INFORMATION TO USERS

This manuscript has been reproduced from the microfilm master. UMI films the text directly from the original or copy submitted. Thus, some thesis and dissertation copies are in typewriter face, while others may be from any type of computer printer.

The quality of this reproduction is dependent upon the quality of the copy submitted. Broken or indistinct print, colored or poor quality illustrations and photographs, print bleedthrough, substandard margins, and improper alignment can adversely affect reproduction.

In the unlikely event that the author did not send UMI a complete manuscript and there are missing pages, these will be noted. Also, if unauthorized copyright material had to be removed, a note will indicate the deletion.

Oversize materials (e.g., maps, drawings, charts) are reproduced by sectioning the original, beginning at the upper left-hand corner and continuing from left to right in equal sections with small overlaps. Each original is also photographed in one exposure and is included in reduced form at the back of the book.

Photographs included in the original manuscript have been reproduced xerographically in this copy. Higher quality 6" x 9" black and white photographic prints are available for any photographs or illustrations appearing in this copy for an additional charge. Contact UMI directly to order.

UMI®

Bell & Howell Information and Learning
300 North Zeeb Road, Ann Arbor, MI 48106-1346 USA
800-521-0600

A Dissertation

entitled

ISO 9000 AS A QUALITY ASSURANCE SYSTEM: A THEORETICAL FRAMEWORK

by

Quentin R. Skrabec, Jr.

Submitted as partial fulfillment of the requirements

for the Doctor of Philosophy Degree in

Manufacturing Management

S. Subba Rao

Advisor: S. Subba Rao

T. S. Raghunathan

Advisor: T.S. Ragu-Nathan

Graduate School

The University of Toledo
May 1999

An Abstract of

ISO 9000 AS A QUALITY ASSURANCE SYSTEM:

A THEORETICAL FRAMEWORK

Quentin R. Skrabec, Jr.

Submitted as partial fulfillment of the requirements for the

Doctor of Philosophy Degree in

Manufacturing Management

The University of Toledo

May 1999

ISO 9000 is an international standard for Quality Assurance and is the focus of this research. ISO 9000 defines twenty elements of Quality Assurance and sets minimum requirements for their use. While the ISO 9000 standard has gained international acceptance as a potential specification for a Quality Assurance system, many questions have also arisen. Firstly, how well do the twenty elements of ISO 9000 represent a functional Quality Assurance system. Secondly, does certification to meeting ISO 9000 requirements result in improved performance. This dissertation addresses the underlying theoretical framework for ISO 9000 as a Quality Assurance system and the benefits and performance resulting from ISO 9000.

Two models are developed: 1) to understand the use of ISO elements in a Quality Assurance system, and 2) to study the system effectiveness and performance of such a system. The first model studies the underlying dimensions of a Quality Assurance system, based on the elements of the ISO standard and review of the Quality Assurance literature. The second model compares the effectiveness of such a system and performance results, addressing the research question of the benefits or lack of for ISO 9000 certification.

The methodology used to achieve the research objectives and model development initially included extensive literature review and interviews with manufacturing firms. Based on these initial studies, a questionnaire was developed to explore the importance, nature, interrelationships of the twenty ISO 9000 elements, and benefits of ISO 9000 registration and implementation. Exploratory factor analysis, along with literature review, was used to identify underlying model components or dimensions of an ISO 9000 based Quality Assurance Model. Moreover, structural equation modeling (LISREL) was used to test the hypothesized relationships of model components in an overall Quality Assurance system.

In addition, structural equation modeling was used to study system effectiveness and performance. Finally, contextual variables were studied, using MANOVA.

The use of exploratory factor analysis identified the underlying model components of an ISO 9000 based Quality Assurance system. These components are system management, product design, ancillary services, process quality management, and system effectiveness. Structural equation modeling was used to establish the relationships among these model components.

Furthermore, the research confirmed a positive relationship between effective Quality Assurance system and firm performance, such as increasing market share and improved product quality. The MANOVA results confirmed that small firms achieve greater system effectiveness and better performance results than large firms. Overall, the work presented in this dissertation offers the first empirically based research study of the benefits of an ISO 9000 based Quality Assurance system, as well as the development of a model base for further research. In addition, the model developed offers insights for practioners for ISO 9000 implementation in a company.

DEDICATION

To Our Blessed Mother

Our Lady of Lourdes

ACKNOWLEDGEMENTS

First, I would like to thank Dr. Subba Rao whose vision and expertise in the area of quality management was the inspiration for this research. Dr. T.S. Ragu-Nathan was also instrumental in the modeling and testing of this research as well as review of the text.

Thanks also to committee members, Dr. Robert Bennett and Dr. Bhal Bhatt, who made many helpful suggestions throughout the research. I would like to specifically thank all of the committee members for their reviews and patience in the development of this dissertation.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE

INTRODUCTION

1.1 OVERVIEW

ISO 9000 evolved out of the need to assure a common operating base for the merger of European manufacturing firms into a European Union. In the Baldridge Criteria for TQM, the Quality Assurance subsystem was defined as "Management of Process Quality" or "Process Management" (Category 6). Baldridge's original development of this section was based on the early works on Quality Assurance by Feigenbaum (1983) and Juran (1986). The Quality Assurance section (Category 6), or as it is now called - Process Management - fully reflects the overall evolution of Quality Assurance (Saco, 1997), and the growing acceptance of ISO 9000 as a Quality Assurance standard (Sayle, 1994). The underlying philosophy is that Quality Assurance represents the "core values" of a TQM system (Sayle 1994; Voehl et al, 1994). ISO 9000 is an international Quality Assurance standard aimed at certifying that a company has established a foundation of Quality Assurance principles or "core values".

The ISO 9000 management system has continued its rapid growth worldwide as well as in the United States. This later momentum was motivated because ISO 9000, as a Quality

Assurance program, offers a foundation on which to build TQM on (Voehl et al, 1994; Saco, 1997; Chowdhury and Zimmer, 1996). Yet empirical research has lagged behind, with most research being based on overall TQM systems versus the Quality Assurance subsystem (Sayle, 1994; Mears and Voehl, 1996). It is estimated that 35% of U.S. manufacturing and 40% of western manufacturing will be ISO certified by the year 2000 (Murphy, 1998). The worldwide acceptance and use of ISO 9000 as a core system for Quality Assurance is one reason for this current research into its structure.

Another motivation for this ISO 9000 research is to fully access the benefits of ISO 9000 to manufacturing. Even with the spectacular growth of ISO 9000, a debate has emerged among quality professionals as to the benefits (Zuckerman and Hurwitz, 1996). Furthermore, its relationship to costs and its contribution to an overall TQM effort needs further evaluation.

1.2 ISO 9000 OVERVIEW

Anticipated benefits and customer pressure has brought exponential growth in the number of ISO 9000 certified companies. ISO 9000 is a Quality Assurance standard for process systems in manufacturing and service industries. Actually, 9000 is a generic reference to one of three Quality Assurance systems. Table 1 shows the three Quality Assurance systems and standard system elements that apply. ISO 9001 is the most comprehensive standard and applies to companies

involved in design, manufacture, and servicing. ISO 9001 consists of twenty elements required in a Quality Assurance system. ISO 9002 is a model for manufacturing Quality Assurance, having 18 elements (design and servicing do not apply). The most widely applied standard is 9002. ISO 9003 certifies the inspection system only and has sixteen elements.

The historical roots of ISO 9000 go back to World War II in Britain. England suffered with armament rejection rates as high as forty percent during the early campaigns of the war (Juran, 1995). The war had also created a manpower shortage in manufacturing which limited inspection. The result was the development of BS 5750 which certified the process versus the product, thus improving product quality without massive inspection requirements. After the War, NATO 6, a European version of BS 5750, was applied for NATO purchasing. In the 1970s, EN 29000 evolved, based on NATO 6, in anticipation of the European Economic community. In the 1980s, the ISO 9000 series was published for application throughout Europe. Originally designed to assure economic equality in purchasing quality product throughout the EEC, it presented a potential trade barrier to non-European countries. The internationally based industries, such as chemical, quickly adopted it as a quality standard. Steel, glass, and electrical industries quickly followed.

TABLE 1

STANDARD QUALITY ASSURANCE ELEMENT ARCHITECTURE OF 9001, 9002, AND 9003

	Standard		
Quality Assurance Element	9001	9002	9003
Management Responsibility	x	x	-
Quality System	x	x	x
Contract Review	x	x	x
Design Control	x	-	-
Document and Data Control	x	x	x
Purchasing	x	x	x
Control of Customer Supplied Product	x	x	x
Product Identification and Traceability	x	x	x
Process control	x	x	x
Inspection and Testing	x	x	x
Control of Inspection, Measuring, and Test Equipment	x	x	x
Inspection of Test Status	x	x	x
Control of Non-Conforming Product	x	x	x
Corrective and Preventive Action	x	x	x
Handling, Storage, Delivery	x	x	x
Internal Quality Audits	x	x	x
Quality Records	x	x	x
Training	x	x	x
Servicing	x	-	-
Statistical Techniques	x	x	-

x - Standard System Elements that Apply

Growth slowed in the early 1990s because the Big Three auto manufacturers held to their supplier quality programs versus ISO 9000 such as Ford's Q1, Chrysler's Pentastar, and GMC's Targets. Automotive top management, however, saw major internal cost savings in moving to a third party registration process such as ISO 9000. A joint automotive group of the Big Three was gathered to look at integrating ISO 9000 into their supplier programs. The gap was rather large; ISO 9000 represented a basic Quality Assurance system, while the auto supplier programs represented a broader Total Quality Management (TQM) system (Stamates, 1996). The group used ISO 9000 as a Quality Assurance foundation to build on, similar to the approach of the Baldridge award. QS 9000 was the end result of this building on an ISO 9000 platform.

QS 9000 approaches the broader scope for TQM, but still is not as extensive as the Baldridge criteria. QS 9000 distinguishes itself from ISO in three of the ISO elements - Management Responsibility, Statistical Process Control, and Corrective Action. Management Responsibility in QS 9000 requires the active management of a Total Quality Management system. Management planning is also expanded beyond the base of ISO 9000 requirements. In statistical process control, the requirements move from the ancillary services for customers in ISO 9000 to an active process management system using statistics. Statistical process control is integrated into

the overall TQM system. For example, it uses process capability to make decisions about taking sales orders and inspection.

Finally, QS 9000 allows for customer specific requirements unique to the individual auto manufacturer. Ford, for example, requires the use of Failure Mode and Effect Analysis (FMEA) while GMC uses quality plans for design analysis.

1.3 RESEARCH QUESTIONS

The development of research questions is the basis for good research (Kerlinger, 1986). The rapid growth and use of ISO 9000 in international business leaves some basic questions unanswered. Debate exists in the literature on the nature and benefits of ISO 9000 (Zuckerman and Hurwitz, 1996; Surkovic and Handfield, 1996; Sayle, 1994; Murphy, 1998). These questions are at the heart of this current research on ISO 9000.

a) How do the twenty elements of ISO 9000 form a functioning Quality Assurance System? (Voehl et al, 1994; Surkovic and Handfield, 1996)

b) How are ISO 9000 and Total Quality Management related? (Stamates, 1996; McTeer and Dole, 1995)

c) What are the benefits of ISO 9000? (Sayle, 1994; Murphy, 1998)

d) Does certification improve performance? (Sayle, 1994; Voehl et al, 1994)

e) Are there important contextual variables, such as company size, that affect benefits? (Voehl, et al, 1994).

1.4 ISO 9000 STANDARD ELEMENTS

This section reviews the Quality Assurance requirements as defined by the ISO 9000 standard elements.

1.4.1 **Management Responsibility**

Management responsibility requires that an organization's responsibilities, mission, and business plan are well defined and documented. It also requires that top management review the effectiveness of the Quality Assurance system. Internal audits and corrective action must be reviewed by top management annually as well as customer trends.

1.4.2 **Quality System**

The ISO standard requires a full documented and organized quality system with documented procedures, quality tracking of internal and external trends, and a corrective action system. Like many of the ISO elements, there is a great deal of overlap, in this case with most of the other twenty elements.

1.4.3 Contract Review

ISO requires a formal review of all contracts and feasibility analysis. The manufacturer must understand and document process capabilities.

1.4.4 Design Control

Design Control is for 9001 only. It specifies the need to document design reviews and verifications. It also requires set procedures and documentation for design changes.

1.4.5 Document and Data Control

Document Control specifically requires documentation of operating procedures which impact quality. Furthermore, the element requires document maintenance and control of revisions. An approval system is also required under documentation.

1.4.6 Purchasing

The purchasing element requires that purchasing orders be detailed, reviewed, and approved. An additional requirement is the development of an approved supplier list. Supplier quality must be rated and tracked, and problems addressed.

1.4.7 Control of Customer Supplied Product

This element applies directly to all processing where the product is owned by the

"supplier". The element requires that product identification and traceability be maintained during processing.

1.4.8 Product Identification and Traceability

The element focuses on traceability through the processing, and ultimately, at the customers.

1.4.9 Process Control

This is the broadest of the elements covering the whole process of production. It requires process control steps throughout the production operation. This element also requires a preventive maintenance program.

1.4.10 Inspection and Testing

This element requires a control plan for the necessary inspection in the manufacture of the product. In particular, it requires receiving, in-process, and final inspection.

1.4.11 Control of Inspection Measuring and Test Equipment

This element specifically requires routine maintenance and documentation of test equipment. Calibration records must be maintained and traceable to product lots.

