000 to prepare for (ISO 9001:1994 or ISO 9001:2000); a decision that was not taken previously since management wanted a better understanding of ISO 9000. They opted for ISO 9001:1994 since it is less demanding than the new version.

7.6.3 Project Team Formation

In the next step, a project team called the Quality Council (QC) was formed. This team consisted of cross-functional members made up of key personnel including the president, the operations, manufacturing, marketing and sales, purchasing, and engineering manager, and floor supervisor. It was decided that this team would conduct management reviews regularly (every three months) and that further, meetings could be called on an as-needed basis. The mandate of the QC was to discuss issues of implementing the new quality management system, setting a timeframe for the assignments given to the responsible functions, providing resources, discussing results of audits and means to resolve disputes that hinder project progress. The QC meetings were chaired by the President, and the minutes were distributed to each member so that they could follow up their activities in order to meet the timelines. All the members were asked to keep minutes of QC meetings properly according to the written procedures for quality records, and the master copy would be kept by an assigned Management Representative, whose responsibilities are described below.

7.6.4 Management Representative

When implementing any new system in a company, it is always important to have someone leading the changes. A Management Representative (MR) was therefore designated. The key responsibilities of the MR include 1) ensuring the establishment, implementation and maintenance of the quality system commensurate to the standard; 2) presenting and sharing results on the performance of the quality system to the President and all team members as a basis for improvement; and 3) liaising with external parties

such as vendors, customers and calibration agencies on matters regarding quality system issues. The MR responsibility was given to the Operations Manager once the quality system was in place. Responsibilities and authorities of the MR were made clear to top management and signed by the President to make it a formal document as objective evidence for one of the mandatory requirements of the system.

7.6.5 Quality Policy and Objectives

An important part of the implementation plan is to develop a quality policy and set objectives for the first three months of the project. The quality policy reflects the commitment of top management towards their quality goals. This commitment needs to be communicated at the grass-roots level through managers and department heads in such a manner that everyone must understand clearly the quality perspective of management. Although Vortex could not come up with the quality policy due to their hectic schedule with marketing and other business activities, quality objectives had been set for each department because of the regular discussion in QC meetings. Not all of the quality objectives were measurable, therefore department heads were asked to translate those objectives that were not into measurable items. For example, quality objectives such as reducing number of complaints, reducing percentage of rework, decreasing number of accidents, decreasing number of NCRs (nonconformance), improving cycle time, etc transforming into measurable objectives by assigning a timeline, percentages, numbers or dollar values.

7.6.6 Documentation Requirements

Another important dimension of setting up a quality system is the documentation of procedures. Documentation is a very important item in ISO 9000 quality systems because it is one of the mandatory requirements, for which it has a section named 'Document and Data Control' in the standard. The quality system will not be effective without fulfilling the requirement of this section. Figure 6 conceptually illustrates the hierarchy of the documentation required. The diagram shows a pyramid divided into four layers, each layer denoting a certain level and type of documentation needed for the quality system. The area of each layer indicates the relative length of documentation required, thus indicating that the documentation requirements of ISO 9000 increase as we move from level I to level IV. The following pyramid shows the ISO 9000 documentation system.

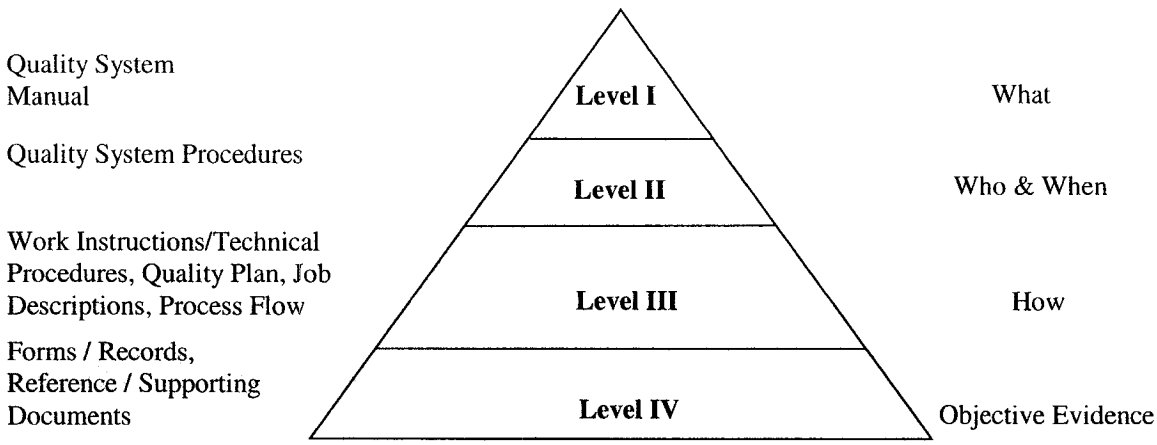

Figure 6. ISO 9000 documentation hierarchy

The level I documentation required is the Quality System Manual (QSM). This manual elaborates *what* the quality system at Vortex is all about. Each section of the

document describes a particular ISO element and refers to more detailed procedures when applicable. This manual forms a basis for quality audits and can be seen by the customers where required.

Level II documents are the Quality System Procedures (QSP), which are also referenced in the QSM. These detailed procedures are a written description of *what* is being done in the company, *who* is responsible and *when* the task is to be performed.

Level III documentation includes Work Instructions/Technical Procedures, Job Descriptions, a Quality Plan, and Process Flow. Work Instructions are detailed instructions that describe *how* an activity is to be performed and are easily understandable. Examples are equipment/machine operating instructions, inspection and testing methods, and design changes. Technical Procedures are the detailed description of a particular department or a specific task, if applicable. Where there are difficulties in describing something, procedures or instructions are displayed through pictures to convey the task reasonably. Job Descriptions define the responsibilities and authorities of personnel. This document also identifies resource requirements and performance of work. The Quality Plan is the document that describes all the activities, from receiving of raw materials to delivery in accordance with the process flow of the product, by identifying control parameters, evaluation techniques, frequency of control, control methods, and action plans in case of nonconformance.

Level IV documents form a basis for proof and evidence that an activity has been completed. These documents include forms, reports, check sheets, work orders, bills of materials, purchase orders, tests, reviews, surveys, audits, etc. These documents reference the Quality System Procedures, Work Instructions, Technical Procedures and

the Quality Plan. Some of these level IV documents were already in practice and required numbers to control them. Some forms, which are necessary from the ISO perspective, have been generated to fulfill the requirements of the system. All of these documents were controlled by issuing each a number systematically, with revision levels and revision dates. The responsibilities of developing these documents have been delegated to various people by top management. The consultant (in this case, the author) was responsible for developing level I and II documents, which were to be reviewed by Operations, Engineering and Sales Managers, with the approval of the President. Department heads were responsible for developing the level III and IV documentation. At all times, various people were solicited for their input in developing the documentation at the various levels.

7.6.7 Training of Shop Floor Personnel

According to the implementation plan, the next step was to provide training to shop floor personnel about their work instructions, inspection sheets, workmanship manual, and the filling out of nonconformance reports. Responsibilities in this area rest with the department heads. A training acknowledgement sheet was developed to ensure that the shop floor personnel understand clearly the training material. The skill and competence of the workers and their supervisors have a decisive effect on the quality of the product. Therefore, they must be trained in the skills required in their tasks. They must know how to operate their machinery, tools, and instruments safely, effectively and efficiently. They must be able to read and understand the drawings, specifications and other

documents that they have to work with and understand the relationship to their duties to the quality of the products, and they must keep their workplace safe.

7.6.8 Internal Audit

Finally, at the end of the project, an internal audit was conducted to determine the gaps and submitted to top management for review in the next QC meeting (Appendix D). In comparison with the gap analysis conducted at the time of initiating the project (Appendix C), the gaps that had filled during the implementation of the project were quite distinct as shown in Appendix D. The appendix reflects that most requirements of the ISO 9000 quality management system have been covered during the implementation process. Now, the company has the documentation structure that works in accordance with the ISO 9000 framework. Having gone through a comparative study, most of the elements were documented and implemented except for few elements, which are: process control, control of inspection, measuring and test equipment, quality records and internal quality audits. However, the documentation requirements are done for these elements but need more attention for effective implementation. As top management was not planning on registering for ISO, this project did not receive high priority; therefore the effect was reflected in the attitude of managers and workers. At the time of the study, the workers did follow the procedures but not very strictly, an indication that there is no rush to do so. Understandably, their motivation was different from that of a typical company working on registration.

7.7 Barriers During Implementation

In the initial stages of implementation, the introduction of a new system into a company and the corresponding implication of change created a number of roadblocks that impeded smooth implementation. The following items were the key factors that slowed down progress: quality perception, lack of top management commitment, problem awareness, lack of resources, lack of training, and resistance to change. These are all discussed below.

7.7.1 Quality Perception

The understanding of the quality system, the implementation requirements, and the benefits, was crucial in order to make the system effective at the grass-roots level. From the start, many employees misunderstood the perception of the quality effort at Vortex. A number of key people considered the study to be a waste of productive time and believed that their current system was good enough as the quality of their product was considered to be the best in market. As one example, the Assembly Supervisor believed that tracking defects at the inspection stage meant that the company has good internal quality. As a result, everyone did not commit to seriously making the changes required to successfully implement a quality system.

7.7.2 Top Management Commitment

Although the President of the company was keen on fostering a quality culture throughout the organization, his commitment was not reflected and communicated from

managers down to the shop floor level. In the following paragraphs, some examples of this problem demonstrate the difficulties that were faced in getting every employee's buy-in to the implementation of a quality system.

The Engineering Manager was not fully committed to the QC program. He felt that Vortex's products and processes were sufficiently good and recognized on the market. As a result, he did not dedicate much of his time to meeting his deadline for setting standard instructions for his department. For example, one of his responsibilities in the implementation was to develop the Sampling Plan, which is the most critical process of the business because if an organization does not have a good control at the receiving dock, then the probability of receiving wrong materials and components is higher. This took five or six months to be completed and ready for use at the receiving station, when it could have taken one month.