1.4.12 Inspection Test Status

This element requires test traceability of product as well as physical control of non-conforming product.

1.4.13 Control of Non-Conforming Product

ISO requires full control and proper disposition of non-conforming product. Records and documentation are also key to this element.

1.4.14 Corrective and Preventive Action

Corrective action is an overlapping theme in ISO 9000. This element specifies a formal system and documentation of corrective action. In particular, a corrective action form is required.

1.4.15 Handling, Storage, Packaging, and Delivery

This is a very extensive element like process control, but focusing on inventory and shipping. Inventory control, including shelf life control, is required.

1.4.16 Quality Records

This is another overlapping element which ISO spells out as formalization of a system. In particular, this element requires that the length of time records are kept is to be specified and documented.

1.4.17 Internal Quality Audits

ISO requires that a company perform internal audits and issue corrective action based on these system effectiveness reviews. As with all of the twenty elements, there is some interaction and interrelationships. The standard, however, does

not define these clearly as an overall functioning system.

1.4.18 **Training**

The training element focuses on two requirements - a person must be trained on his job and on the overall quality system.

1.4.19 **Servicing**

The element of servicing is only included in ISO 9001, where companies are responsible for contractual service of a product such as equipment or rental units.

1.4.20 **Statistical Techniques**

This element is not an SPC requirement. It requires only trend charting, not the application of SPC in the process. This deficiency was the major reason for the development of QS 9000, to assure SPC applications in the automotive industry.

1.5 ISO CERTIFICATION AND REGISTRATION

ISO Certification is achieved by third party auditors, certifying that the ISO standard is fully implemented and effective. The third party auditors or registars must also be certified by an overseeing body - the Registar Accreditation Board (RAB).

Certification is a statement of compliance to the ISO standard as well as system effectiveness. Certification does

not certify the product, but that the Quality Assurance system exists and is functioning. Performance is not audited. As noted in the research questions, the relationship of system effectiveness to quality performance has not been demonstrated. Furthermore, practioners have voiced serious doubts that certification to ISO 9000 will result in any improvement in quality performance (Stamates, 1996). The next chapter will review the Quality Assurance literature, specifically the elements identified in ISO 9000 as Quality Assurance elements. Additionally, the literature will be surveyed on Quality Assurance's impact on quality performance.

CHAPTER TWO

A REVIEW OF LITERATURE

2.1 INTRODUCTION

This chapter will deal with the concepts that define Quality Assurance via a literature survey. In addition, the relationship between Quality Assurance and TQM will be reviewed. The concept of Quality Assurance has been summarized in recent years into concise definitions such as "the total effort involved in planning, organizing, directing, and controlling quality in a production system, with the objective of producing the consumer with products of appropriate quality" (Evans and Lindsay, 1993). Another concise and widely accepted definition is the "activity of providing the evidence needed to establish confidence, among all concerned, that the quality function is being effectively performed" (Juran and Gryna, 1988). Both definitions focus on the assurance of quality which goes to the historical roots of Quality Assurance in the crafts paradigm. In the crafts paradigm, early Roman legions used a "mark" to represent an assurance of quality (Juran, 1995). This led to the widespread use of craftsmen's marks in medieval Germany and later, most of Western culture. The above two definitions, however, no longer focus on end products as the crafts

paradigm, but on the industrial system which assures product quality via the process.

The two definitions above are similar, but reflect different manufacturing paradigms. The first definition is from the industrial paradigm using Fayol's functions of management (Luthans, 1977). This definition is popular in management textbooks. The second definition represents the post-industrial paradigm where activity is used so that non-traditional approaches to quality management, such as quality circles, can be encompassed or aligned with the Quality Assurance function. The second definition is the official definition of the American Society of Quality and is used in this research.

While both definitions have the same objective of assurance of quality, they are reflective of the long evolution of Quality Assurance. Quality Assurance is a concept that has evolved as manufacturing paradigms also evolved from craft to industrial to post-industrial (Juran, 1995).

2.2 THE EVOLUTION OF QUALITY ASSURANCE

The first concept of Quality Assurance as a function for assuring quality was developed in the crafts paradigm. The crafts and guild system developed process control steps for product manufacture, defined an administrative system, controlled required training, and ultimately, through a mark

or sign, assured product quality. The crafts concept of Quality Assurance included both process and product. The Quality Assurance, under the crafts, was a self controlled feedback system which can be compared to today's systems (Juran, 1995). This system model was developed by Juran, based on biological system models. Juran defines the crafts model for Quality Assurance as self-controlling. Still, the heart of the model might be called workmanship, which remains today the heart of Quality Assurance.

The industrial revolution and mass specialized production eliminated the possibility of a self controlling system. Frederick Taylor pioneered the scientific approach to productivity and manufacturing. During this initial phase of the industrial revolution, productivity had the focus versus quality (Sinha and Willborn, 1985). Effectively, no Quality Assurance system existed as in the crafts paradigm.

The risk of poor workmanship became apparent in the industrial paradigm as we approached the turn of the century. In the 1870s, the United States saw years of scandal in the national press, resulting from questionable Quality Assurance in the steel industry supplying Navy contracts. The resulting government action forced a system of Quality Assurance inspection in most major industries. This era of quality inspection saw the rise of an independent inspection force to assure quality. Initially, the government hired and controlled inspectors. By the 1920s, the inspection

department became an independent group within the manufacturing organization. Table 2 shows the historical evolution of Quality Assurance, in phases, starting after the crafts paradigm.

A third distinct evolutionary phase of Quality Assurance evolved in the late 1920s. This phase stressed statistical quality control. These statistical inspection techniques were attributed to the work of Walter Shewhart (1923), H.F. Dodge, and H.S. Romig (1928). The foundation of their work in such areas as control charting for attributes was the beginning of a scientific approach to basic inspection.

The 1950s saw the rise of a unique development in Quality Assurance. Through techniques such as reliability and maintainability, quality engineering changed the focus from correction (removal of defects) to prevention of defects by prediction (Juran, 1995). This movement in the United States was still product oriented. In this phase, Quality Assurance also moved to upfront product design as a Quality Assurance function. At the end of World War II, Europe, which had a shortage of inspection manpower and an inferior manufacturing system, had turned to a process system focus. This European stream of Quality Assurance would be united to the American experience in the 1990s. However, to a smaller degree, the American approach to Quality Assurance was encompassing the process. American Quality Assurance still focused on product inspection versus Quality Assurance system. The basic

government requirement of MIL-9858A required the existence and verification of a Quality Assurance system. Still, the major focus of the military standards remained on inspection techniques.

In the 1960s, America again was seeing the risk of poor workmanship, even with sophisticated inspection (Juran, 1995). This era saw the rise of motivation programs focusing on the worker. Phil Crosby and A. Feigenbaum (1983) broadened the concept of Quality Assurance to include the involvement of the worker as well as top management. In his book, Total Quality Control, Feigenbaum (1983) expanded the overall domain of Quality Assurance to include: (a) Planning and Control, (b) Quality Control, and (c) Inspection as Subsystems. During this evolutionary phase, Quality Assurance reached its zenith as a quality system for manufacturing and moved into the post industrial manufacturing paradigm. It was also during this phase that the focus and techniques of inspection moved from sorting to diagnostic, or problem solving inspection.

TABLE 2

HISTORICAL EVOLUTION OF QUALITY ASSURANCE							
PARADIGM	**CRAFTS**			**INDUSTRIAL**		**POST-INDUSTRIAL**	
Time Period	Colonial	1850-1880	1880s - 1910	1920s - 1940s	1950s	1960s - 1970s	Present
Organization	Self Controlling	None	Outside Police Force	Independent Force	Specialized QA System	Total Organization	Total Organization
Inspection	Build in	None	Required	Large Requirements for Sorting	Reliability	Motivation of all *Employees*	Everyone's *Responsibility*
Focus	Excellence	Productivity	Productivity	Productivity	Productivity	Quality	Excellence
Techniques	Self Controlling Skill Training	None	Sort Inspection	Statistical Techniques	SPC R & M	TQM Diagnostic Inspection	Customer Driven Manufacture
Standards	Craft Guild Requirements	None	Government Inspection	MIL Standards	Industry Standards	Specific Supplier Ford Q1	ISO 9000 Baldridge
Feedback	Direct	None	Major Disasters	Internal Rejects	Prediction	Customer and Internal	Global including Suppliers
Norm	Crafts Standard or Excellence	None	Avoid Disaster	Compliance to Requirements	Fitness for Use	Customer Satisfaction	Global Standard of Excellence

The final evolutionary phase of post industrial Quality Assurance is its development as a quality subsystem and integration into Total Quality Management systems. In Total Quality Management, Quality Assurance is united with the best philosophical, human resource, and overall management concepts to develop a comprehensive management system. Even though Quality Assurance as a concept has evolved into a subsystem of a broader concept, Quality Assurance has itself continued to improve and evolve. For example, the inspection part of Quality Assurance evolved from 100% sort to a diagnostic role in the feedback loop of Quality Assurance (Ross, 1995). The use of statistics moved beyond statistical product monitoring to process control. Finally, the rapid development of verification audits for the assurance of systems evolved in the 1990s. Furthermore, Quality Assurance systems have expanded also to include supplier control and supplier system verification.

While the interest and research moved from Quality Assurance to TQM in the 1990s, ISO 9000 sparked more interest in Quality Assurance subsystems. Quality Assurance subsystems are viewed as foundational requirements to build TQM systems on. The quality movement of the late 1990s is again focusing on the Quality Assurance subsystem and its integration into the more comprehensive TQM system. The integration of Quality Assurance subsystems into TQM has resulted in changes in the

Quality Assurance subsystem, as seen in the changes in the Baldridge criteria from 1988 to present. Table 2 is an overall summary of the evolution of Quality Assurance as a subsystem of TQM just discussed. Review of this revolution of Quality Assurance leads to a basis for an operational definition of Quality Assurance.

2.3 AN OPERATIONAL DEFINITION OF QUALITY ASSURANCE

The two definitions presented in the beginning of this chapter are constitutional definitions, that is, they define Quality Assurance in terms of other concepts. A constitutional definition's purpose is to improve understanding. For a testable research question, an operational definition is needed (Kerlinger, 1986). An operational definition is developed from the literature in terms of measurable constructs, which leads to a research hypothesis (Kerlinger, 1986).

Table 3 is a typology of key Quality Assurance system components in the literature. In reviewing the literature, several common components can be found - top management support, feedback, system control, product design, process/operations control, and ancillary controls. In addition to these specific components, more recent literature suggests the emergence of Quality Assurance as a TQM subsystem (Flynn et al, 1994; Voehl et al, 1994). Clearly, in the

1990s, research has identified the critical components of Quality Assurance; but there is still a lack of a unified model.

2.4 QUALITY ASSURANCE AND TQM

As noted in the earlier discussion, Quality Assurance is part of the overall Total Quality Management model. The Baldridge Criteria is generally accepted as a model for TQM (Benson et al, 1991; Anderson et al, 1995; Saraph et al, 1989). Figure 1 uses the Baldridge criteria to model the dynamic relationships in the TQM framework (Saco, 1997). Figure 1 shows the seven sections of the Baldridge criteria, five of which are system components - Leadership, Process Quality (QA), Human Resources, Strategic Planning, and Information Analysis. The other two sections - Customer Satisfaction and Operational Results - are performance measures. In the Baldridge model of TQM, the management of process quality is the Quality Assurance component, and is modeled as one part of the Quality System (Saco, 1997). More recently, research on TQM models has distributed Quality Assurance into several factors - Process Management, Product Design, Quality Information, and Supplier Management (Flynn et al, 1994). From a modeling standpoint, Quality Assurance is best presented as a subsystem of TQM (Surkovic and Handfield, 1996; Voehl et al, 1994). Modeling Quality Assurance as a

subsystem of TQM is also consistent with Quality Assurance standards such as ISO 9000 (Schlickman, 1998). Furthermore, treating Quality Assurance as a subsystem of TQM allows for a building of a TQM system in logical implementation steps (Sitkin et al, 1994; Voehl et al, 1994). ISO 9000 is a quality standard, addressing the elements of the TQM subsystem of Quality Assurance.

2.5 ISO 9000 DEVELOPMENT: A SHORT HISTORY

Quality Assurance, unlike the current TQM quality movement, was enforced by material and industry standards in its early phases. It has been shown that the early definition of Quality Assurance was the assurance of product quality (Feigenbaum, 1993; Juran, 1995). The development of these national Quality Assurance standards evolved during World War II from the need to assure quality product to the military. In particular, the original Quality Assurance standard, British BS 5750, recognized a shortage of inspectors and, therefore, focused on the process and system assurance over product inspection. The BS 5750 standard title was "Quality System - a Model for Quality Assurance". Its development was a direct result of a war board of quality and manufacturing managers, in England, to address poor mutions quality. At the same time the United States, not being limited by an inspector shortage, held to principles of mass inspection to achieve the

same end. Even after the development of a national standard for a Quality Assurance system, the United States showed little acceptance for the application. However, the NATO-6 Quality Assurance system standard was rigidly applied in occupied Europe by the United States. The NATO-6 standard did, however, incorporate more of the United States' view of massive inspection. This expansion of BS 5750 into NATO-6 is the historical root of the three inspection elements (Inspection and Test, Inspection Equipment, and Test Status) in the ISO 9000 today.