The Purchasing Manager and Assembly personnel were also not fully committed to the quality effort. Since Vortex did not employ a Quality Manager at the time of the study, the Purchasing Manager was responsible for the receiving of items. He was therefore delegated the responsibility of implementing instructions and sampling plans for the receiving activity, but even after five or six months, he was unable to meet his timeline. Again, a commitment to this effort would have enabled him to complete this task within one month. The Assembly Supervisor employed for the last couple of years, was very dedicated to his job. However, his perception of the quality effort also prevented him from changing his way of doing his job. He felt that the status quo at Vortex did not need any changing, and as a result, put little effort in completing his

responsibility of following the written instructions, and was therefore unable to keep up with his timeline.

Although the QC meetings were conducted every three months and were chaired by the President, the minutes of the meetings show that department heads were too busy to devote their time to set their procedures and standards. An independent quality function in the company had not even been set. As a result, many managers adopted an attitude of 'all talk no action', which became a symbol of disappointment for the rest of the organization.

7.7.3 Resistance to Change

Employee resistance to change was found in the organization. Manufacturing personnel believed that they would be overburdened with working in parallel with the implementation of a quality system, which is why they did their best to defeat the improvement scheme. While some managers were supportive in explaining how important the initiative was for the company, it was ineffectual in assisting in implementation. This resistance was due in part to the lack of top management commitment, and also due to the lack of training and understanding of how the quality system would benefit the organization. People will accept or reject change, depending on how the change will affect them. A strategy that convinces employees is needed to break this hurdle through emphasis on teamwork, brainstorming sessions, and consistent meetings. Employees' participation and cooperation in the improvement programs must be recognized and encouraged for effective implementation of the improvement program.

7.7.4 Lack of Resources

While many employees in the company were not committed to the quality effort, a newly appointed Manufacturing Manager was enthusiastic and eager to implement the quality system. However, due to a lack of resources such as unavailability of manpower and budget allocation, he could not continue in his commitment to developing the preventive maintenance procedure for the company.

At the time of the study, Vortex did not have a resource committed solely to quality. It was believed that the company needed a full time Quality Manager to supervise activities related to quality throughout the organization, and to assign inspectors for reporting problems related to the inspections. This Quality Manager would also play the role of the Management Representative (MR), a role that entails responsibilities that include: ensuring the processes needed for quality management system have been established, implemented and maintained; reporting to top management about the performance of quality management system; ensuring the awareness of customer requirements throughout the organization; and maintaining liaison with external agencies such as the registration body, customers, calibration agencies and consultants. In this way, quality would be expected to be free from any kind of bias, which could occur when the production head supervises quality-related issues. Since an MR is a mandatory requirement of the ISO 9000 system, it would beneficial to have one in the event of future registration. Unfortunately, management felt that investing any amount in an MR would be a waste of time and money at the time of the study due to their budget constraints.

7.7.5 Lack of Training

Vortex's management was not convinced that allocating funds for training at all levels of the company was necessary. They believed in training only selected capable persons who were expected to never leave the organization. As a result, only a few people understand the system and if they should leave the organization, they will take the knowledge of the system with them. Sadgrove (1994) pointed out the importance of training since quality depends on the employees.

7.8 Design of Experiment (DOE) at Vortex

During the implementation of the quality system, it was noted that the welding process is critical for the quality and the timely development of the company's products, as mentioned previously. For this reason, Vortex's management was keen on improving the welding process, specifically by developing standardized procedures for welding. In order to do so, Design of Experiments (DOE), a quantitative analysis technique, was performed to optimise the welding process. This technique, which will be described shortly, was used to control welding parameters for a specific type of welding so that the process could be optimized by reducing variation in weld quality. This standardized method of welding provides a guideline for all workers, current and future, to obtain a good quality weld on the structures.

Many researchers have attempted to combine ISO 9000 with just-in-time (JIT), TQM, reliability, dependability, and DOE. Perez (1993) has presented a cost-effective model of ISO 9000 by using DOE for a company involved in friction welding. Hence, in

this thesis, an experiment has been performed for the Shielded Metal Arc Welding (SMAW) process as a part of the implementation of ISO 9000.

7.8.1 Design of Experiments

Design of experiments provides a powerful means of achieving breakthrough improvements in product quality and process efficiency, leading to decreased costs and potential gains in profits (Montgomery, 2001). Since the quality of a part that undergoes some manufacturing process is largely determined by the quality of the machine (or process) that is used, the ideal parameters that can be set to achieve top quality parts are of high interest to production managers. Experimentation is one way of determining desired settings. By adjusting the parameters on a machine, for example, or 'experimenting' with them, it is possible to determine which factors might affect the quality of the output. Furthermore, certain factors may interact with one another to produce a certain effect. Using the DOE approach, experiments are designed and set up, and input parameters are varied and adjusted until some target level is achieved. The goal is to determine how statistically significant is an effect that a certain factor has on a dependent variable. In this way, for a particular manufacturing process, the ideal settings that have an impact on the process for various factors can be determined.

7.8.2 DOE Planning

To conduct an experiment, the planning stages of the design itself is crucial to make sure that goals of the experiment can indeed be met. The way in which the experiment is set up and the data collected and analyzed is called experimental design. Generally

speaking, this requires several planned and systematic steps to conduct the experiment effectively and efficiently:

a. Problem statement and objectives: understanding the problem and the goal(s) that need to be accomplished. DOE generally has two main objectives: one is to reduce the amount of variation in the response by controlling critical process parameters, and the other is to shift mean of the response towards a target value.
b. Response Variables: identifying the expected outcomes of the experiment.
c. Control Factors: identifying which factors need to be adjusted to study the effect of the changes on the response variables.
d. Uncontrollable factors: identification of variables that might affect the response variable(s).
e. Conducting the experiment: factorial design, replications, randomization, blocking, data collection methods
f. Data analysis: specific analyses used to study the data obtained from the experiment
g. Verification of results
h. Recommendations.

A cross-functional team was formed to perform DOE in a systematic way. The team consisted of a Quality Representative, the Director of Operations, and the Welding Supervisor. Experienced welders also participated to share their experience in selecting factors. The team adopted the Deming PDCA (Plan-do-check-act) approach, whereby they planned and investigated the problems of interest, performed experiments and recorded results on a data sheet. After verification of results, appropriate action was taken where applicable. Each of the steps of DOE is described below. A detailed

analysis of the method and the results can be found in Appendix B. In this chapter, the main steps and findings are presented only.

7.8.3 Problem objectives

The objective of the present experiment was to determine and optimize the factors required to produce good quality weld with the least amount of variation and to set up the standard procedure to do so. Introducing DOE into the implementation project was done to determine whether or not DOE could be incorporated in the ISO 9000 system successfully.

7.8.4 Response Variables

The next step of the experiment was to define the outcomes expected from the experiments. The company's desired response was to produce a good quality weld with the least amount of variation. Because of the difficulty in quantifying this, a ranking system was used to associate a number to the weld quality. The ranking system was agreed upon by the welders and the team on the basis of weld appearance, uniformity of the weld, weld-ring continuity, and based on the results of the weld-leak test. Subsequently, it was decided whether a weld was superior, good, acceptable, or did not meet the acceptance criteria. Hence, a ranking system using numerical values from 1 to 8 was used, with 1 corresponding to a superior quality weld, 2 to 4 representing good quality, 5 to 6 given to acceptable welds, and 7 and 8 indicating an unacceptable weld.

7.8.5 Control Factors

The next step entailed determining the control factors, which the team generated as being: material, operator, machine, current, wire feed rate, welding speed, gas flow, number of pass and wire diameter. Out of all these factors, three dominating parameters were chosen for study: current, measured in amperes (amp), wire feed rate, measured in inches per minute (ipm), and welding speed, measured in inches per minute (ipm). On the basis of process history, these factors were believed to have the greatest impact on the weld quality. Due to the unavailability of a gage to measure the feed rate and welding speed, a simple calculation was performed by using a stopwatch and inch-tape, which was sufficient for the experiment. Other controllable factors were fixed, such as the use of stainless steel of the same thickness for all welding purposes. Similarly, the same wire was used for a single pass weld with a constant gas flow. The selection of the control factors for the DOE was a crucial stage and involved input from process owner as well as the people who understands the process theoretically and practically. Factors such as humidity and welder capability were considered as uncontrollable factors. The SMAW process produces shield during welding, therefore minimizing the environmental effect, whereas experiments were conducted by two specialist welders to minimize the variation in the capability of welders.

7.8.6 Results Verification and Action

Results were verified by the process owner after monitoring the process. It was the responsibility of the Quality Supervisor to make sure that a consistent quality of weld is obtained. The welders were also asked to report any cases of contradiction in the

experimental output. A follow-up was carried out during the regular production of the part. Once the results were verified, the next step was to standardize the method. A work instruction was written to standardize the machine set-up procedure so that all welders have a guideline to follow the same procedure. This is also an important document for the requirement of ISO 9000 registration.

7.8.7 Recommendations

Based on the experiment and analysis of the results, the following points can be concluded as recommendations:

- The analysis of results shows that the factor welding speed has significant effect on the response (weld quality)
- The best weld quality with the least amount of variation can be achieved by setting the process at the best factor-level combination which is Current = 120 ampere, Wire-Feed Rate = 3.5 ipm and Welding Speed = 3.0 ipm.

The DOE was useful in helping to standardize an important manufacturing step. As such, it would seem to be an important component of ISO 9000 systems, where the main goal is standardization. DOE is one of the statistical techniques that improve the process by optimizing and reducing variation. While statistical technique is one of the mandatory requirements of ISO 9000 quality management system. From literature and web sources, it has been found that numerous companies including Allied Signal, General Electric, and Lockheed Martin have reported savings and benefits by applying statistically designed experiments for improving their business processes. There are many statistical tools that

can be used to fulfill the requirements of an ISO 9000 clause, however the consideration of DOE will lead to:

- reduced process variation
- optimized processes
- standardized process

The standard does not identify specifically which statistical tool needs to be implemented. It depends on the nature of business to consider an appropriate tool to implement a clause related to a statistical technique. In this study, the aim of linking DOE with ISO 9000 system is to provide quality practitioners an option of using statistical techniques for improving business processes. This will also add value to the ISO 9000 system.