After the acceptance and application in Europe of NATO-6, a revised standard of EN 29000 evolved, with only minor changes from NATO-6. EN 29000 did accept and adopt a broader role of inspection, in a Europe no longer short of inspection forces. As with the development of BS 5750, EN 29000 was a result of a committee of practicing quality managers. In the initial publication of EN 29000 in the 1960s, the stated philosophy was the <u>minimum Quality Assurance requirement</u> (Juran, 1995). That initial and basic philosophy remains that of ISO 9000 today (Voehl et al, 1994).

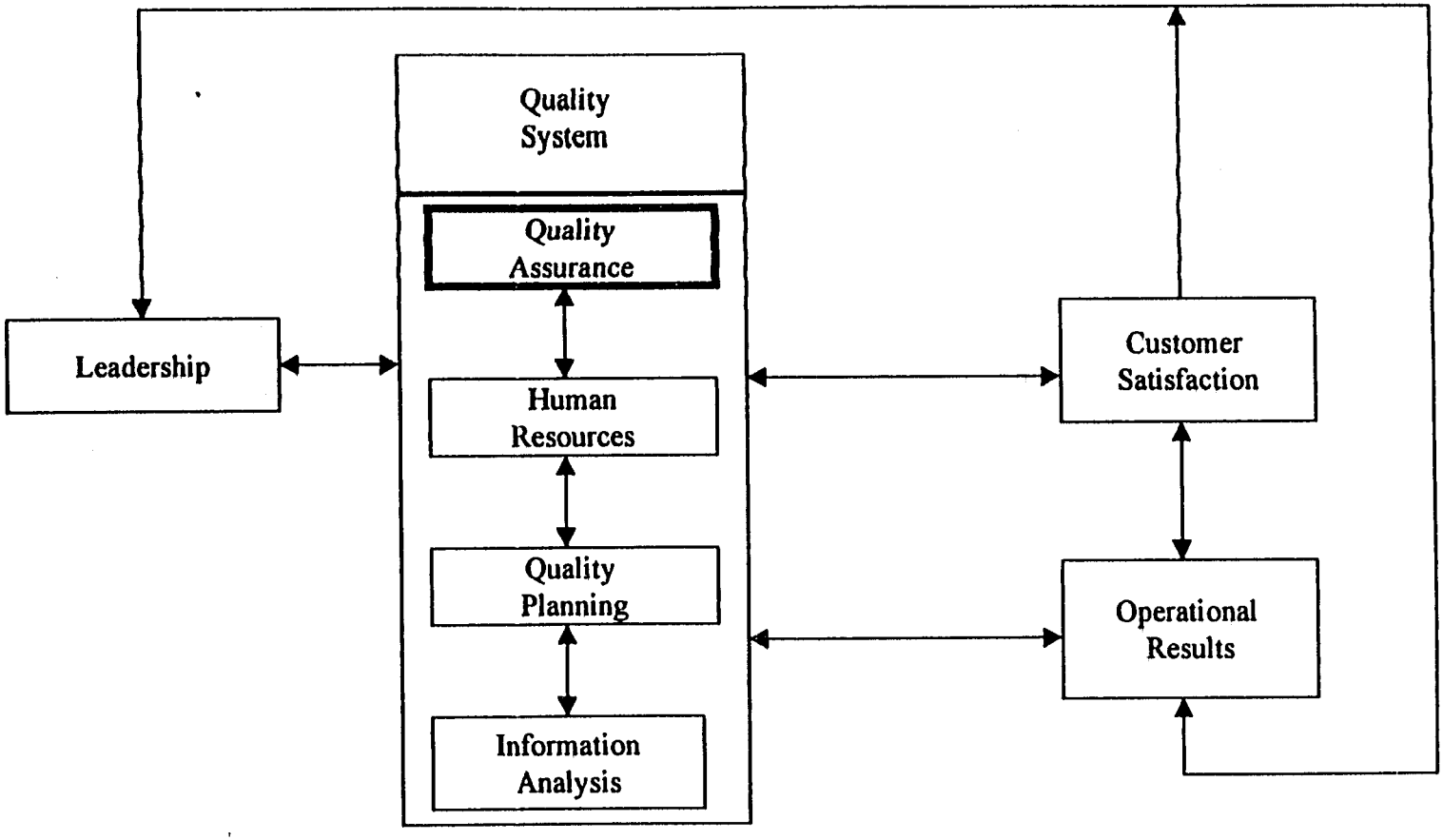
TABLE 3

TYPOLOGY OF QUALITY ASSURANCE CONCEPTS

Source	Process Control	System Control	SPC	Feedback	Support Activities	Planning	Design	Supplier Quality	System Assessment	Inspection Control	Product Development	Records Documentation	Corrective Action
1) Ishikawa	x	x		x			x				x		x
2) Juran	x			x			x	x		x	x		
3) Imai	x	x		x				x					
4) Baldridge 97					x			x					
5) Baldridge 88							x		x	x	x	x	
6) Saco		x		x		x							
7) Voehl et al	x	x	x	x	x	x	x	x	x	x		x	x
8) Flynn et al	x	x	x	x			x				x		x
9) Feigenbaum	x	x	x	x	x	x	x		x	x	x	x	x
10) Sinha & Willborn	x	x	x	x	x	x	x	x	x	x	x	x	x
11) Juran & Gryna	x	x	x	x		x	x	x	x	x	x	x	x
12) Slater	x	x	x	x	x	x		x				x	x
13) ISO 9000	x	x		x	x	x	x	x	x	x		x	x

1) Ishikawa, 1995
2) Juran, 1986
3) Imai, 1986
4) Saco, 1997
5) Saco, 1997
6) Saco, 1997
7) Voehl et al, 1994
8) Flynn et al, 1994
9) Feigenbaum, 1983
10) Sinha & Willborn, 1985
11) Juran & Gryna, 1986
12) Slater, 1991
13) ISO 9000, 1993

x - included



Saco, 1997; Baldridge Award Guidelines

FIGURE 1 TQM MODEL BASED ON BALDRIDGE CRITERIA

In the 1970s, as part of the proposed political alliance of the European community, another committee of quality managers was assembled. The working philosophy was to develop and agree on a minimum Quality Assurance standard that would eliminate any trade restrictions between European countries, based on quality. Since the scope crossed many borders, it evolved into a voluntary international effort of 79 countries. The result was ISO 9000, "A Quality System Model", which clearly incorporated the original guidelines of BS 5750 and EN 29000. The United States also incorporated its own national standard of ANSI/ASQC Q90, which was a copy of BS 5750, but had never gained acceptance in United States manufacturing. The only thing approaching a true national standard in the United States was the heavily focused inspection standards of the United States military. The agreement on an international standard represented a major shift in the United States, from an inspection orientation to a Quality Assurance system orientation.

2.6 LITERATURE SURVEY

The result of the multinational committee on Quality Assurance was a standard (ISO 9000), comprising twenty elements of Quality Assurance. The standard sets minimum requirements in each of the twenty elements. As noted in the research questions, the real issue is whether these twenty elements define a model for Quality Assurance. This

literature survey will address the strengths and weaknesses of the ISO elements, based on the Quality Assurance literature and current research available. In addition, the literature will be reviewed for any proof of that element's impact on quality performance.

The twenty elements of the ISO 9001 standard are:

Management Responsibility

Quality System

Contract Review

Design Control

Document and Data Control

Purchasing

Control of Customer Supplied Product

Product Identification and Traceability

Process Control

Inspection and Testing

Inspection, Measuring, and Test Equipment

Inspection and Test Status

Control of Nonconforming Product

Corrective and Preventive Action

Handling, Storage, and Delivery

Quality Records

Internal Quality Audits

Training

Servicing

Statistical Techniques

The literature survey will look at the following criteria for each element of the standard.

a) What are the strengths and weaknesses for including it in a Quality Assurance model?
b) Is there proof that the element affects quality performance?

Management Responsibility

Most authors recognize management responsibility as a key factor or element in Quality Assurance (Feigenbaum, 1983; Deming, 1982). Many authors believe that management responsibility is the cornerstone of both Quality Assurance and TQM (Heady and Smith, 1995). ISO 9000 defines management responsibility as evidence of a corporate mission, management evolvement in system review, and a clear definition of supporting resources. This definition is characteristic of the minimum philosophy applied by ISO 9000. A more extensive view would include the concept of leadership found in TQM models (Sayle, 1994). Based on the more inclusive view of leadership, there is ample evidence that management has a direct impact on quality performance (Benson et al, 1991; Anderson et al, 1995). Even based on limited management involvement, a number of studies support a positive relationship with quality performance (Ross, 1995).

Quality System

The actual quality system in ISO 9000 should be evidenced by documented procedures, preparation of quality plans, and the existence of a quality manual detailing system design, the key components of this element being documentation of the system and quality planning. Quality planning, in particular, has been addressed as a Quality Assurance function by many authors (Saco, 1997; Schlickman, 1998). The impact of quality planning on quality performance has been well documented (Saraph et al, 1989; Anderson et al, 1989). System documentation is somewhat overlapping and will be addressed in a later element.

Contract Review

The element of contract review is defined in ISO 9000 as the clear definition of customer requirements, review of the supplier's capability to meet these requirements, and documentation. The quality and Quality Assurance literature is thin on this element as a factor in Quality Assurance. More recently, the use of statistics to analyze process capability has been identified as part of TQM (Stamates, 1976; Juran and Gryna, 1986). However, statistical process capability is not a required element in ISO 9000. It is required in the beyond minimum requirements specified for the

automotive industry in QS 9000. The relationship of the ISO elements to quality performance has not been fully explored in the literature. The more advanced TQM literature stream has shown a positive impact of statistical techniques such as process capability (Evans and Lindsay, 1993).

Design Control

Design Control covers product design and customer requirements again. Historically, product design was recognized as a key component of Quality Assurance as early as the 1950s (Feigenbaum, 1983). In addition, many authors have shown the positive relationship between product design and quality performance (Flynn et al, 1995; Garvin, 1987).

Document and Data Control

Document Control is the heart of ISO 9000's Quality Assurance system with particularly strong support from the literature. A number of authors have shown that document control is a fundamental element of Quality Assurance and has a positive relationship to quality performance (Benson et al, 1991; Saraph et al, 1989).

Purchasing

Purchasing, as defined as an element in ISO 9000, includes purchasing product specifications and assessment of supplier's quality system. The functional area of purchasing and its Quality Assurance role has not been studied in the literature. Supplier assessment has received much review in the literature as a positive impact on quality performance and part of an overall quality program (Asanuma, 1989). The extent of development of these supplier programs reviewed in the literature is beyond the minimum requirements of the ISO elements.

Customer Supplied Product

This ISO element is basically a practical specific application of two other Quality Assurance elements - product traceability and documentation. There is no specific literature references other than discussions of the ISO 9000 standard itself.

Product Identification and Traceability

The early literature of Quality Assurance was prolific on this element of ISO 9000 (Juran, 1996). The practioner literature also is highly focused on identification and traceability as a fundamental principle of Quality Assurance (Ross, 1995). Yet, no

studies deal directly with the relationship of this element with quality performance.

Process Control

Process Control is an element of ISO 9000 that deals with production processes that directly affect quality. Three specific areas are covered in the ISO standard: 1) work procedures, 2) process monitoring, and 3) workmanship criteria. These are the basic concepts originally laid out by classical works on Quality Assurance such as Feigenbaum's book - Total Quality Control. It is also consistent with Asian authors such as Ishikawa (1985). Many authors view process control as the management of process quality (Ross, 1995). This element is both fundamental to Quality Assurance as a foundation as well as the broader concept of TQM (Anderson et al, 1995). There is also very strong support in the literature for the positive impact of process control on quality performance (Benson et al, 1991; Flynn et al, 1995).

Inspection Elements

Specifically, ISO 9000 has four elements that deal directly with the whole inspection process from equipment to procedures, as well as control of non conforming products. As discussed earlier, the historical evolution of these elements focuses on inspection efficiency versus

the amount (Mears and Voehl, 1996). While inspection represents a significant emphasis in the ISO 9000 quality model, it is generally overlooked in quality management studies in the literature (Skrabec, 1989). Early Quality Assurance writers did, however, emphasize the importance of inspection and inspection management (Feigenbaum, 1983; Ishikawa, 1974). Still, there are no significant studies on inspection management and quality performance with the exception of statistical techniques. There is, however, a significant amount of anecdotal evidence.

Corrective and Preventive Action

Corrective and preventive action is the key cybernetic component of ISO 9000 which allows for system improvement based on system performance. ISO 9000 does go beyond corrective action and includes "to detect and eliminate potential causes of non conforming product", generally classified as preventive action. Early Quality Assurance definitions by Feigenbaum (1983) and Ishikawa (1974) clearly incorporated both corrective and preventive action in the scope of Quality Assurance. The quality literature, in general, is rich in the incorporation of preventive and corrective action (Juran, 1995). Furthermore, a number of authors have demonstrated a strong correlation between corrective action and quality performance (Imai, 1986; Evans and

Lindsay, 1993; Deming, 1982; Flynn et al, 1994). Historically, ISO's corrective action element was the key component of initial standards such as BS 5750.

Handling, Storage, and Delivery

The three key factors of this ISO element are reflected in the name. Handling, packaging, and storage have been identified by a number of authors as elements in a Quality Assurance system (Garvin, 1987; Sayle, 1994). Somewhat surprising is the emphasis that ISO 9000 puts on delivery performance in a Quality Assurance system. However, strong support for delivery performance of quality systems can be found in the literature (Flynn et al, 1995; Chase et al, 1983). Many authors have demonstrated a very direct relationship between poor delivery and poor quality (Black, 1991; Saco, 1997).