In a study conducted by Perez (1993) for the implementation of a cost effective ISO 9000 model, experiments undertaken to link DOE with the implementation of the ISO 9000 quality assurance system produced better products with reduced cost and hence improved customer confidence. Based her study, using DOE during ISO 9000 implementation can indeed help to improve products, processes and systems. This combination will lead to tangible benefits of internal and external nature.

7.8.8 Case Study and Empirical Findings

The case study presented in this chapter was conducted to verify the findings of the empirical study. The study was conducted on a Canadian-owned company with under 50 employees involved in manufacturing aquatic structures for playgrounds for almost seven years. The company was implementing the ISO 9000 system for internal reasons. The

major market of the company is North America and as the company did not face any pressure to register from the customer, management's intention was not to streamline their business processes through ISO quality assurance compliance and to prepare for eventual registration.

The dominating reason for implementing ISO 9000 at Vortex was internal and their intention was to put a formal quality system in place on the basis of availability of resources. During implementation, human resources were busy executing other organizational tasks, such as enterprise resource planning. Also delivering manufactured products on time with limited resources was the priority at the time of the study, which made ISO 9000 implementation a bit difficult. Difficulties faced were not due to understanding ISO 9000 clauses, which is in contrast with the findings of empirical study that internally driven companies face lesser degree of difficulty as compared to externally motivated companies.

Vortex enjoyed benefits similar to the top three found from the results of the empirical study. These benefits are internal in nature, and are: improved documentation, improved quality perception, and a disciplined work environment. Before the implementation of ISO 9000, the organization did not have any documentation structure. Quality awareness had been increased through training and procedure implementation, and an increase in discipline was found at the workplace by employees following defined instructions.

Budget allocation, time devotion, and scarcity of resources have created obstacles in smooth implementation of ISO 9000 quality assurance system. The empirical study showed that scarcity of resources was found to be the biggest hurdle for organizations.

Other barriers such as lack of training, employee resistance, and top management commitment, were also found in respondent companies, similar to barriers found at Vortex.

The present empirical study shows that companies that are rich in resources face a lesser degree of difficulty as compared to small companies that have 1-100 employees. This finding proved to be true with Vortex, a small-sized company that had thirty employees at the time of study. The unavailability of required resources was found to be the biggest hurdle during implementation. Most employees were over-burdened to fulfil their tasks. This is a typical problem that occurs in small companies.

Vortex has been in business for the last seven years and is expanding gradually. Therefore, it is considered as a young growing company for which creating a balance between production and quality was found to be a bit difficult at such an early stage. In the empirical study, it has been found that more mature companies also faced difficulty in preparing for ISO 9000, and results had shown that the level of difficulty did not vary significantly with respect to the years in operation of the company. Therefore, it seems plausible to state the maturity of a company does indeed have little to do with the level of difficulty faced during implementation.

The case study presented in this thesis demonstrated issues raised during the implementation of ISO 9000 in a small manufacturing company, and discussed the consideration of DOE into the quality assurance model so that productivity can be increased by implementing a cost-effective model. The case study also supports some of the findings of the empirical study.

8.0 CONCLUSIONS

No great thing is created suddenly.

—Epictetus, Roman Stoic Philosopher

This chapter identifies contribution to research and the existing literature and proposes opportunities for future exploration.

In this thesis, an empirical analysis has been conducted to investigate ISO 9000 implementation issues in Canadian organizations, with a special focus on version 2000. The study focused on the dominating reasons for seeking registration, the most commonly occurring obstacles that arise during the implementation process, the perceived degree of difficulty in implementing ISO 9001:2000 processes, and the perceived benefits of achieving registration. This study empirically investigated the link between the degree of perceived difficulty and reasons for seeking registration, as well as the link between the degree of perceived benefits with the reasons seeking registration. The links between the degree of perceived difficulty with the factors such as: reasons seeking registration, market share, ownership, company size and operating years of the company, were also included in the study. In addition, a case study is presented in which an ISO 9000 system is implemented in a small Canadian manufacturing company. Major ISO 9000 issues and the roadblocks faced during the implementation are identified and findings from the case study are compared to the findings of the empirical study. The results of the empirical and case studies provide a better understanding of the factors that

influence ISO 9000 implementation, and should help companies better prepare for the registration process.

Results show that, whether external or internal reasons provided the impetus for registration, Canadian companies registered under the new ISO standards generally face the same degree of difficulty in implementation. However, internally driven companies have less difficulty for certain items, which are continual improvement process, management review process, product protection process and record keeping process. Results also reveal that factors such as market share, nature of ownership, and size of the company have significant affect in implementation, whereas companies with different maturity level perceive similar degree of difficulty in satisfying ISO 9000 requirements. In terms of benefits obtained due to ISO 9000 registration, externally driven companies perceived a higher degree of benefits as compared to internally driven companies for the respondent companies. In addition, case study for a small-sized Canada-based manufacturing company provides practical insight to the implications of ISO 9000 implementation.

8.1 Contributions to Previous Research

Many studies have investigated the issues involved with ISO 9000 implementation around the world (Carlsson and Carlsson, 1996; Lipovatz et al., 1999; Yahya and Goh, 2001; Santos and Escanciano, 2002). Implementation issues faced by companies during the registration process are well documented, as evidenced by the literature review presented in Chapter 2. The scope of the present study differs from previous research and and adds to the existing literature in a number of ways.

To begin with, no study to date, to the author's knowledge, has examined the issues associated with the most recent version of the standard, ISO 9001:2000. The focus of this study is solely on this version. Furthermore, as mentioned earlier, studies have been conducted on companies across the globe, but presumably, none have focused on companies in Canada. The scope of the empirical study is on the provinces of Quebec and Ontario.

While studies have extensively listed the type of barriers faced during ISO 9000 registration, the level of difficulty in doing so has not been studied to a great extent. Only Yahya and Goh (2001), in a study conducted on 405 Malaysian companies, have attempted to analyse the link between the degree of perceived difficulty of satisfying the requirements of ISO 9001:1994, but to date, no attempt has been made to analyse the degree of difficulty in implementing the new standard requirements of ISO 9001:2000. The present study analyses the difficulties of satisfying the requirement of the ISO 9001:2000 process-based approach.

This study will be useful to quality management, quality assurance and/or quality control practitioners, as well as researchers seeking to further understand quality practices and issues surrounding them. The study will also be beneficial to organizations that are either planning to implement ISO 9000, in the implementation phase, or already practicing or registered with ISO 9000. Finally, it adds value to the existing literature as little research has been conducted on the latest version of ISO 9000, the version 2000.

8.2 Future Research

There are several opportunities to expand the research presented in this thesis.

To begin with, the survey used in the empirical study can be broadened to include more sections on ISO 9000 implementation, for example, referring to particular processes and outcomes in the new standard. More specific comparisons between the newer and older standard can be addressed to understand more clearly how the changes in the standard have affected internal operations and resulting outcomes.

Next, the sample size surveyed can also be increased in the future, both within the provinces of Quebec and Ontario, but also, to other provinces in the country. Future work can also encompass other countries, beginning with the US. Conducting the survey in Europe would also be important since a large sample could be obtained, and since ISO is so important in European countries, data on changes in perception, operations, and outcomes related to the new standard would be interesting to collect.

The most recent version of ISO 9000 is more compatible with the environmental management system standard than the previous edition. Due to this compatibility, many organizations are seeking an integrated management system rather than focusing on a single standard. Therefore, the integration of ISO 9000 and ISO 14000 raises some interesting questions for investigation:

- What are the improvement opportunities for the ISO 9001:2000 quality assurance model?
- What obstacles arise when implementing the ISO 9000 quality assurance system and the ISO 14000 environmental management system together?
- What effective measures should be taken to reduce the roadblocks when implementing ISO 9000 and ISO 14000 together?

- What will be the perceived degree of difficulty when implementing ISO 9001 and ISO 14001 together in a company?

In addition, other management systems such as occupational health and safety management, financial management and risk management can also be considered for integration into the ISO 9001:2000 standard.

REFERENCES

Calingo, L.M.R., Leong, Y.M., et. al. (1995), "Achieving total quality management through ISO 9000 certification: a research note", *Accounting and Business Review*, Vol. 2, No. 1, pp. 173-186.

Carlsson, M. and Carlsson D. (1996), "Experiences of implementing ISO 9000 in Swedish industry", *International Journal of Quality and Reliability Management,* Vol. 13, No.7, pp. 36-47

Chin, K.W., Poon, G.K.K., et. al. (2000), "The critical maintenance issues of the ISO 9000 system: Hong Kong manufacturing industries' perspective", *Work Study*, Vol. 49 No. 3, pp. 89-96.

Fuentes, C., Benavent, F., et. al. (2000), "Analysis of the implementation of ISO 9000 quality assurance systems", *Work Study,* Vol. 49, No. 6.

Heras, I., Dick, G.P.M., et. al. (2002), "ISO 9000 registration's impact on sales and profitability", *International Journal of Quality and Reliability Management*, Vol. 19, No. 6, pp. 774-791

Hill, F.M., Hazlett, S., et. al. (2001), "A study of transition from ISO 9000 to TQM in the context of orgnizational learning", *International Journal of Quality and Reliability Management*, Vol. 18, No. 2, pp. 142-168.

International Organization for Standardization (2000), ISO 9001:2000(E) standard, *Quality Management Systems-Requirements.*

Jones, R., Arndt, G., et. al. (1997), "ISO 9000 among Australian companies: impact of time and reasons for seeking certification on perceptions of benefits received",

International Journal of Quality and Reliability Management, Vol. 14, No. 7, pp. 650-660.

Kanji, G.K. (1998), "An innovative approach to make ISO 9000 standards more effective", *Total Quality Management Journal*, Vol. 9, No. 1, pp. 67-78

Kim, Y. (1994), "ISO – making companies competitive", *Quality in Manufacturing,* November-December, p. 26

Laframboise, K. (2003), "An empirical study of the relationship between quality practices and business performance excellence in Central Canada", *Doctoral Thesis*, Department of Administration, John Molson School of Business, Concordia University.