Quality Records

Quality records, while a separate element in ISO 9000, is really an overlap with the documentation element. The same comments covered under documentation also apply here.

Internal Quality Audits

In the early work of Juran (1981) and Feigenbaum (1983), internal quality audits were a critical part of

a Quality Assurance system. In Japanese Quality Assurance systems, we even see functional departments for quality auditing (Ishikawa, 1985; Imai, 1986). Some studies have included the variable of internal auditing as a sub-factor in quality performance studies (Heady and Smith, 1995). There has been no effort to explore a larger role of internal auditing in quality management, Quality Assurance, and quality performance.

Training

Like many of the other ISO elements, training has strong support in the practioner literature for its enclosure in a Quality Assurance system, but lacks formal academic study (Anderson et al, 1995). Training, as part of the larger concept of learning, does have support as a Quality Assurance element that could improve performance (Garvin, 1993; DiBella and Gould, 1995). The general subject of training and TQM has been the focus of a number of anecdotal studies (Takenchi, 1981; Lee et al, 1985; Slater, 1991). In addition, the rich learning literature offers some support for a relationship between quality performance and training (Garvin, 1993).

Servicing

Servicing in ISO 9000 is used in a very limited sense where service is part of sales contract. For

others, servicing must meet requirements. It is clear that ISO 9000 does not recognize the importance of servicing in a manufacturing setting (Chase et al, 1992; Chase and Garvin, 1989). The literature supports a much more important role for servicing than minimum requirements (Stamates, 1996). QS 9000, on the other hand, which approaches a TQM, has a much more expanded role for servicing (Schlickman, 1998).

Statistical Techniques

Statistical techniques in ISO 9000 is a very weak element. Statistical process control is not required. In fact, this element has no specific statement as to what are statistical techniques. Auditors have loosely interpreted it to mean graphical presentation of data (Schlickman, 1998). There are extensive studies on the use of advanced statistics, such as SPC, to improve quality (Mears and Voehl, 1996). The very minimum requirements of ISO 9000 have no support, even in the practioner literature. It would appear that this element contributed little to a Quality Assurance system, as stated as a minimum requirement in ISO 9000. The advanced application of SPC in QS 9000, however, has strong support from a number of authors (Saraph et al, 1989).

2.7 CONCLUSION

The literature survey, in general, gives strong support for the inclusion of ISO elements in a Quality Assurance system with the exception of servicing, customer purchased product, and statistical techniques, which are based on a minimum requirement approach. The link between the ISO elements surveyed and quality performance cannot be assured individually in many cases. This leads to the overall research question as to whether ISO 9000 elements can be implemented as a Quality Assurance system that improves performance. Furthermore, the literature does not develop the system relationships of the various ISO elements, but treats each element as an individual requirement. The next chapter looks at the potential for developing a model for Quality Assurance system from the ISO elements.

CHAPTER THREE

MODEL DEVELOPMENT

3.1 INTRODUCTION

As noted in the literature survey, ISO 9000 and the twenty elements are based on a minimum philosophy of applied Quality Assurance techniques (Schlickman, 1998). The research question becomes whether ISO 9000 offers the interrelationships and coordination between these elements and Quality Assurance requirements, to be used as a system model for Quality Assurance. In this chapter, the ISO elements and Quality Assurance components will be reviewed, and possible relationships will be discussed. Furthermore, support from the literature for various quality components will be developed for the basis of a system model. In particular, potential Quality Assurance system components of feedback, system management, product design, process quality management, and ancillary services will be reviewed. Finally, a Quality Assurance model will be developed from the literature and ISO standard.

Previously in Chapter 2, the literature survey of the ISO elements and their relationship to Quality Assurance systems and quality performance was reviewed. In this chapter, the

Quality Assurance system components are developed from the literature survey. These theoretical system components will make up the framework of the research model. The Quality Assurance components developed from the literature survey are feedback, system management, product design, process quality management, ancillary services, and system effectiveness. The next section reviews the theoretical basis for each of these system components.

3.2 QUALITY ASSURANCE SYSTEM COMPONENTS: THEORETICAL APPROACH

3.2.1 Feedback

Feedback is one of the most commonly identified characteristics of a Quality Assurance system. Control, through the feedback loop, is the oldest process used in managing quality (Juran, 1995). The simplest model for management of quality consists of the following steps:

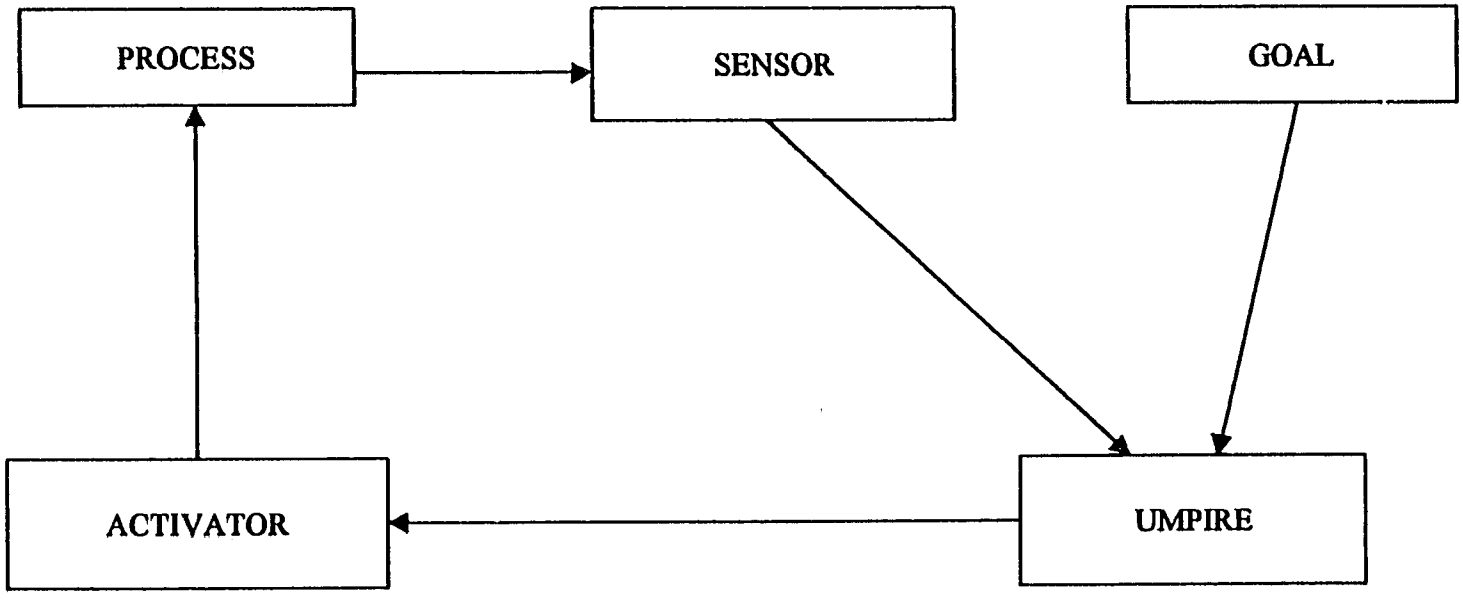
1. Establish a quality goal.
2. Know the actual quality being produced.
3. Keep readjusting the quality based on non-conformance to the goal (Feedback loop).

Juran further states that the industrial revolution destroyed the crafts system and the worker's ability to

know and adjust for the quality level (Juran, 1995).

Establishing a feedback loop is the central issue in implementing a Quality Assurance system (Feigenbaum, 1983; Deming, 1982). The feedback component interacts with all other components of the Quality Assurance system. Feedback, in this respect, is composed of several sub-components such as sensors, umpires, and activators (Figure 2). The sensor monitors quality level; the umpire compares that level to the goal; and the activator sets into action, and adjustment is made to eliminate non-conformance. A Quality Assurance program may have a number of feedback loops (Sinha and Willborn, 1985).

Inspection, for example, may be part of one feedback loop, while suppliers and customers represent other loops. Establishing a feedback loop to inspection moves inspection from a 100% sort function to a diagnostic function (Skrabec, 1994; Slater, 1991). Feedback is, therefore, represented as a connecting line in model components versus a unique component box. Feedback to various Quality Assurance components establishes a cybernetic system which is self correcting.



Juran, 1995

FIGURE 2 THE FEEDBACK LOOP FOR A SYSTEM

Feedback loops are sometimes described in terms of non-system techniques, departments, and management programs. For example, fishboning techniques developed in the 1940s was an effort to establish worker feedback (Ishikawa, 1974). Some functional approaches use organizational components such as customer service, supplier programs, etc. Feedback, however, is much broader and must be integrated throughout the system (Feigenbaum, 1983; Ishikawa, 1974; Imai, 1986; Deming, 1984). Feedback also requires a closed loop system (Slater, 1991). Feedback must cover all employees and be available for use by all employees (Deming, 1984; Juran, 1995). Furthermore, all employees must be active in the feedback loop (Von Hippel, 1978; Day, 1994). Feedback loops can also be viewed as continuous learning (Day, 1994; Garvin, 1993). This makes possible modeling Quality Assurance as a learning model (Anderson, 1995).

ISO addressed feedback in a number of the ISO elements including internal audits, corrective action, and management review. Figure 3 is the proposed model of this research. The next sections show the support of the literature for this model.

3.2.2 Quality Assurance System Management

System Management is a complex component which is related to and/or contains top management support (Ross, 1995; Voehl et al, 1994; Saco, 1997). System management goes beyond the scope of process control in that it is cybernetic in nature. In this respect, the Quality Assurance system is evaluated by management and adjusted based on system effectiveness. Some researchers have viewed this as positive environment to develop continuous improvement (Slater, 1991). Other researchers have viewed it as a leadership role of top management (Saraph et al, 1989; Flynn et al, 1995). Another view is to look at system control as an organizational contextual variable (Benson et al, 1997). Regardless of the view accepted, the responsibility of system management is that of top management.

The key areas of system management include work force management, problem solving, and system assessment. Work force management is defined as enhancing work attitudes to problem solving (Flynn et al, 1995). Training is the key activity required in work force management (Garvin, 1993; Senge, 1990; Mai, 1996). Other authors view training in a much broader scope of a learning environment (Cohen and Levinthal, 1990; Anderson et al, 1995; Deming, 1982). The conclusion is that

system management requires employee training and learning, and the responsibility for this learning environment is clearly that of top management.

Another factor noted in the literature under Quality Assurance system management is corrective action or problem solving. Here we are looking at employee decision making in managing the overall system (Flynn et al, 1994). The efficiency of problem solving or corrective action, is related to the strength of positive employee relations (Flynn et al, 1995; Anderson et al, 1995). The component of system management is linked to feedback from the customer, process, and suppliers. It is this problem solving activity, under system management, that is part of the cybernetic feedback loop (Evans and Lindsay, 1993; Imai, 1986). Top management, by means of system management via feedback on system effectiveness, keeps the overall organization focused on continuous improvement (Imai, 1986; Chase et al, 1992; Chase and Tansik, 1983). It is this problem solving activity in system management, where the feedback information is plugged into, to improve the overall system. In basic models of Quality Assurance such as ISO 9000, this factor embodies all corrective actions (Ross, 1995).

Another key factor under Quality Assurance system management is system assessment or internal quality

audits. Internal audits are necessary for upper management to evaluate the efficiency of the system (Feigenbaum 1983; Voehl et al, 1994; Juran and Gryna, 1986). Internal audits give management a systematic and independent look at system effectiveness (Sinha and Willborn, 1985; Ross, 1995). In this respect, internal audits are similar to other system control functions such as problem solving and corrective action. ISO 9000 embodies these system management functions under the elements of corrective action, internal uqality auditing, and training.

3.2.3 Product Design

As seen, Quality Assurance started as an inspection system and evolved into a broader scope. Initially, therefore, product design was not included in the field of Quality Assurance (Feigenbaum, 1983). However, by the 1960s, people were becoming aware that the most likely source of product failure was in the design of product (Juran and Gryna, 1986). Product design may be the key measure of quality based on Garvin's (1987) eight dimensions of quality. Product design is a broader concept than Quality Assurance; it can only be fully integrated under the full concept of TQM (Ross, 1995; Flynn et al, 1994). Still, some basic components of

product design make up part of Quality Assurance. These basic Quality Assurance practices are reliability engineering and manufacturability. Manufacturability starts with a simple review of the customer requirements and the manufacturer's capability to meet these requirements (Feigenbaum, 1983; Evans and Lindsay, 1993). This phase of contract review is embodied in the ISO 9000 Quality Assurance elements as well (Voehl et al, 1994).

A more far reaching Quality Assurance component of design is reliability engineering. This particular component is of importance to equipment manufacturers versus parts manufacturers. Reliability engineering focuses on lower failure rates over time through improved design (Juran and Gryna, 1986). It is directly related to four of Garvin's (1987) eight quality dimensions. It is addressed in the Design Control element of ISO 9000.

3.2.4 Process Quality Management

Process Quality Management is a widely accepted factor in TQM (Flynn et al, 1994; Anderson et al, 1995). It is also well defined in the Quality Assurance literature (Sinha and Willborn, 1985). The views, however, do differ in the TQM and Quality Assurance approach. In general, TQM is the broader approach including statistical process control, preventive

maintenance, and overall operations (Flynn et al, 1994; Heady and Smith, 1995). Another difference is the lack of emphasis of inspection in TQM literature (Heady and Smith, 1995), while inspection and quality control are key factors in the Quality Assurance literature (Ross, 1995; Feigenbaum, 1983).

As noted, a key factor in Quality Assurance that is lacking in the TQM literature is the area of inspection. Part of this discrepancy is a misinterpretation of Deming, that TQM eliminates the need for inspection (Slater, 1991). The Quality Assurance view is that inspection remains, but more diagnostic in nature (Skrabec, 1994). Inspection covers three of the twenty sections of ISO 9000 which demonstrates its central role in Quality Assurance. The corrective and preventive action element of ISO defines the diagnostic role of inspection. Furthermore, the importance of inspection in assuring acceptable product and customer satisfaction has been demonstrated by a number of authors (Evans and Lindsay, 1993; Ross, 1995). In addition, recent TQM studies are supporting the underlying role of inspection in an overall TQM model (Anderson et al, 1995). The problem again is related to 100% sort inspection versus diagnostic inspection or statistical inspection. The 100% sort inspection lacks a corrective action loop and, therefore, falls short of the continuous improvement

objective of TQM (Slater, 1991; Evans and Lindsay, 1993; Skrabec, 1994). Still, inspection in any form is consistent with the basic Quality Assurance subsystem (Sinha and Willborn, 1985; Juran and Gryna, 1986).

Process Quality control is another factor under process quality management. The Quality Assurance literature combines manufacturing management, preventive maintenance, documentation, and supplier management under process quality management (Juran and Gryna, 1986; Feigenbaum, 1983). In the TQM literature, supplier programs take on a broader scope, becoming a separate factor under TQM (Flynn et al, 1994; Kalwani and Narayandas, 1995). One difference between the TQM approach and Quality Assurance approach to supplier management is that TQM focuses on relationships, while Quality Assurance focuses on incoming product quality. In ISO 9000, supplier management includes process certification as well as product inspection. Incoming product inspection is covered under the overall ISO element for inspection (4.10), as well as related elements such as non-conforming product (4.13).

Another aspect of process quality management, particularly under the TQM models, is that of statistical process control (Flynn et al, 1995). Statistical process control, in this context, is preventive in nature. Earlier Quality Assurance models do not include

statistical control but do emphasize the use of basic statistics.

Finally, process quality management contains the aspect of documentation such as standard operating procedures. This, to a large degree, is the heart of Quality Assurance and is reflected in international standards such as ISO 9000. Also, documentation has been identified as a foundation required for TQM (Flynn et al, 1995; Slater, 1991). A number of studies have shown that documentation of quality information and process standards leads to improved quality performance (Tokeuchi and Queich, 1983).

3.2.5 Ancillary Services

In TQM models, as noted, statistical process control (SPC) is a major factor (Flynn et al, 1995; Larson and Sinha, 1995; Evans and Lindsay, 1993). In Quality Assurance models, the role of SPC is less developed and can be considered as ancillary customer services (Sinha and Willborn, 1985). In many cases, statistical control is a customer requirement. While SPC is clearly helpful to a Quality Assurance program, it is not a necessary requirement. In basic Quality Assurance standards such as ISO 9000, we see minimal statistical use; while in the broader QS 9000 which is a TQM model, we see many SPC

requirements (Ross, 1995). Furthermore, in basic Quality Assurance, the use of statistics is more focused on inspection techniques versus preventive control (Evans and Lindsay, 1993).

In general, statistical techniques in the Quality Assurance model can be considered ancillary because it is a customer reporting requirement versus a preventive program. Other ancillary requirements are sometimes required by customers. This may be particularly true if the manufacturer functions as a toll processor, where the Quality Assurance requirements are set by the contractor. Additional ancillary services can be supplier programs and/or external standards such as military standards.

3.2.6 Quality Assurance System Effectiveness

System effectiveness is the measure to which a Quality Assurance system develops competitive capabilities (Nakane, 1990; Noble, 1994). These capabilities are, at times, a complex set of goals and/or measures of progress (Ross, 1995; Porter, 1985). A number of models have been proposed for measuring manufacturing capabilities. These models include the following potential factors of cost, flexibility, quality, delivery, and innovation (Ferdows and DeMeyer, 1990; Nakane, 1990). In particular, quality, cost,

flexibility, and delivery can be measured overall as production or manufacturing efficiency (Porter, 1985; Lewin and Minton, 1986; Nagal and Bhargava, 1991).

Innovation has more recently been viewed as a unique manufacturing system capability related to knowledge (DiBella and Gould, 1995; Nunaka and Takenchi, 1995). Innovation, knowledge, and learning are considered by many authors to be a critical manufacturing capability (Sitken et al, 1994; Day, 1994; Sohal and Morrison, 1995). A Quality Assurance system, to be effective, must promote employee learning and problem solving (Takenchi, 1981; Feigenbaum, 1983, Evans and Lindsey, 1993). Some authors believe the learning is a measure of a Quality Assurance system (Anderson et al, 1995). Juran (1995) clearly demonstrated the use of learning in the ability of a craftsman to improve product quality. In manufacturing, systems learning is part of system effectiveness and is needed to establish Quality Assurance (Ross, 1995).

The measure of system effectiveness does present research problems. System effectiveness is not actual performance numbers but capability (Kuei and Modu, 1995; Porter, 1985; Saco, 1997). ISO 9000 evaluates system effectiveness by certification audits of the system. Ultimately, high system effectiveness leads to improvement in actual performance (Kaplan and Norton,

1992; Lewin and Minton, 1986). Another practical reason in research to measure system effectiveness as well as performance is the fact that performance numbers often lag improvements. A major reason for this is actual inventory issues in manufacturing; that is, a current month's shipment may include previous month's production. Feedback, in particular, must be based on current system effectiveness (Juran, 1995) to assure quality. To be successful, the manufacturing system must approach the immediate product quality feedback of the crafts system. Ross (1995) notes that "the control component (Quality Assurance) has moved from measuring output (traditional control system) to controlling the continuous improvement of the process". This approach is consistent with the evolution of Quality Assurance, moving from the inspection of output as feedback to the process for feedback. The use of system effectiveness, as feedback for controlling continuous improvement versus inspection of product alone, is a faster cybernetic signal for the overall system. This new emphasis is the basis for international Quality Assurance standards such as ISO 9000 which audit system effectiveness (Mears and Voehl, 1996).

3.3 ISO ELEMENTS AND QUALITY ASSURANCE SYSTEM COMPONENTS

Table 4 is a qualitative summary and typology of the literature review. Table 4 summarizes the previous literature review section and estimates the strength of the relationship based on the literature survey. System Management is the component that embodies top management's decision making, leadership, and system feedback actions. This component is highly aligned with ISO elements: training, management responsibility, corrective action, and internal audits.

The Process Quality Management component of the Quality Assurance model deals directly with operational factors in Quality Assurance management. This component is highly aligned with three ISO elements dealing with inspection as well as elements of process control, control of non-conforming product, product ID, and document control.

The Ancillary Services component, as discussed, relates to customer required documentation or process control. The ISO elements related to ancillary services are SPC, servicing, and control supplier product.

The Product Design component of the Quality Assurance model deals with the translation of customer requirements into a product. Besides the product design ISO element, ISO's contract review is also related because, during this procedure, design changes, modification, and new requirements are addressed.

TABLE 4

THE EXTENT TO WHICH ISO 9000 ELEMENTS ALIGN WITH QUALITY ASSURANCE COMPONENTS					
ISO Elements	System Management	Ancillary Services	Process Quality Management	Product Design	Feedback
Mgt Responsibility	H	S		H	
Quality System	H				H
Contract Review	S			H	
Design	S		S	H	H
Document and Data Control	S		H		S
Purchasing	S		H		
Customer Supplied Product		H			
Product ID	S				S
Process	S		H		H
Inspection and Testing			H		
Inspection Equipment			H		
Inspection Status			H		H
Control of Non Conforming Product	S	S	H		H
Corrective Action	H	S	S		
Handling, Delivery, Storage		S	S		
Quality Records		S	S	S	H
Internal Quality Audits	H		S		H
Training	H				
Servicing		H		S	
Statistical Techniques		H	S		

H - Highly Aligned
S - Somewhat Aligned

3.4 QUALITY ASSURANCE SYSTEM COMPONENT DEFINITIONS

A. **Quality Assurance System Management** is the management of all activities related to providing evidence needed to establish confidence, among all concerned, in the Quality Assurance function.

B. **Process Quality Management** is management of those activities directly related to the production, testing, and shipping of quality products and services.

C. **Ancillary Services** are those services and/or requirements specified by customers as needed evidence of product and/or service quality.

D. **Product Design** are the activities related to the design of product or the transformation of specified customer requirements into a usable product.

E. **System Effectiveness** is the system measures related to the functioning of the Quality Assurance system.

3.5 PROPOSED ISO QUALITY ASSURANCE SYSTEM MODEL

As noted earlier, research based Quality Assurance models

are lacking in the literature. The literature is rich in typology of components and essential elements of Quality Assurance which have been reviewed. Several clearly identifiable components of Quality Assurance arise from such a review: system control, process quality management, ancillary services, product design, system effectiveness, feedback loops, and performance measures.

Figure 3 is the proposed Quality Assurance model. System management is the top management component that drives the overall model. System management also functions as a cybernetic component, reacting to a feedback loop from system effectiveness monitoring such as internal audits. The position of the feedback loop from system control and system effectiveness has been demonstrated by a number of authors (Garvin, 1993; Benson et al, 1991; Chase and Tansik, 1983). It also fits the historical evolution of Quality Assurance from the crafts paradigm (Juran, 1995). System control is the function that manages operations control, ancillary services, and product design. In turn, both ancillary services (customer required) and product design are input factors in operations control. It is the process quality management that directly affects system effectiveness. From this aspect, process quality management is the central core of the model. System effectiveness then directly affects both internal and external performance measures.

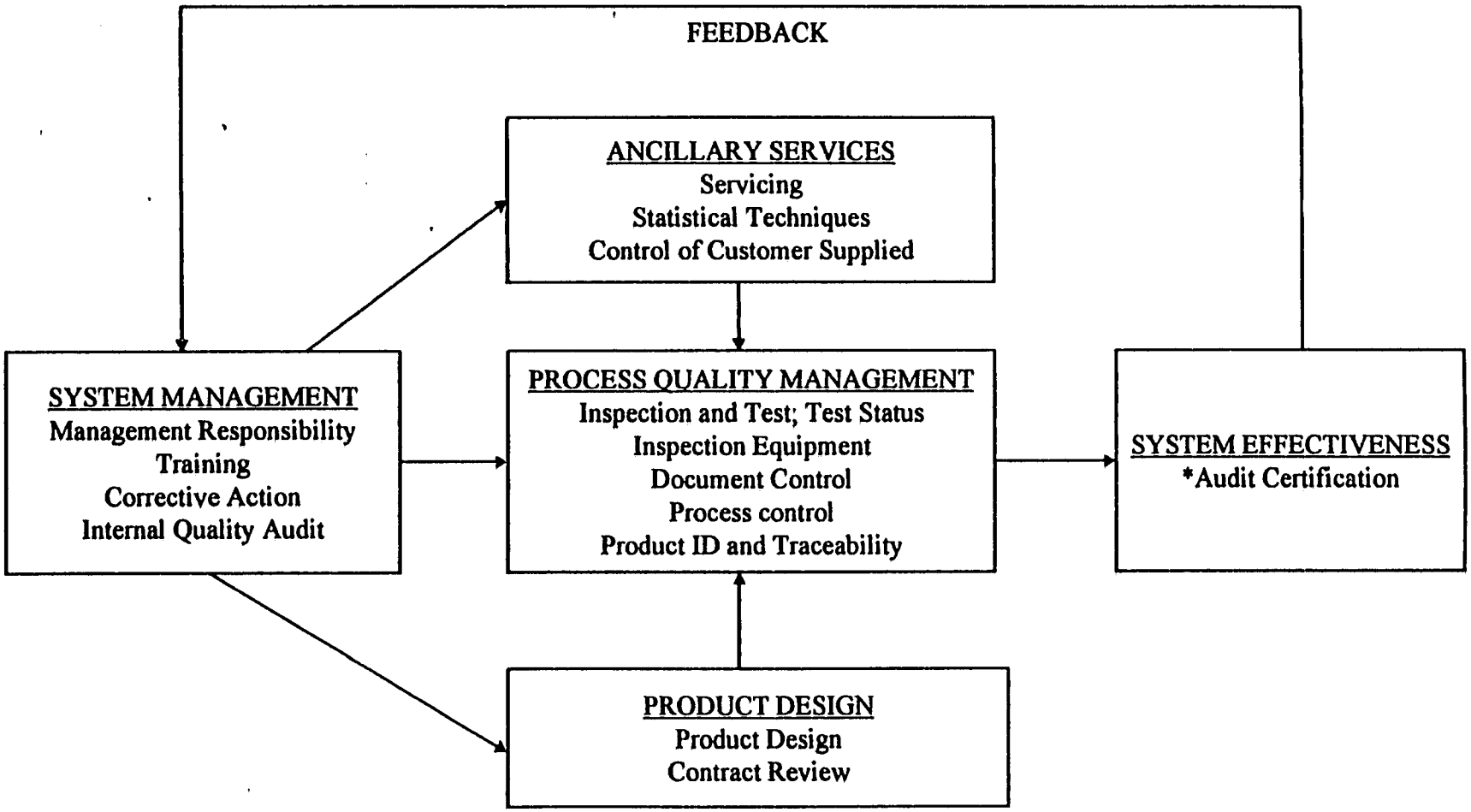


FIGURE 3 ISO ELEMENTS IN THE QUALITY ASSURANCE SYSTEM MODEL

3.6 PERFORMANCE MEASUREMENTS FOR A QUALITY ASSURANCE SYSTEM

The proposed Quality Assurance model is a cybernetic system, that is, the system is adjusted based on feedback about the principal functioning or effectiveness of the system. The main tool used in ISO 9000 to assure cybernetic feedback is that of internal auditing. Internal quality auditing measures system effectiveness (McTeer and Dole, 1995; Mears and Voehl, 1998). In fact, the ISO registration process and certification audit is only a measure of system effectiveness (Zuckerman and Hurwitz, 1996). The critical research question remains on how system effectiveness relates to product performance. Asked another way, does the implementation of an ISO 9000 Quality Assurance system relate to improved performance of the product? Of course on a practical level, it must be assumed that a Quality Assurance system fully implemented should lead to improved performance. More recently, a number of authors have questioned whether an ISO 9000 based Quality Assurance system does actually improve performance (Sayle, 1994; Murphy, 1998; Lamprecht, 1994; Larson and Sinka, 1995).