Lee, S.F., Roberts, P., et. al. (1999), "Survey on ISO 9000 quality management system implementation in Hong Kong", *Managerial Auditing Journal*, Vol. 14, No. 1/2, pp. 79-88.

Leung, H.K.N., Chan, K.C.C., et. al. (1999), "Costs and benefits of ISO 9000 series: a practical study", *International Journal of Quality and Reliability Management,* Vol. 16, No. 7, pp. 675-690

Lipovatz, D., Stenos, F., et. al. (1999), "Implementation of ISO 9000 quality systems in Greek enterprises", *International Journal of Quality and Reliability Management,* Vol. 16, No.6, pp. 534-51.

McDonald, M., Mors, T., et. al. (2003), "Management system integration: can it be done?", *Quality Progress,* Vol. 36, No.10, pp. 67-74.

Montgomery, D.C. (2001), Design and analysis of experiments, fifth edition.

Perez, E. (1993), "Model for the design and implementation of reliable and cost effective ISO 9000 quality control system", *Master's Thesis*, Department of Mechanical Engineering, Concordia University.

PIQC (1997), "Training on ISO 9000 quality management system", *The ISO 9000 Series*. pp 32-43.

Quazi, Hesan A. and Padibjo, Samuel (1998), "A journey toward total quality management through ISO 9000 certification-a Singapore experience", *International Journal of Quality & Reliability Management*, Vol. 9, No. 5, pp. 489-508.

Rahman, S. (2001), "A comparative study of TQM practice and organizational performance of SMEs with and without ISO 9000 certification", *International Journal of Quality & Reliability Management*, Vol. 18, No. 1, pp. 35-49.

Sadgrove, K. (1994), ISO 9000 BS 5750 made easy: a practical guide to quality, London: Kogan Page.

Salegna, G. and Fazel, F. (2000), "Obstacles to Implementing Quality", *Quality Progress,* Vol. 33, No.7, pp. 53-57.

Santos, L. and Escanciano, C. (2002), "Benefits of ISO 9000:1994 system", *International Journal of Quality and Reliability Management,* Vol. 19, No.3, pp. 321-344.

Seddon, J. (1997), In pursuit of quality: the case against ISO 9000, Dublin: Oak Tree Press.

Singels, J., Ruel, G., et. al. (2001), "ISO 9000 series: certification and performance", *International Journal of Quality and Reliability Management*, Vol. 18, No. 1, pp. 62-75

Skrabec, Q.R., Ragu, N., et. al. (1997), "ISO 9000: do the benefits outweigh the costs", *Industrial Management,* Vol. 39, No.6, pp. 26-30.

Taylor, W.A. (1995), "Organizational differences in ISO 9000 implementation practices", *International Journal of Quality and Reliability Management,* Vol. 12, No. 7, pp. 10-27.

West, J.E., Haworth, G., et. al. (2002), "Should you transition to ISO 9001:2000?", *Quality Progress*, Vol. 35, No. 9, pp. 58-64.

Yahya, S. and Goh, W (2001), "Implementation of an ISO 9000 quality system", *International Journal of Quality and Reliability Management,* Vol. 18, No.9, pp. 941-966.

Major Web Links

Canadian General Standard Board (CGSB)

http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwGeneratedInterE/ah00286e.html

International Organization for Standardization (ISO)

http://www.iso.ch/iso/en/ISOOnline.openerpage

Kruskal-Wallis Test

http://udel.edu/~mcdonald/statkruskalwallis.html

Standard Council of Canada (SCC)

http://www.scc.ca/publicat/storysofar_e.html

The Praxiom Research Group Limited

http://www.praxiom.com

BIBLIOGRAPHY

Beckford, J. (2002), Quality, second ed., New York: Routledge.

Block, M.R. (2000), "Leveraging a quality system to establish an EMS", *Quality Progress*, Vol. 33, No. 7, pp. 82-85.

Box, G.E.P., Hunter, W.G., et. al. (1978), Statistics for experimenters: An introduction to design, data analysis and model building, New York, Chichester, Brisbane, Toronto and Singapore: John Wiley & Sons.

Culley, W.C. (1998), Environmental and quality systems integration, Florida: CRC Press.

Detweiler, D.F. (2003), "Process improvement", *Quality Progress*, Vol. 36, No. 5, p 112.

Dretzke, B.J. and Heilman, K.A. (1998), Statistics with microsoft excel, New Jersey: PRENTICE HALL, INC.

Goldstein, S. (2003), "ISO 9000 for small service companies", *Quality Progress*, Vol. 36, No.2, pp. 82-87.

Gordon, D. K. (2002), "Quality management system vs. quality improvement", *Quality Progress*, Vol. 35, No.11, pp. 86-88.

Graves, S. (2000), "Why do we need international standard?", Quality Progress, Vol. 33, No.6, pp. 138-139.

Larochelle, L. (1993), "An examination of the applicability and impact of ISO 9000 quality standards on Quebec manufacturers", *A Research Project*, Department of Commerce and Administration, Concordia University.

Liebesman, S. (2003), "Continual improvement using ISO 9000", *Quality Progress*, Vol. 36, No.1, pp. 62-63.

Liebesman, S. (2003), "Auditing a process based system", *Quality Progress*, Vol. 36, No.8, pp. 90-92.

Mercier, D. J. (2002), "A global approach to ISO 9000", *Quality Progress*, Vol. 35, No.10, pp. 56-60.

Mouradian, G. (2002), The quality revolution: a history of the quality movement, Maryland: university press of America.

Munro, R. A. (2003), "Roadblocks to quality", *Quality Progress*, Vol. 36, No.2, pp. 49-54.

Reid, R. D. (2003), "ISO 9000 and more", *Quality Progress*, Vol. 36, No. 4, pp. 90-93.

Shipley, D., Keller, C.W., et. al. (2003), "Multiple choice", *Quality Progress*, Vol. 36, No. 7, pp. 25-45.

Stimson, W.A. (1998), Beyond ISO 9000: how to sustain quality in a dynamic world, New York: AMACOM.

Taguchi, G., Clausing, D. (1990), "Robust quality", *Harvard Business Review*, Vol. 68, No. 1, pp. 65-75.

Warnack, M. (2003), "Continual improvement programs and ISO 9001:2000", *Quality Progress*, Vol. 36, No.3, pp. 42-49.

Westcott, R. (2003), "Process identification", *Quality Progress*, Vol. 36, No.8, pp. 104.

APPENDICES

APPENDIX A: QUESTIONNAIRE

Section A: Background Information

1. **Organization:** _____
2. **Address:** _____
3. **Phone:** _____
4. **Fax:** _____
5. **Website:** _____
6. **ISO 9000 Registered:** ❒ Yes ❒ No
7. **Current Version:** ❒ 1994 ❒ 2000
8. **Dominating Reason for Registration:** ❒ Internal ❒ External (Please choose one)
9. **Industrial Sector:** _____
10. **Major Product (s):** _____
11. **Major Process (es):** _____
12. **Major Market: (Please place a check mark ✓ in one of the following)**

    ❒ North America (if 51% or more products are shipped within North America)

    ❒Other Continent (If Yes, please specify with the approx. %) _____

13. **Ownership (Major Share): (Please place a check mark ✓ in one of the following)**

    ❒ Canadian-based (if 51% or more shares are held by Canadian Owners)

    ❒ Foreign based (if less than 51% shares are held by Canadian Owners)

14. **Number of Employees (approx.):** _____
15. **Operating Years:** _____
16. **Sources of Information: (place a check mark ✓ in one of the following)**

    ❒ Manuals ❒ Journals ❒ Books ❒ Internet ❒ Seminars ❒ Consultants

17. **Please indicate any thoughts, comments or suggestions for improving ISO 9001:2000 process based approach:**

    (Your input is valuable in helping to study and improve quality systems; please attach a sheet if needed)

_____

_____

_____

_____

Section B: Reasons for seeking ISO 9000 Registration

Please place a check mark ✓ for each item with respect to the following scale, which expresses the company's:

5 - Strongly Agree; 4 - Agree; 3 - Neutral; 2 - Disagree; 1 - Strongly Disagree

Item	5	4	3	2	1
Customer demands / expectations					
Competitive thrust					
Market advantage					
Assistance in export					
Potential access to export market					
Consultants approach to help implementation					
Government purchasing policy					
Corporate mandate					
Improved quality of products					
Improved quality management practices					
Cultured / disciplined organization					

Section C: Barriers in preparing for registration

5 - Strongly Agree; 4 - Agree; 3 - Neutral; 2 - Disagree; 1 - Strongly Disagree

Item	5	4	3	2	1
Lack of management commitment					
Constraints on resources (manpower, time, finance)					
Calibration of instruments					
High preparation cost					
Employee resistance					
Document development					
Document approval process					
Implementation of set procedures					
Misinterpretation of standard					
Training requirements					
Underestimation of efforts needed for registration					
Unclear benefits of obtaining registration					

Section D: Factors for selecting registration body

5 - Strongly Agree; 4 - Agree; 3 - Neutral; 2 - Disagree; 1 - Strongly Disagree

Item	5	4	3	2	1
Market reputation					
Country affiliation \ accreditation					
Industry experience					
Corporate dictate					
Consultant dictate \ opinion					
Geographic proximity					
Registration cost					

Section E: Satisfaction with registration process

5 - Very Satisfied; 4 - Satisfied; 3 - Neutral; 2 - Dissatisfied; 1 - Very Dissatisfied

Item	5	4	3	2	1
Overall attitude of the auditor					
Auditor's process understanding					
Auditor's experience					
Openness of the auditor					
Registrar's availability					
Cost of registration					
Assistance provided by registrar					

Section F: Attitude towards ISO 9000

5 - Strongly Agree; 4 - Agree; 3 - Neutral; 2 - Disagree; 1 - Strongly Disagree

Item	5	4	3	2	1
ISO 9000 registered companies can compete globally					
ISO 9000 is effective for European market					
ISO 9000 is for system not for the process / product improvement					
ISO 9000 is suitable for large companies					
ISO 9000 does not have competitive edge in the Canadian market					
An organization that moves to ISO 9000 does not get benefit					
Implementing ISO 9000 is an unnecessary bureaucratic process					
Expected benefits of ISO 9000 is much less than investment					

Section G: Benefits of achieving registration

5 - Strongly Agree; 4 - Agree; 3 - Neutral; 2 - Disagree; 1 - Strongly Disagree

Item	5	4	3	2	1
Able to stay in business / not excluded from tenders					
Customer satisfaction					
Improved market share					
Advertising / marketing					
Improved customer confidence					
Improved documentation					
Improved customer service					
Improved quality perception					
Disciplined work environment					
Consistency across the organization					

Section H: Degree of difficulty in implementing the ISO 9001:2000 process-based approach

5 – Very Difficult; 4 - Difficult; 3 - Neutral; 2 – Not Difficult; 1 - Easy

Item	5	4	3	2	1
Quality management process					
Resource management process					
Regulatory research process					
Market research process					
Product design process					
Purchasing process					
Production process					
Service provision process					
Product protection process					
Customer needs assessment process					
Customer communication process					
Internal communications process					
Document control process					
Record keeping process					

Item	5	4	3	2	1
Planning process					
Training process					
Internal audit process					
Management review process					
Monitoring and measuring process					
Nonconformance management process					
Continual improvement process					

Name: _____ Title: _____ E-mail: _____

Signature: _____ Date: _____

Thank you very much for taking time to fill this survey sheet. Please return it using the pre-paid postage envelopes provided with this survey.

APPENDIX B : FACTORIAL DESIGN

Factorial Design

An experiment can be used to test a single factor's effect on the outcome, while holding other variables constant. In factorial design, the effect of several factors on outcome can be studied simultaneously, as well as the interaction effects of several factors. A factor's 'level' is used to describe its value, that is, a factor is assigned +1 or –1 to indicate a high or low level, respectively. In this way, a table of levels can be constructed for various factors. Thus, various combinations of each factor's level could be run and a test would determine the main effect of a variable on outcome when other factors are varied. For example, a 2 factor, 2-level factorial design would indicate the study of two factors (or independent variables), each of which are described by two levels (also designated as a 2^2 design); there are 2 (factors) that can be varied to study a total of four possible combinations of the factors. A table could then be created using the levels. The development of the table will be described in detail for the welding process.

Replication, Randomization, and Blocking

The choice of experiments involves the consideration of the number of independent repetitions of an experiment (replication), the selection of a random order for experimental runs (randomization), and the determination of whether or not blocking is involved; these are three basic principles of any experimental design (Design and Analysis of Experiments, Montgomery 2001). Replication is defined as the number of times a run of an experiment is to be repeated, and is useful in showing that experimental results can be reproduced under set conditions, which in turn can help in reducing errors

in the experiment. In any experiment, during the planning phase, it is desired to minimize the introduction of any biases in experiments; randomization is used for this purpose. Randomization refers running the order of experiments arbitrarily. Blocking can be used to prevent experimental results from being influenced by variations due to nuisance factors; that is factors that may influence the experimental response but have no direct concern in the experiment. In general, a block is a set of homogeneous conditions. In this case, welders capability have been blocked by conducting experiments with two welders, which forms two different homogeneous set of experiments. Results of these two blocks will be analyzed and presented in later sections.

Experimental Design for the Welding Process

Recall that three factors were chosen for study. Based on the process knowledge and the practical experience of the welders, the project team came up with two levels for each factor, as shown in the following Table 1:

Table 1: Factors and Levels

Factor	Unit	Low Level (-)	High Level (+)
Current	amp	110	120
Wire Feed Rate	ipm	3.0	3.5
Welding Speed	ipm	2.5	3.0

A 2^3 full factorial design was selected, where the exponent 3 represents the number of factors and the base 2 represents the levels for the factors (high and low). For a 2^3 factorial design, the total number of runs is 8, and with a replication of 2, thus the experiment is made up of runs using each of these eight combinations multiplied by two, giving an experimental design containing 16 runs in total (Table 2). Column 1 in the

table refers to standard order of each experiment set by the software. Column 2 is the run number (for a total of 16 runs). Column 3 shows two sets of homogeneous experiments. The next three columns show the level of each factor, the current, wire feed rate, and welding speed for each run. The last column displays the responses from the experiment that are obtained by running each experiment and recording the result, which in this case a grade/rank (1 to 8) to each weld quality has been given according to the definitions described above.

Table 2: Experimental Design (2^3 Factorial)

Std. Order	Run	Block	Current	Wire Feed Rate	Welding Speed	Weld Quality
3	1	1	-1	1	-1	6
9	2	1	-1	-1	-1	2
2	3	1	1	-1	-1	7
7	4	1	-1	1	1	4
8	5	1	1	1	1	1
1	6	2	-1	-1	-1	2
12	7	1	1	1	-1	8
4	8	2	1	1	-1	7
10	9	2	1	-1	-1	8
6	10	1	1	-1	1	5
11	11	2	-1	1	-1	6
5	12	1	-1	-1	1	3
14	13	2	1	-1	1	5
15	14	2	-1	1	1	4
13	15	2	-1	-1	1	3
16	16	2	1	1	1	1

Performing the Experiment

All runs were performed randomly to avoid systematic bias in the results. These random orders were generated by using MINITAB, statistical software. Using the same factor-level combination, the experiments were conducted by two welders, thus providing two replications under the same experimental conditions. In this way, each welder also forms a block because the variability within a welder would be expected to be smaller than the variability between welders. Similarly, in order to reduce variation, both welders used the technique Tungsten Inert Gas Welding (TIG).

During the execution of experiment, the team leader and other associated members were monitored the process carefully to ensure that everything was being done according to plan. For this reason, a few trial runs were conducted. These runs ensured information about material selection, factors and its level adequacy, a check on the measurement system, a rough idea of experimental error, and a chance to grasp the overall practical experience of the technique. These trial runs were very helpful to assure the selection of factors and to set the levels of factors meaningfully.

Data Analysis

The analysis begins with the identification of the significant factor(s) that affect the expected response. Recall that the response for the experiment was defined on a ranking system, where a response of 1 indicates low quality weld, and a response of 8 indicates a superior quality weld. Analysis of variance (ANOVA) was used to determine the significance of factors. The results are summarized in Table 3.

Table 3: Analysis of variance (ANOVA) for weld quality

Source of	DOF	SS	MS	F	P
Current (A)	1	9.00	9.00	1.68	0.216
Wire Feed Rate	1	0.25	0.25	0.04	0.841
Welding Speed (C)	1	25.00	25.00	**5.93**	0.029
Error (A)	14	75.00	5.36		
Error (B)	14	83.75	5.98		
Error (C)	14	59.00	4.21		
Total	15	84.00			

Table 3 is the one-way ANOVA for weld quality versus current, wire feed rate and welding speed. Column 1 of the table indicates the sources of variation of the experiment. Column 2 gives the Degrees of freedom (DOF), Column 3 shows the Sum of Squares (SS), Column 4, the Mean Square (MS), and Columns 5 and 6 give the F-statistic (F) and p-statistic (p) respectively. The value of sum of squares (total) shows the total variation in overall data, which must be equal to variation of a factor plus the variation within the factor (error). As the degrees of freedom for all three factors are the same, the mean square is equal to the sum of squares. The data revealed that the F-value for welding speed is relatively large as compared to current and wire feed The F-value for the welding speed is greater than F-statistic from the 'Statistical Table' (i.e. F=4.60) which provide evidence that null hypothesis should be rejected and that there is a significant effect of factor C, i.e., the weld speed, on weld quality. Hence, welding speed is found to be significant factor.

In the next step, a normal probability graph of the residuals is plotted to check the adequacy of the model, which is shown in Figure 1. It is a graphical representation between the normal score and the residual (difference between actual and predicted value). The normal score is spread from –1.5 to +1.5 on the vertical axis, while residual is spread from –0.5 to +0.5. The graph shows that data falls between –0.5 and +0.5 residuals, suggesting that there is no significant indication of nonnormality and the data is distributed in a linear fashion, which concludes that the model is adequate.

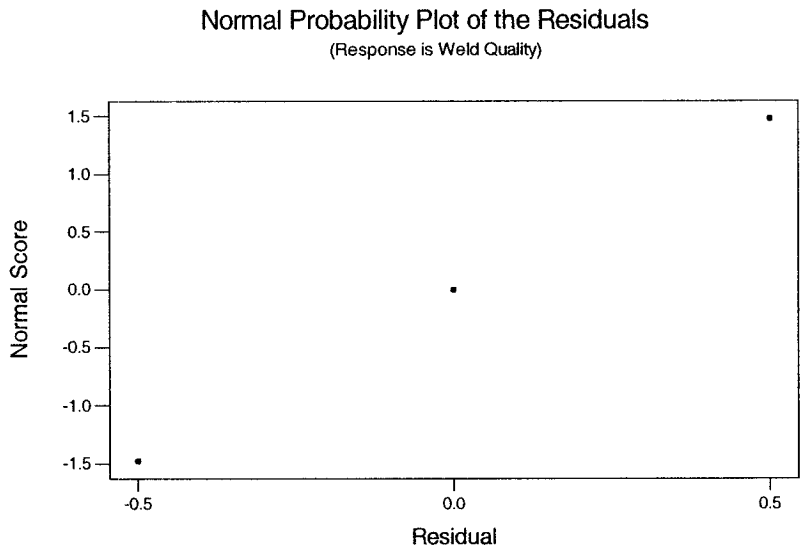

Figure 1: Normal Probability Plot (Residuals)

Another normal probability graph of the effects is shown in Figure 2. This graph shows the dependency between the normal score and standard effects of the factors. The normal score values range from –1.5 to +1.5 on vertical axis, whereas standard effects are ranging from –15 to +5 on horizontal axis. The factors are denoted by A, B, and C, i.e. the current, wire feed rate and welding speed, respectively. The response is the weld quality and the readings are taken at 10 percent significance level, α=0.10. Two points B

and ABC are close to the line. Points close to the line are insignificant, which means that the feed rate and interactions of all the three factors have an insignificant effect on the response of the process. Factor C has the largest negative effects, whereas the interaction of A & B, A & C and B & C also shows large negative effects. Only factor A and factor B shows positive effect with A has greater effect than B. Therefore, from this graph it can be concluded that factor C, the welding speed, has a significant effect on the process. Two-way interactions also have considerable effects on the process. From the graph, it is obvious that the combined effect of AB is much greater than AC and BC. Three-way interaction does not show any significant effect. This graph supports the ANOVA analysis.