The first step in evaluating performance is to identify what performance measures should be used. For this, the literature review looked at internal measures such as scrap, and external measures such as customer rejection.

As noted, system effectiveness is antecedent to internal and external performance measures. Ultimately, system effectiveness improvements must lead to quality improvements. The best quantitative measures of quality improvement are linked to manufacturing performance and the bottom line (Kaplan and Norton, 1992). A number of quality performance measures have been suggested but few common factors have emerged. Some notable exceptions are waste reduction, market share, and productivity measures (Saco, 1997; Sayle, 1994; Ross, 1995). Two broad categories of quality performance measures are internal and external (Noble, 1995; Shores, 1990). Internal relates to manufacturing floor measures such as scrap rate, while external relates to customer performance such as market gain. To fully capture quality performance requires external as well as internal measures. While both internal and external performance measures are outcomes of Quality Assurance, there are some distinctions. Internal measures are more reflective of Quality Assurance systems (Feigenbaum 1983), while external measures reflect both Quality Assurance and TQM. Furthermore, improvements in internal measures such as scrap ultimately are reflected in improvements in external measures (Kaplan and Norton, 1992). Table 5 is an overall summary of performance measures in both the Quality Assurance and TQM literature. Table 5 shows the alignment of this performance measure with various quality assurance components.

TABLE 5

ALIGNMENT AND TYPOLOGY OF QUALITY ASSURANCE COMPONENTS WITH QUALITY PERFORMANCE

	QUALITY ASSURANCE COMPONENTS				
Quality Performance Components	System Management	Process Quality Management	Ancillary Services	Product Design	Feedback
Scrap Rate	M (5)	H (1),(4)	M (2),(10)	H (2),(12)	H (3)
Customer Rejection	H (5)	H (6)	H (4),(10)	H (7),(12)	H (1),(3)
Rework	M	H (3)		H (5),(12)	H (5)
Market Share	H (9)		H (9),(2),(10)	H (9),(2)	H (9),(10)
Delivery Time	H (11)	M (11)	H (7)	H (11)	H (11)

(1) Leong et al, 1990
(2) Bonaccossi and Lipparini, 1994
(3) Imai, 1986
(4) Kaiwani and Narayandas, 1995
(5) Kaplan and Norton, 1992
(6) Heady and Smith, 1995
(7) Nagal and Bhargava, 1991
(8) Noble, 1995
(9) Day, 1994
(10) Chase and Garvin, 1989
(11) Flynn et al, 1995
(12) Von Hippel, 1978

H - High
M - Medium
L - Low

3.7 INTERNAL QUALITY PERFORMANCE MEASURES

As noted, internal measures are related to the manufacturing operation. In the broader TQM model (Figure 1), internal measures are defined as operational results. The most commonly used internal performance measure is scrap rate or rejection rate. Scrap rate is a direct measure of factory performance and is a result of system effectiveness (Juran, 1995). Scrap rate, however, in one sense, is a limited measure. For example, companies which do rework can substantially reduce their scrap rate performance, possibly overestimating quality performance if percent rework is not also included. This is why TQM researchers have favored percent rework as an overall measure (Flynn et al, 1995). Another suggested measure of internal performance which directly reflects the effectiveness of the Quality Assurance system is customer returns or claims (Heady and Smith, 1995). For example, if the Quality Assurance system is not effective, one might expect rejects to get to the customer (Chase and Garvin, 1989).

3.8 EXTERNAL QUALITY PERFORMANCE MEASURES

External measures deal directly with customer satisfaction. A direct external measure of quality is market share (Kaplan and Norton, 1995). Market share can reflect other non-quality factors which is a weakness (Von Hippel,

1986). Another suggested external quality measure is delivery performance (Flynn et al, 1995; Larson and Sinka, 1995). Delivery performance does highlight the potential relationship with internal measures. For example, high rework rates, high scrap rates result in increases in throughput time, thus impacting delivery (Shores, 1990; Chase and Garvin, 1989). Finally, some authors have suggested that gains or losses in market share is a strong reflection of customer satisfaction and external performance (Chase et al, 1983; Whybark, 1994).

3.9 PERFORMANCE MEASUREMENT MODEL

System effectiveness is the actual perception component of the ISO Quality Assurance model. Via internal audits and external audits, system effectiveness is evaluated for management review. System effectiveness, as reviewed in the literature, should have a direct relationship to both internal and external quality performance. Furthermore, internal quality performance such as rejection rate, rework rate, and customer returns have a direct impact on external quality performance such as delivery and market share. Figure 4 is the proposed model to measure the impact of system effectiveness on quality performance. This model deals directly with the research question of, does ISO 9000 certification lead to improved performance? Figure 4 is the proposed performance measure model.

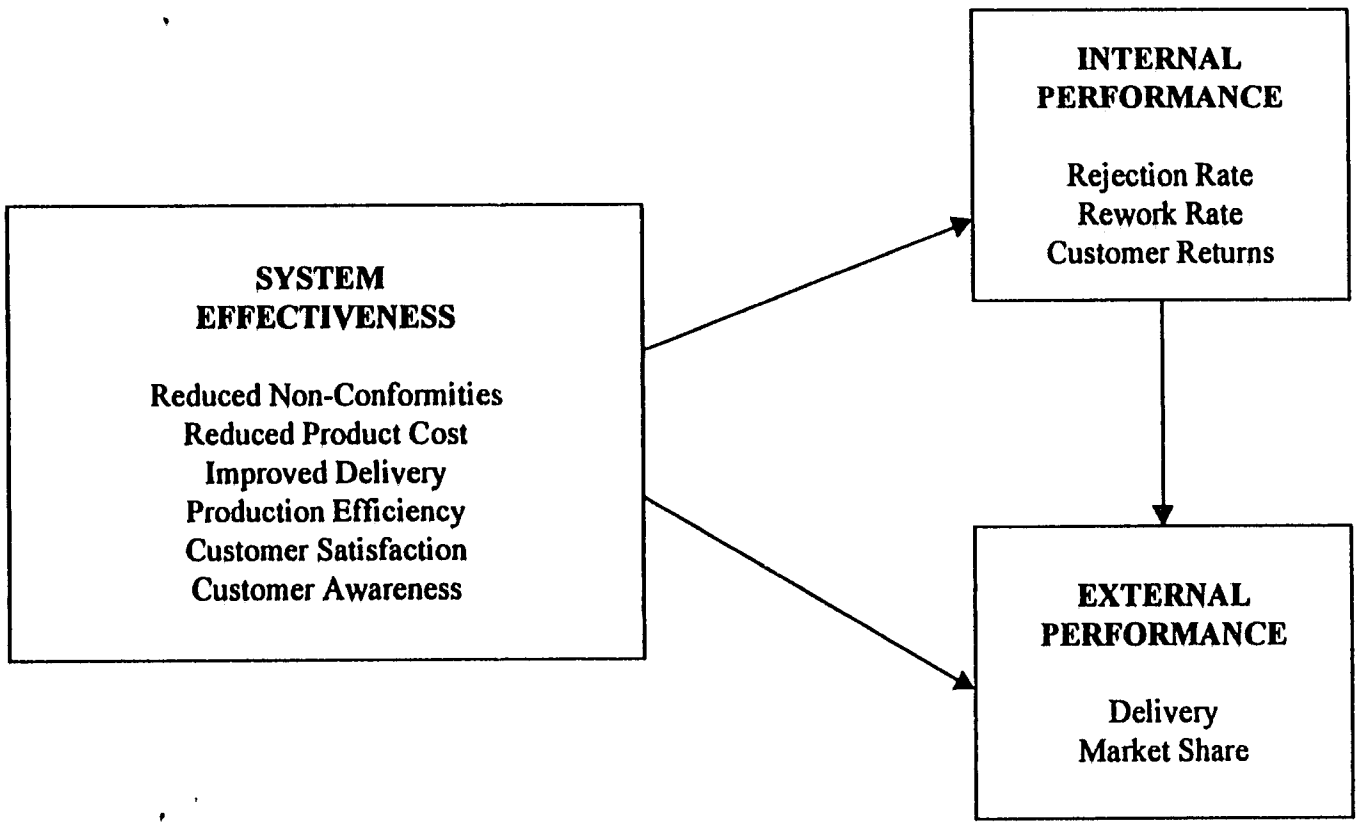


FIGURE 4 PERFORMANCE MODEL OF
SYSTEM EFFECTIVENESS MEASURES AND QUALITY PERFORMANCE

CHAPTER FOUR

HYPOTHESES

4.1 INTRODUCTION

One issue identified with ISO 9000 as a model for Quality Assurance is that it does not address the coordination and interrelationships of the twenty elements (Zuckerman and Hurwitz, 1996; Stamates, 1996). In Chapter 3, a theoretical model for Quality Assurance was developed. The Quality Assurance model is based on the literature review and the Quality Assurance elements defined in the ISO standard. Hypotheses are developed in this chapter to test the proposed Quality Assurance model as shown in Figure 5.

Another issue discussed in respect to ISO 9000 was that performance is not measured in certification to the standard. In Chapter 3, an overall model was developed to study the relationship of the Quality Assurance system to actual quality performance. Figure 6 is this overall performance model and the appropriate hypotheses developed in this chapter.

The hypothesis developed will be in presented null form.