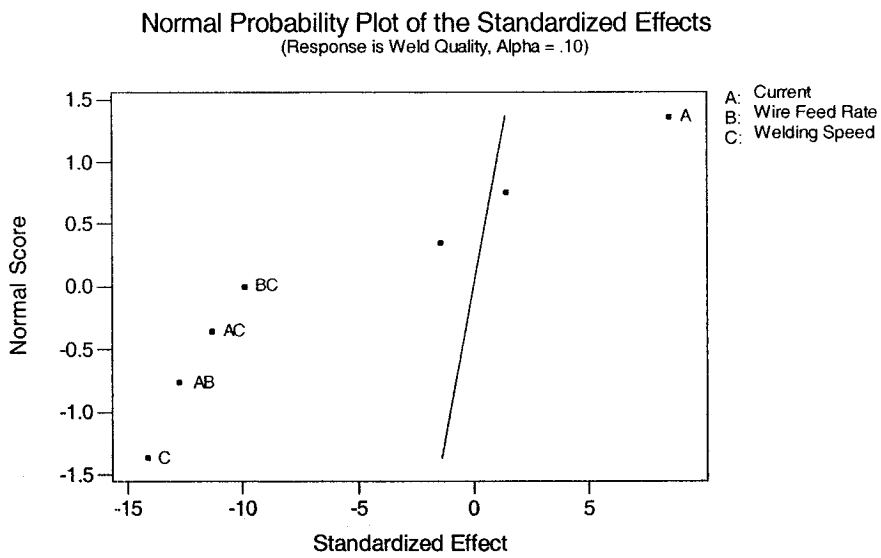

Figure 2: Normal Probability Plot (Standardized Effects)

The next part of the analysis deals with the Pareto Chart, plotted to prioritize the effects, which is shown in Figure 3. From this prioritization diagram, it is clear that the factor C has the largest effect among all factors and the interaction of three factors has the

smallest effect on the process. Factor C has large negative effect as identified in Figure 2 also. The main effects versus weld quality shown in Figure 4 also satisfy the ANOVA and Pareto analysis, which show that only factor C indicates a considerable change on weld quality when the level changes from –1 to +1.

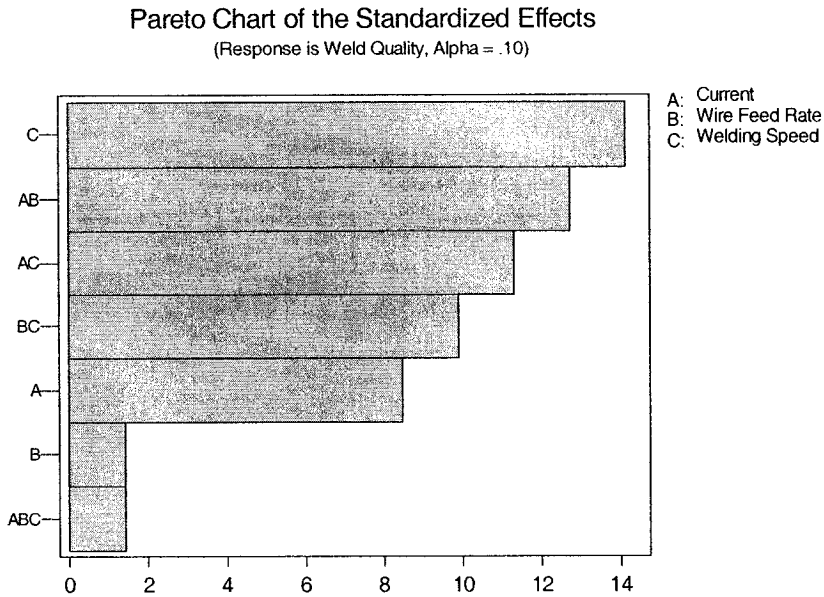

Figure 3: Pareto Chart (Standardized Effects)

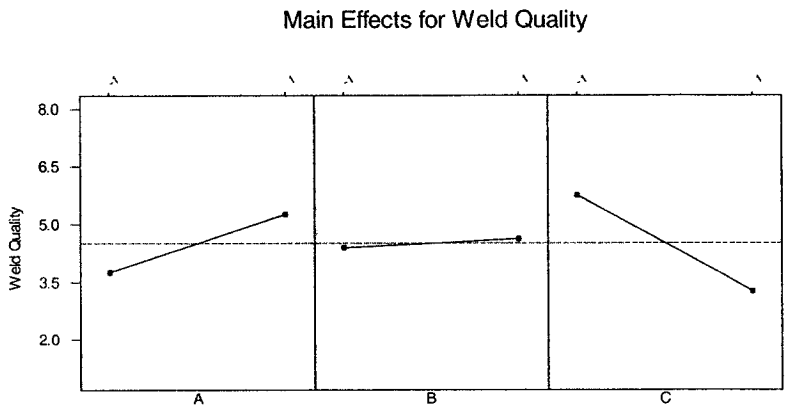

Figure 4: Main Effects for Weld Quality

From the previous graphs it was obvious that a 2-way interaction exist between factors. For this reason, an interaction plot for weld quality is shown in Figure 5. In this graph, the numbers associated with the weld quality are recorded from 2.0 to 7.0 on the vertical axis, whereas low (-1) and high (+1) values for factors are marked on horizontal axis. There are two lines: the solid line is for low level (-1) and the dashed line is for high level (+). As the lines are not parallel, this indicates that there is a significant interaction between factors A, B and C. From the graph, a study of interaction A and B shows that a better quality of weld will be obtained by keeping A and B at negative levels. Another interpretation is that weld quality gets worse when factor B changes from low to high level. These interaction plots strongly suggest that interaction exist between factors.

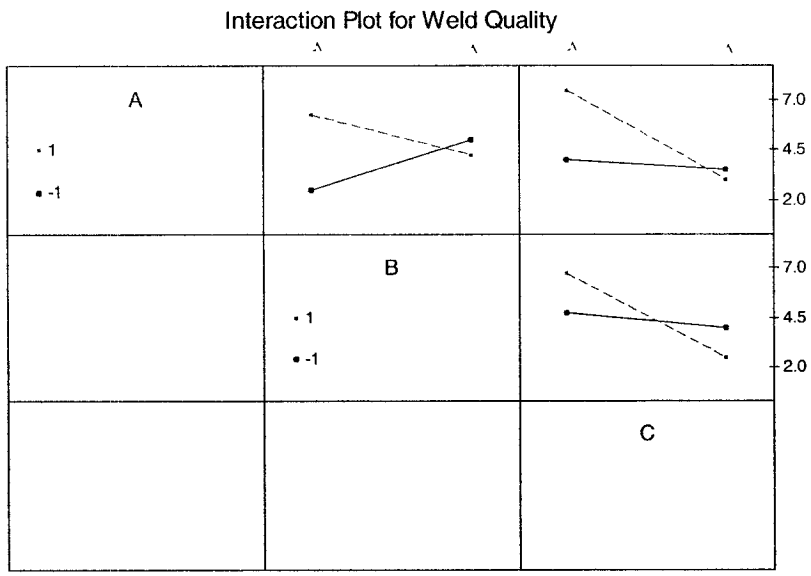

Figure 5: Interaction Plot

A contour plot of the weld quality is also used to analyze interaction effects of the factors. These plots are presented in Figure 6, 7 and 8. The first contour plot is the plot

between the current and the wire feed rate by keeping welding speed constant at a low level. This shows that weld quality gets better in a nonlinear fashion when the current changes from high level to low level. This trend justifies the analysis that a better quality weld will be obtained when both current and wire feed rate are at a low level. Graphical representation of contour plots in Figure 7 and 8 shows a little similarity in trends of the contour curves. In Figure 7, the plot is in between current and welding speed, indicating that a weld quality improves when the current changes from high to low level by keeping wire feed rate at a low level. A constant contour curve of weld quality 3 gives various combinations of current and welding speed at constant feed rate (what does this mean?). It is clear from the graph that a little change in the current will need a comparatively large change in welding speed to get a weld quality of 3. Another graphical representation between the wire feed rate and the welding speed in Figure 8 indicates that a better weld quality will be obtained when the wire feed rate changes from a high to low level by keeping current at a low level. The trend for the contour curve of weld quality at 3 is quite similar as the trend found between current and welding speed.