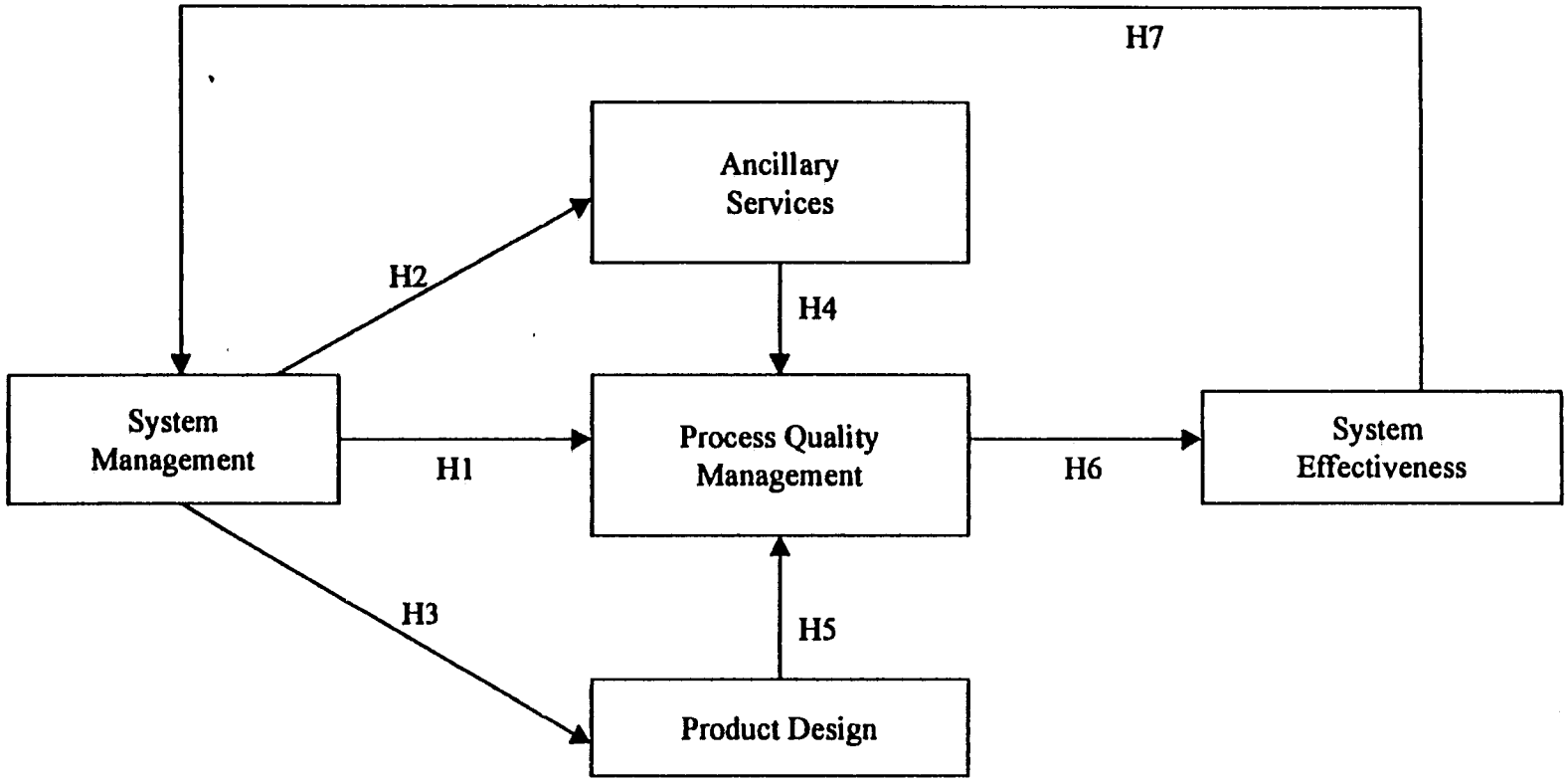


FIGURE 5 ISO QA SYSTEM MODEL

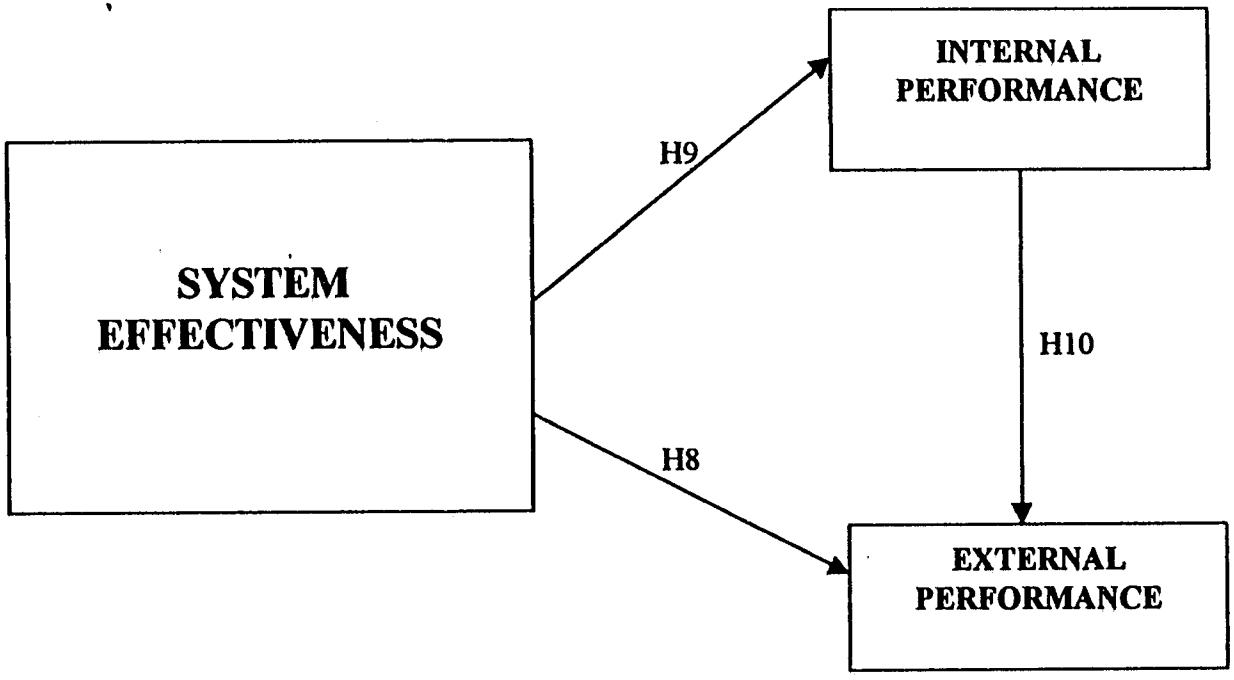


FIGURE 6 PERFORMANCE MODEL OF
SYSTEM EFFECTIVENESS MEASURES AND QUALITY PERFORMANCE

4.2 NULL HYPOTHESES FOR QUALITY ASSURANCE SYSTEM MODEL

H1: There is no relationship between system management and process quality management.

Quality Assurance system management is the driving force to the cybernetic nature of the Quality Assurance. System management consists of system review and improvement (Surkovic and Handfield, 1996). The literature suggests a relationship of system management with the process quality management (Sayle, 1994). The process quality management deals directly with elements of Quality Assurance such as inspection and test, process control, and purchasing. Since this aspect of process quality is the operating core of a Quality Assurance system, system review and continuous improvement functions of the system management are directly related to the smooth operation of process quality management. Furthermore, system management distributes resources which are essential to the proper functioning of process quality management. The literature supports rejecting the null hypothesis and accepting the alternate hypothesis, that system management is antecedent to process quality management.

H2: There is no relationship between system management and ancillary services.

Ancillary services, as previously discussed, are customer driven requirements such as statistical process control data and product records (Stamates, 1996). The relationship with system management arises from the review and identification of customer services needed, as well as cybernetic feedback from the customer (Voehl et al, 1994). In some cases, the amount and extent of ancillary services required is a direct reflection of the functioning of the overall Quality Assurance system (Surkovic and Handfield, 1996). Furthermore, the definition of customer requirements and its application as an ancillary service is the direct result of the system management component reviewing contract and customer needs (Stamates, 1996). The literature supports rejecting the null hypothesis and accepting the alternative hypothesis, that system management is antecedent to ancillary services.

H3: There is no relationship between system management and product design.

Product Design has a very large scope in ISO 9000. In particular, manufacturing reviews of contracts for customers are considered part of product design (Sayle, 1994). Product Design review is a necessary responsibility of system management (Stamates, 1996). As with ancillary services, product design is related to the overall cybernetic control of the Quality Assurance system. The literature supports

rejecting the null hypothesis and accepting the alternative hypothesis, that system management is antecedent to product design.

H4: There is no relationship between ancillary services and process quality management.

Ancillary services are the customer requirements for processing and documentation. In many cases, process control charts and flow charts are part of the necessary documentation to define process control steps needed for quality. These customer requirements become the major guidance to process quality management (Schlickman, 1998). To a large degree, the role of process quality management is defined and simplified by the required process requirements and documentation (Sayle, 1996) on these specific products. The movement is clearly increasing that customer requirements for processing are clearly defined in the initial contract (Saco, 1997). Once these ancillary service requirements are defined and agreed to, then they must be monitored as part of process quality management. The literature supports the null hypothesis and accepting the alternative hypothesis, that ancillary services are antecedent to process quality management.

H5: There is no relationship between product design and process quality management.

As discussed earlier, product design includes the activity of contract review and setting manufacturing standards based on customer requirements (Ross, 1995). Many authors have recognized the importance of product design to manufacturability and process quality (Saraph et al, 1989; Flynn et al, 1994). Early Quality Assurance authors, as well, have emphasized the relationship of product design and the ability to achieve product quality during processing (Feigenbaum, 1983). The literature supports rejecting the null hypothesis and accepting the alternative hypothesis, that product design is antecedent to quality management.

H6: There is no relationship between process quality management and system effectiveness.

System effectiveness is the perception of benefits devised from the implementation and functioning of the Quality Assurance system. Process quality management is the core of the overall Quality Assurance system dealing with elements of inspection and process control. Any breakdown of the process quality management would have a direct impact on system effectiveness (Flynn et al, 1990). Other authors have demonstrated the strong positive relationship between process

quality management and system effectiveness (Benson et al, 1991; Anderson et al, 1995). This relationship is supported in both the Quality Assurance literature and the TQM literature. This literature supports rejecting the null and accepting the alternative hypothesis, that process quality management is antecedent to system effectiveness.

H7: There is no relationship between system effectiveness and system management.

Hypothesis 7 represents the feedback loop inherent to the Quality Assurance model. Key factors in the Quality Assurance system management are management review and internal audits. Both these Quality Assurance management factors allow for evaluation of system effectiveness. System management uses the Quality Assurance tool of internal auditing. The evaluation of the system effectiveness is a basis for management action to correct and/or improve on the Quality Assurance system. This cybernetic feedback is the key to the Quality Assurance system (Lamprecht, 1994). In one view, this hypothesis is a micro approach to certification, requiring system effectiveness to be documented and proven by management (MacLean, 1993). In particular, auditing is considered a primary management tool to evaluate system effectiveness (Imai, 1986; Ishikawa, 1985). The literature supports rejecting the null and accepting the alternative hypothesis, that system effectiveness is antecedent to system management.

4.3 NULL HYPOTHESES FOR QUALITY ASSURANCE PERFORMANCE MODEL

H8: There is no relationship between system effectiveness and external performance.

Figure 6 is the model for the quality performance model. This relationship has some support in the literature (Ross, 1995; Saco, 1997). Some authors view this relationship as fundamental to competitive advantage (Porter, 1985; Peters, 1988). Again, early Quality Assurance designers justified Quality Assurance on its ability to improve both internal and external performance (Feigenbaum, 1983). Since system effectiveness is measured by ISO certification, many authors suggest that ISO implementation can be expected to improve both internal and external performance (Schlickman, 1998; Sayle, 1994). The literature supports rejecting the null hypothesis and accepting the alternative hypothesis, that system effectiveness is antecedent to external performance.

H9: There is no relationship between system effectiveness and internal performance.

Hypothesis 9 deals with the performance model prepared in Figure 6. Once an effective Quality Assurance system is in place as verified by ISO certification, then internal quality

performance is expected to improve. Internal performance is measured by such indicators as rejection rate. The literature does suggest a relationship between system effectiveness and internal performance (Surkovic and Handfield, 1996). Many authors have suggested that there is a strong relationship between system effectiveness and internal scrap rate (Kaplan and Norton, 1992). Customer product rejection rate is also related to system effectiveness (Imai, 1986). The literature supports rejecting the null hypothesis and accepting the alternative hypothesis, that system effectiveness is antecedent to internal performance.

H10: There is no relationship between internal performance and external performance.

Another proposed relationship is between internal performance and external performance. It is hypothesized that improvements in internal performance such as scrap rate, affect external performance such as customer satisfaction and delivery. Early Quality Assurance writers have suggested this relationship (Juran, 1981; Ishikawa, 1974). Some very specific measures such as internal scrap rate and external delivery performance have been shown to be related (Handfield, 1993; Flynn et al, 1995). Flynn et al (1995), in their study of relationships between TQM and JIT, showed strong support and a positive relationship between internal and external

quality performance. The literature supports rejecting the null hypothesis and accepting the alternative hypothesis, that internal performance is antecedent to external performance.

CHAPTER FIVE

INSTRUMENT DEVELOPMENT AND RESEARCH METHODOLOGY

5.1 INTRODUCTION

The research instrument developed covered both the current research and potential areas of future research in Quality Assurance. The development of questionnaire items to test the proposed research models for Quality Assurance came from four sources. Those four sources were: 1) the Quality Assurance literature, 2) company case studies, 3) personal experience, and 4) the ISO 9000 standard. This chapter looks at scale selection, item generation, questionnaire development, and data collection.

5.2 SCALE SELECTION

As noted in the introduction, scales were developed to test the Quality Assurance and performance models as well as future research areas such as costs, barriers, and implementation issues of ISO 9000. Three scales were developed for model testing in the research and were selected.

5.2.1 ISO Section/Elements relevance to Quality Assurance

5.2.2 System Effectiveness and Certification (Benefits)

5.2.3 Quality Performance Measures (before/after)

The three scales are included in Appendix A. A cover letter and full questionnaire are included in Appendix B.

5.3 ITEM GENERATION

As noted, a large list of initial items for each of the three scales was developed based on the literature and ISO standard requirements for a Quality Assurance system. From this base, a set of items was generated by this researcher and three University of Toledo faculty members. This set of items was further reviewed by a group of faculty at the University of Australia, who were engaged in similar research on ISO 9000. A measure has content validity based on how well researchers create measurement items to cover the content domain of the variable being measured (Nunnally, 1967). The use of a number of researchers and several reviews assured that measurement items covered all aspects of the variable being measured.

In addition, ten practioners from manufacturing in the Toledo area were given an opportunity to comment on the comprehensiveness and readability of the instruments. These practioners allowed for expert review. These practioners were asked if: A) the right items were included, B) whether the questions were readable and understandable, and C) if any other questions were needed to cover each scale. A number of changes were made, based on this review, and the final questionnaire was reviewed by five additional practioners.

For the system effectiveness instrument, items were generated, based on extensive review of the literature (Schlickman, 1998; Sayle, 1994; Voehl et al, 1994; Chowdhury and Zimmer, 1996). Based on this review, forty-three items were initially generated to analyze system effectiveness. After expert evaluation, this was reduced to thirty-seven items. A five point Likert scale was used with a 'not applicable/don't know' option. Both anticipated benefits and actual benefits were surveyed.

The ISO section relevance instrument was based on the twenty elements of the ISO standard. A five point Likert scale was again used to evaluate the degree of relevance where: 5 = highly relevant, 4 = somewhat relevant, 3 = neutral, 2 = somewhat not relevant, and 1 = not at all relevant.

The performance instrument was developed, using common measures of manufacturing performance, as generated by literature review (Noble, 1995; Nakane, 1990; Saraph et al, 1989; Porter, 1985; Flynn et al, 1994). Quantitative measures were categorized into five groupings using a five point Likert scale. Eleven items were initially generated. Expert review by manufacturing practioners kept all eleven items, but adjustments were made to grouping of performance levels. Again, the survey measured before/after levels of performance.

5.4 DATA COLLECTION

The survey was sent to certified ISO 9002 companies. The sample was based on a Dun and Bradstreet list of certified ISO companies. A sample of 2,000 certified companies, out of a population of 7,000 certified companies, were randomly selected for mailing. The mailings were directed at the listed ISO 9000 company representative, which represents a variety of job occupations.