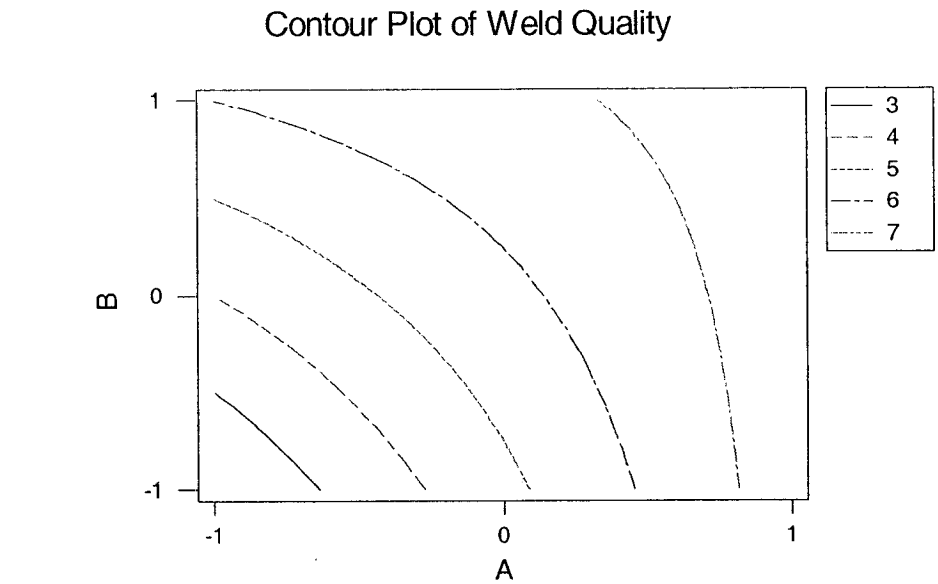

Figure 6: Contour Plot of Weld Quality with C at -1

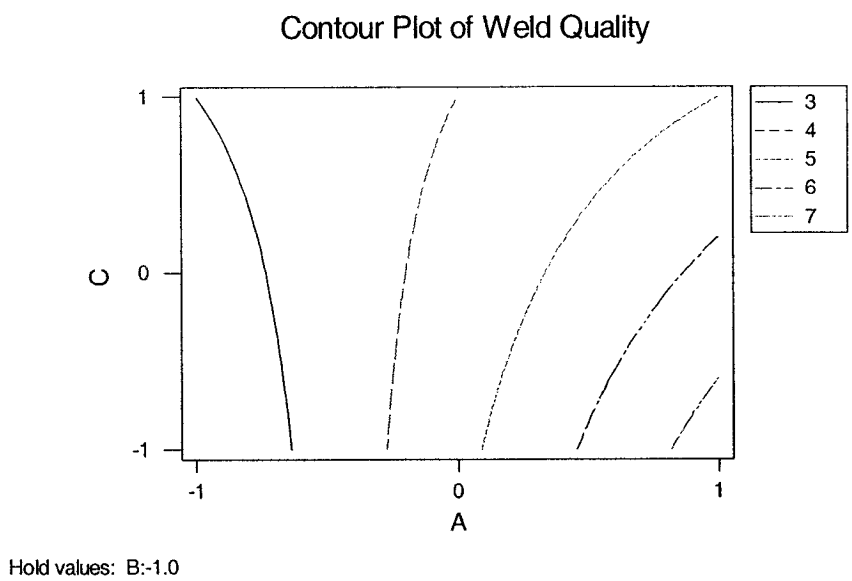

Figure 7: Contour Plot of Weld Quality with B at -1

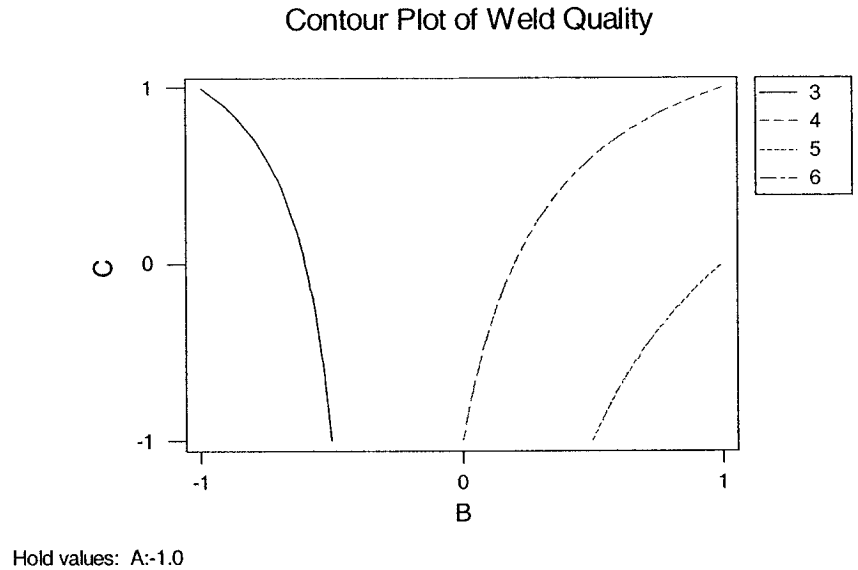

Figure 8: Contour Plot of Weld Quality with A at -1

The analysis is continued with a cube plot for thickness and is shown in Figure 9. It is a three dimensional representation of the current, wire feed rate, and the welding speed. From the graph, it is clear that the best quality weld will be obtained when all the factors are at +1, whereas the second best weld quality is obtained when all three factors were at low levels. That means that the best factor level combination is obtained by keeping the current at 120 ampere, the wire feed rate at 3.5 inch per minute, and the welding speed at 3.0 inch per minute.

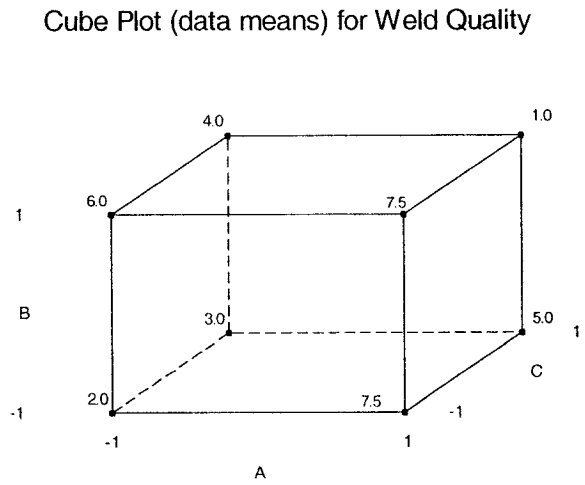

Figure 9: Cube Plot

The final part of the analysis deals with a regression equation. This study is conducted to know understand how weld quality is related to the factors (current-A, wire feed rate-B, and welding speed-C). The following regression equation was found:

Weld Quality = 4.50 + 0.75 A + 0.125 B - 1.25 C

The above equation shows a linear behavior between the predictor variables (current, wire feed rate and welding speed) and the criterion variable (weld quality). Thus the predicted value of weld quality can be obtained by inputting various levels of factors A, B, and C. Using actual data for weld quality can be useful in determining the residual of the weld quality (or the absolute error) by taking the difference between the actual value of weld quality and its predicted value.

APPENDIX C : GAP ANALYSIS (START OF PROJECT-APR 2002)

No.	ISO 9000 Requirement	D	I
4.1	*Management Responsibility*		
	Development and implementation of quality policy up to the shop floor level	×	×
	Identification and announcement of company's quality objectives	×	×
	Responsibility, authority, and the interrelationship of all personnel managing, performing and verifying tasks affecting quality	×	✓
	Availability of internal resources to manage, perform, and verify these tasks	×	✓
	Role of independent quality	×	×
	Appointment of a representative from the executive management ensuring implementation of quality system	×	×
	Review of quality system by the Management	×	×
4.2	*Quality System*		
	Presence and control of a documented quality system complying with the requirements of the standard	×	×
	Availability of the Quality Manual	×	×
	Availability of the quality system procedures	×	×
	Availability of Work Instructions	×	×
	Availability of Technical Documentation	✓	✓
	Availability of Quality Plans	×	×
4.3	*Contract Review*		
	Order processing and planning	✓	✓
	Order amendment	✓	✓
	Records of contract review	✓	✓
	Verification and approval of incoming orders	✓	✓
	Definition of product specifications	✓	✓
	Process capability to meet order requirements	✓	✓
4.4	*Design Control*		
	Availability of the procedures for design review	×	×
	Planning and follow-up of the development	✓	✓
	Identification of the different design activities	✓	✓
	Identification of responsibilities and interfaces per project	×	×
	Availability of qualified personnel provided with adequate resources	×	✓
	Documented design input related to the contract review	×	✓
	Control of design output related to the input data	×	✓
	Planning of formal design reviews	×	✓
	Design verification at appropriate steps	×	✓
	Participation of representatives of all functions concerned with the design stage being reviewed	×	✓

	Design validation in conformity with identified needs	×	✓
	Control of design modifications	×	✓
4.5	*Document and Data Control*		
	Availability of procedures for document and data control	×	×
	Verification and approval of documents and data	×	×
	Control of computer data	×	✓
	Distribution of documents and data	×	×
	Availability of master list of documents	×	×
	Modification and updating of documents	×	×
4.6	*Purchasing*		
	Availability of purchase procedures	×	×
	Definition of specification for the purchased products	×	✓
	Definition of subcontracted services	×	✓
	Evaluation of suppliers related to pre-established criteria	×	×
	Selection of new suppliers based on their capability	×	×
	Identification of approved suppliers	×	×
	Purchasing process	×	✓
	Verification at source of purchased products or services (at request of the client)	×	×
4.7	*Control of customer-supplied product*		
	Availability of procedures for customer-supplied product	◆	◆
	Identification of customer-supplied products	◆	◆
	Verification, storage and preservation of these products	◆	◆
	Information to purchaser in case of damage, loss or incompatibility	◆	◆
4.8	*Identification and traceability of the product*		
	Availability of identification procedures	×	×
	Identification of purchased products or subcontracted services	×	✓
	Identification of the product/service at all process stages	×	✓
	Identification of the finished product	×	✓
	Availability of traceability procedures (if contractually required)	×	×
	Availability of traceability records	×	×
4.9	*Process control*		
	Planning of the activities and the different process steps	✓	✓
	Availability of adequate work instruction and criteria	×	×
	Use of adequate equipment in an appropriate environment	×	✓
	Conformity with the quality plan	×	×
	Monitoring and control of the process	×	✓
	Control of special processes	×	×
	Workmanship Standards	×	×

4.10	*Inspection and testing*		
	Availability of inspection procedures in relation to the quality plan	×	×
	Availability of the product specifications	✓	✓
	Availability of instructions for analysis and testing	×	×
	Availability of inspection plans	×	×
	Receiving inspection	×	×
	Hold or control of product as long as the test results are not known	×	×
	In process inspection	×	×
	Final inspection and testing	×	×
	Recording of the results-certificates of analysis/conformity	×	×
	Disposition for release or hold	×	×
	Identification of the authority for release of the product	×	×
4.11	*Inspection, measuring and test equipment*		
	Availability of procedure for control of test equipment	×	×
	Verification and protection of the equipment and the appropriate software	×	×
	Definition of the equipment accuracy related to the measurements	×	×
	Selection of suitable measuring equipment	×	×
	Inventory of equipment affecting quality	×	×
	Traceability to recognized standards	×	×
	In process inspection	×	×
	Availability of a calibration plan	×	×
	Availability of calibration instructions	×	×
	Definition of calibration frequency and acceptance limits	×	×
	Performance of calibration and record	×	×
	Action to be taken when results are unsatisfactory	×	×
	Identification of the validity of the equipment	×	×
	Control of the environment and of the equipment used for calibration	×	×
4.12	*Inspection and test status*		
	Methods for the identification of status of conformity or non conformity of the product	×	×
	Instructions for release and hold	×	×
4.13	*Control of nonconforming product*		
	Availability of procedures for control of non conforming products	×	×
	Identification and documentation of non conforming products	×	×
	Prevention for further use	×	✓
	Assessment by an authorized and identified responsibility	×	✓
	Request for waiver (if contractually negotiable)	×	×
	Recovering of the product according to the quality plan	×	×
4.14	*Corrective and Preventive Actions*		
	Availability of procedure	×	×

	Objective evidence for the closing of nonconformities	×	×
	Handling of customer complaints	×	✓
	Treatment of internal nonconformance	×	✓
	Follow-up of the corrective actions	×	×
	Analysis of nonconformance related to the product, process, and system	×	×
	Objective evidence for preventive measures	×	×
4.15	*Handling, Storage, Packaging, Preservation and Delivery*		
	Availability of procedures	×	×
	Appropriate method for handling products	×	✓
	Identification of Storage areas	×	×
	Control of storage process	×	✓
	Appropriate packaging against stated requirements	×	✓
	Approval of packaging materials in accordance with the specifications	×	×
	Identification and information on packaged product	×	✓
	Preservation of products during storage	×	×
	Inspection of carrier before loading	×	×
	Loading under controlled conditions	×	✓
	Control of the delivery process	×	✓
4.16	*Quality Records*		
	Availability of procedures	×	×
	Identification of quality records	×	×
	Definition of retention time	×	×
	Storage of records	×	×
4.17	*Internal Quality Audit*		
	Availability of procedures	×	×
	Planning of internal audits	×	×
	Execution of internal audits	×	×
	Qualification of the auditors	×	×
	Indèpendent audits	×	×
	Report of internal audits	×	×
	Follow-up of audit results and feedback to management review	×	×
4.18	*Training*		
	Availability of procedures	×	×
	Identification of training needs	×	×
	Appropriate Training provided to the personnel	×	✓
	Qualification Identification	×	×
	Availability of records for all kinds of training (including safety and on-job training)	×	×
4.19	*Servicing*		
	Availability of procedures	×	×

	Servicing according to contractual requirements	×	×
	Verification of servicing	×	×
	Objective evidence in the form records	×	×
4.20	*Statistical Techniques*		
	Availability of procedure	×	×
	Identification of needs for statistical technique	×	×
	Use of SPC to verify process capability/product characteristics	×	×

Legends:

D Documentation
I Implementation
✓ Exist but not in accordance with ISO 9000 system
× Not existing
◆ Not Applicable

APPENDIX D : Gap Analysis (End of Project-Jan 2003)

No.	ISO 9000 Requirement	D	I
4.1	*Management Responsibility*		
	Development and implementation of quality policy up to the shop floor level	×	×
	Identification and announcement of company's quality objectives	✓	×
	Responsibility, authority, and the interrelationship of all personnel managing, performing and verifying tasks affecting quality	✓	✓
	Availability of internal resources to manage, perform, and verify these tasks	✓	✓
	Role of independent quality	×	×
	Appointment of a representative from the executive management ensuring implementation of quality system	×	×
	Review of quality system by the Management	✓	✓
4.2	*Quality System*		
	Presence and control of a documented quality system complying with the requirements of the standard	✓	×
	Availability of the Quality Manual	✓	×
	Availability of the quality system procedures	✓	×
	Availability of Work Instructions	✓	×
	Availability of Technical Documentation	✓	✓
	Availability of Quality Plans	✓	×
4.3	*Contract Review*		
	Order processing and planning	✓	✓
	Order amendment	✓	✓
	Records of contract review	✓	✓
	Verification and approval of incoming orders	✓	✓
	Definition of product specifications	✓	✓
	Process capability to meet order requirements	✓	✓
4.4	*Design Control*		
	Availability of the procedures for design review	✓	✓
	Planning and follow-up of the development	✓	✓
	Identification of the different design activities	✓	✓
	Identification of responsibilities and interfaces per project	✓	✓
	Availability of qualified personnel provided with adequate resources	✓	✓
	Documented design input related to the contract review	✓	✓
	Control of design output related to the input data	✓	✓
	Planning of formal design reviews	✓	✓
	Design verification at appropriate steps	✓	✓
	Participation of representatives of all functions concerned with the design stage being reviewed	✓	✓

	Design validation in conformity with identified needs	✓	✓
	Control of design modifications	✓	✓
4.5	*Document and Data Control*		
	Availability of procedures for document and data control	✓	✓
	Verification and approval of documents and data	✓	✓
	Control of computer data	✓	✓
	Distribution of documents and data	✓	✓
	Availability of master list of documents	✓	✓
	Modification and updating of documents	✓	✓
4.6	*Purchasing*		
	Availability of purchase procedures	✓	✓
	Definition of specification for the purchased products	✓	✓
	Definition of subcontracted services	✓	✓
	Evaluation of suppliers related to pre-established criteria	×	×
	Selection of new suppliers based on their capability	×	×
	Identification of approved suppliers	✓	✓
	Purchasing process	✓	✓
	Verification at source of purchased products or services (at request of the client)	×	×
4.7	*Control of customer-supplied product*		
	Availability of procedures for customer-supplied product	×	×
	Identification of customer-supplied products	×	×
	Verification, storage and preservation of these products	×	×
	Information to purchaser in case of damage, loss or incompatibility	×	×
4.8	*Identification and traceability of the product*		
	Availability of identification procedures	✓	×
	Identification of purchased products or subcontracted services	×	✓
	Identification of the product/service at all process stages	✓	✓
	Identification of the finished product	✓	✓
	Availability of traceability procedures (if contractually required)	✓	×
	Availability of traceability records	✓	×
4.9	*Process control*		
	Planning of the activities and the different process steps	×	✓
	Availability of adequate work instruction and criteria	×	×
	Use of adequate equipment in an appropriate environment	×	✓
	Conformity with the quality plan	×	×
	Monitoring and control of the process	×	✓
	Maintenance of the process equipment	×	×
	Control of special processes	×	×
	Workmanship Standards	×	×

4.10	*Inspection and testing*		
	Availability of inspection procedures in relation to the quality plan	×	×
	Availability of the product specifications	✓	✓
	Availability of instructions for analysis and testing	×	×
	Availability of inspection plans	✓	×
	Receiving inspection	✓	✓
	In process inspection	✓	✓
	Final inspection and testing	✓	✓
	Recording of the results-certificates of analysis/conformity	✓	✓
	Disposition for release or hold	✓	✓
	Identification of the authority for release of the product	✓	✓
4.11	*Inspection, measuring and test equipment*		
	Availability of procedure for control of test equipment	✓	×
	Verification and protection of the equipment and the appropriate software	×	×
	Definition of the equipment accuracy related to the measurements	×	×
	Selection of suitable measuring equipment	×	×
	Inventory of equipment affecting quality	×	×
	Traceability to recognized standards	×	×
	Availability of a calibration plan	×	×
	Availability of calibration instructions	×	×
	Definition of calibration frequency and acceptance limits	×	×
	Performance of calibration and record	×	×
	Action to be taken when results are unsatisfactory	×	×
	Identification of the validity of equipment	×	×
	Control of the environment and of the equipment used for calibration	×	×
4.12	*Inspection and test status*		
	Methods for the identification of status of conformity or non conformity of the product	✓	✓
	Instructions for release and hold	✓	✓
4.13	*Control of nonconforming product*		
	Availability of procedures for control of non conforming products	✓	✓
	Identification and documentation of non conforming products	✓	✓
	Prevention for further use	✓	✓
	Assessment by an authorized and identified responsibility	×	✓
	Request for waiver (if contractually negotiable)	×	×
	Recovering of the product according to the quality plan	×	×
4.14	*Corrective and Preventive Actions*		
	Availability of procedure	✓	×
	Objective evidence for the closing of nonconformities	✓	×
	Handling of customer complaints	✓	✓

	Treatment of internal nonconformance	✓	✓
	Follow-up of the corrective actions	✓	✓
	Analysis of nonconformance related to the product, process, and system	×	×
	Objective evidence for preventive measures	×	×
4.15	*Handling, Storage, Packaging, Preservation and Delivery*		
	Availability of procedures	✓	×
	Appropriate method for handling products	✓	✓
	Identification of Storage areas	✓	×
	Control of storage process	✓	✓
	Appropriate packaging against stated requirements	✓	✓
	Approval of packaging materials in accordance with the specifications	✓	✓
	Identification and information on packaged product	✓	✓
	Preservation of products during storage	✓	✓
	Inspection of carrier before loading	✓	✓
	Loading under controlled conditions	✓	✓
	Control of the delivery process	✓	✓
4.16	*Quality Records*		
	Availability of procedures	✓	×
	Identification of quality records	×	×
	Definition of retention time	×	×
	Storage of records	×	×
4.17	*Internal Quality Audit*		
	Availability of procedures	✓	×
	Planning of internal audits	×	×
	Execution of internal audits	×	×
	Qualification of the auditors	×	×
	Independent audits	×	×
	Report of internal audits	×	×
	Follow-up of audit results and feedback to management review	×	×
4.18	*Training*		
	Availability of procedures	✓	×
	Identification of training needs	×	×
	Appropriate Training provided to the personnel	✓	✓
	Qualification Identification	×	×
	Availability of records for all kinds of training (including safety and on-job training)	✓	×
4.19	*Servicing*		
	Availability of procedures	✓	✓
	Servicing according to contractual requirements	✓	✓
	Verification of servicing	✓	✓

	Objective evidence in the form records	✓	✓
4.20	*Statistical Techniques*		
	Availability of procedure	✓	×
	Identification of needs for statistical technique	✓	×
	Use of SPC to verify process capability/product characteristics	✓	×

Legends:

D Documentation
I Implementation
✓ Exist up to some extent
× Not existing

APPENDIX E : VORTEX'S PRODUCTS