The response rate for the 2,000 certified companies was 10.75% (215 responses). The response rate was affected by the eight page length, which required a minimum of 40 minutes to complete. Such a response rate, however, is not unusual for extensive research questionnaires. There were 213 usable responses.

Tables 6, 7, 8, and 9 are an analysis of the sample data. The firms represented showed a diverse cross section of American industry. The majority of respondents were from middle management, with ten percent represented by CEOs or presidents. Eighty-six percent of the responding firms had less than 500 employees. The nature of corporate ownership was also surveyed. Sixty-nine percent of the responding firms were domestically owned, with sixteen percent foreign owned. Fifteen percent of the firms were classified as international and/or joint ventures. The average annual sales was sixty million dollars.

TABLE 6

RESPONDENTS BY INDUSTRY	
Industry	Percent
Miscellaneous	18
Electronics	14
Chemical	13
Fabricated Metals	8
General Manufacture	8
Electrical	7
Primary Metals	6

TABLE 7

RESPONDENTS BY POSITION	
Position	Percent
President	10
Quality Managers	34
Operating Managers	28
Miscellaneous	28

TABLE 8

FIRMS BY SIZE	
Number of Employees	Percent
1 to 50	10
50 to 100	15
100 to 250	35
250 to 500	26
More than 500	14

TABLE 9

RESPONDENTS BY NATURE OF OWNERSHIP	
Position	Percent
Domestic	69
Foreign Owned	16
Multinational	10
Joint Venture	5

CHAPTER SIX

EXPLORATORY FACTOR ANALYSIS OF ISO QUALITY ASSURANCE ELEMENTS

6.1 INTRODUCTION

One of the research questions initially stated was the validity of ISO 9000's twenty elements as a Quality Assurance model. The initial phase of research was to explore the defined elements of ISO 9000 in relationship to the theoretically developed model for a Quality Assurance system. This research focused on the relevance of the ISO elements in the Quality Assurance function of the firm. Exploratory factor analysis is useful as a tool in searching for structure among a set of variables (Kachigan, 1991). The literature survey had developed a set of factors or components to represent a Quality Assurance system. The literature, however, did not clearly position the arrangement of the twenty elements of ISO 9000 into system components. Efforts to do this in the literature were not based on statistical data analysis, but on individual experiences (Voehl et al, 1994). . Exploratory factor analysis offered a method to determine the factor loading for each ISO element on each factor or Quality Assurance model component. Factor analysis, therefore, allows survey items to be related to specific

components or constructs in the model. Exploratory factor analysis allowed the strong theoretical supports for the ISO element architecture, into Quality Assurance components, to be statistically tested.

Two basic empirical approaches are available: factor analysis and principal components. The selection of the model to apply depends on the research objective and prior knowledge of a theoretical basis (Stevens, 1996). The selection of principal components is based on the research objective of combining the twenty ISO elements into Quality Assurance model components. Using principal component analysis, a set of correlated variables is transformed into a set of uncorrelated variables known as components (Kachigan, 1991). Principal component analysis is an empirical approach to select how many dimensions or underlying constructs account for most of the variance in the instrument scale (Stevens, 1996). Principal components analyses allowed for grouping of ISO elements into related Quality Assurance model components. In addition, using the twenty defined elements of ISO 9000, we are not interested in reducing the original variables. The research goal was to simply transform the original variables (elements) into a new set of linear combinations (components).

6.2 FACTOR NUMBER SELECTION

Table 10 is the original factor loadings generated from SPSSX using an oblique rotation. The oblique rotation versus

the orthogonal rotation was selected because the underlying dimensions need not carry the assumption of being uncorrelated with each other. In actual testing, both oblique and orthogonal were run, with the best fit being the oblique rotation. Based on the literature review of the ISO 9000 elements, it could be assumed that a number of them would be correlated.

Several criteria are available for determining the number of factors to be extracted. These criteria are outlined as follows and summarized in Table 10.

6.2.1 Latent Root Criterion

The latent root criterion is its mostly widely used criterion for component selection and is known as the Kaiser criterion (Stevens, 1996). This criteria retains only eigenvalues of one or greater and is the default option of SPSSX.

Using the Kaiser criterion, four factors were identified. The Kaiser criteria is deemed accurate if the number of variables is less than 30 and communalities are greater than .70, or when N > 250, and the mean communality is ≥.60 (Stevens, 1996). In this case, we had twenty variables, and seventeen out of twenty variables had communalities greater than .70.

TABLE 10

ORIGINAL FACTOR LOADINGS FOR QUALITY ASSURANCE COMPONENTS				
	Factor 1	Factor 2	Factor 3	Factor 4
1. Inspection and Testing	.84		.38	
2. Inspection, Inspection and Test Equipment	.83		.31	
3. Document and Data Control	.67			
4. Product ID Traceability	.66			
5. Test Status	.61			
6. Process Control	.61			
7. Purchasing	.51			
8. Quality Record	.41			
9. Control of Nonconforming Product			.42	.44
10. Contract Review		.82		
11. Design Control		.64		
12. Servicing		.48	.71	
13. Control of Customer Supplied Product			.69	
14. Statistical Techniques			.53	
15. Training				.79
16. Internal Quality Audits				.70
17. Corrective Action				.68
18. Management Responsibility				.65
19. Quality System		.39	.40	.42
20. Handling, Storage, Delivery		.40		.43

6.2.2 Percentage of Variance Criterion

This criteria is based on a specified amount of total variance. The generally accepted amount of needed total variance is seventy percent (Kachigan, 1991), while others support a minimum of 60% (Hair et al, 1991). Again, the use of four factors is supported.

6.2.3 Factor Extraction

Table 11 shows the summary result of factor extraction.

6.3 FACTOR PURIFICATION AND IMPROVEMENT

Criteria for the item selection of significant factor loadings varies by author. The literature is rich in item criteria; thus, for purposes of this research, the most conservative approaches were selected. Conservative authors have proposed a factor loading of +.50 or greater which can be considered very significant (Hair et al, 1991; Kachigan, 1991; Stevens, 1996). In addition, successful application of the above criteria requires sample size greater than 50 (Hair et al, 1991). The sample size of 213 achieves this boundary requirement. The .50 was chosen as the cutoff for significant factor loadings. The elimination of factor loadings below .50 also resulted in improvement.

TABLE 11

RESULTS OF FACTOR EXTRACTION						
Factor	**Eigenvalue**	**Percent of Variance**	**Reliability Chronbach Coefficient**	**Factor Name**	**ISO Elements**	**Corrected Item Total Correlation**
1	9.2	48.1	.82	Process Quality Management	Inspection/Testing Inspection Equipment Document and Data Control Traceability and Identification Inspection and Test Status Process Control Purchasing	.82 .79 .73 .69 .72 .68 .70
2	1.3	10.1	.79	Product Design	Contract Review Design	.71 .73
3	1.2	9.2	.82	Ancillary Services	Servicing Customer Supplied Product Statistical Techniques	.81 .79 .80
4	1.1	6.9	.89	System Management	Training Internal Quality Audits Corrective Action Management Responsibility	.85 .79 .76 .91

After test for potential item elimination, items were reviewed for the existence of high cross loadings. Items are considered factorially impure if there are additional or cross loadings of .40 (Stevens, 1996). Where cross loadings of .40 or greater were found, all items were eliminated.

Internal consistency, or reliability of the scale after eliminated items, was studied using Cronbach's Alpha. This approach allows for elimination of items, if the reliability of the remaining items was at least .80 and the content of the scale is not significantly altered (Kachigan, 1991). The following is a review of item elimination and scale improvement. Table 12 is the final factor loadings after item and scale improvement. Using the identified factors and item loadings, names were developed for the factors based on theory and the item loadings. The following are the defined factor names.

Factor 1 - Process Quality Management

The ISO items grouped according to factor analysis were inspection and testing, inspection and measuring equipment, document and data control, purchasing, process control, and product and identification traceability. Clearly, these elements are directly related to process quality management functions. This factor is further supported by the literature on process quality management and Quality Assurance (Voehl et al, 1994; Lamprecht,

1994; Randall, 1995). Furthermore, this component is also related with the process quality section of the Baldridge Award (Surkovic and Handfield, 1996). The reliability coefficient was .82, and no improvement was possible by dropping any items.

Factor 2 - Product Design

Two ISO elements grouped into factor 2: contract review and design control. Contract review is focused on specifications and product design in manufacturing firms. This factor, as shown in the literature review, is a key component of Quality Assurance (Asanuma, 1989; Benson et al, 1991; Chase and Tansik, 1983). Reliability coefficient was .79 for this factor, and .81 after item elimination of servicing, quality system, and handling items.

Factor 3 - Ancillary Services

Three ISO elements loaded into this factor: servicing, statistical techniques, and customer supplied product. This factor, as covered by the literature, is directly related to required services for customers (Chase et al, 1992; Von Hippel, 1986). The reliability coefficient was .82 for this factor, and .88 after item elimination of control of non-conforming product.

Factor 4 - Quality Assurance System Management

Four ISO elements loaded on this factor: management responsibility, internal quality auditing, corrective and preventive action, and training. These elements are those classically assigned to Quality Assurance management (Feigenbaum, 1983; Evans and Lindsay, 1993; Juran, 1995). The reliability coefficient was .89, with no improvement possible by dropping items.

6.4 MODEL COMPONENTS

The ISO 9000 Quality Assurance model components which were developed theoretically are supported by the exploratory factor analysis. A confirmatory factor analysis of this basic model, using the ISO elements, will be carried out using LISREL in Chapter 8.

TABLE 12

FINAL FACTOR LOADINGS				
	Factor 1	Factor 2	Factor 3	Factor 4
1. Inspection and Testing	.8417			
2. Inspection and Measuring Equipment	.8386			
3. Document and Data Control	.6716			
4. Product ID and Traceability	.6639			
5. Inspection of Test Status	.6188			
6. Process Control	.6155			
7. Purchasing	.5100			
8. Contract Review		.8249		
9. Design Control		.6447		
10. Servicing			.7108	
11. Control of Customer Supplied Product			.6965	
12. Statistical Techniques			.5303	
13. Training				.7902
14. Internal Quality Audits				.7006
15. Corrective and Preventive Action				.6825
16. Management Responsibility				.6559

CHAPTER SEVEN

EXPLORATORY FACTOR ANALYSIS OF SYSTEM BENEFITS AND SYSTEM EFFECTIVENESS

7.1 INTRODUCTION

The survey scale on system benefits used thirty-seven items to measure system effectiveness. Unlike the scale for ISO elements where the ISO standard specified all twenty elements, system benefits are not clearly specified in the standard. Factor analysis allows the researcher to perform three basic functions (DeVellis, 1991). The primary function is to allow the investigator to determine how many latent variables underlie a set of items. The second purpose is to explain variation among many original variables, using newly created factors. Finally, factor analysis allows the researcher to assign meaning to the factors. The main research objective in this specific analysis was to determine the underlying latent variables. The research focus here was to establish the nature of system effectiveness for modeling and testing of the Quality Assurance model.

7.2 FACTORS

The same rules reviewed in Chapter 6 were applied here to determine the number of factors. Table 13 is the result of

principal component analysis showing the original factor loadings. Again an oblique rotation was used, as discussed.

Several criteria were used, as in Chapter 6, to select the number of factors. SPSSX, using the latent criteria as a default, gave the extraction in Table 14. Table 14 is the factor selection analysis, using several criteria.

7.3 FACTOR PURIFICATION AND IMPROVEMENT

Table 15 shows the final factor loadings after purification. As in Chapter 6, a .50 cutoff of factor loadings was used to identify significant items. In addition, items with cross loadings above .30 were considered for elimination, using reliability analysis. Cronbach alpha reliabilities were calculated. In general, reliabilities across a scale above .80 would indicate the scale performs well (Nunnally, 1978). Elimination of marginal items can improve reliabilities and, thus, scale performance. CITC (expon) is used for this purpose. These are discussed in the following sections. Factor names are also developed, based on theory and the item groupings.

TABLE 13

ORIGINAL SYSTEM BENEFITS FACTOR LOADINGS					
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Reduction of Non Conformities	.83				
Reduction of Production Cost	.79				
Improve Delivery Time	.75				
Improve Production Efficiency	.72				
Improve Customer Satisfaction	.68				
Improve Customer Awareness	.65				
Improve Customer Service	.63				
Improve Employee Morale	.61	.47			
Improve Job Satisfaction	.52	.46			
Improve Management Control	.48				.43
Improve Human Resources		.75			
Improve Accounting Practices		.69			
Improve Safety		.68			
Improve Product Design	.42	.63			
Improve Job Skills		.55			
Improve Job Performance		.54			
Market Increase			.72		
Sustain Market			.69		
Reduce Customer Rejects	.42		.61		
Reduce Customer Complaints	.48		.54		
Improve Profits	.49		.55		
Improve Documentation				.79	
Improve Order Processing				.77	
Improve Response to Customer				.51	
Clearer Responsibility				.56	
Improve Purchasing				.55	
Improve Export Access					.78
Improve Domestic Market					.62
Improve Communication	.49				.52
Improve Competition	.51				.58

TABLE 14

FACTOR EXTRACTION ANALYSIS						
Name	Factor	Eigenvalue	Percent of Variance	Related Benefits Measures	Corrected Item Total Correlation	Reliability
System Effectiveness	Factor 1	16,0	48,0%	Reduction of Non-Conformities Reduction of Production Cost Improved Delivery Production Efficiency Customer Satisfaction Improved Customer Service	,78 ,75 ,80 ,76 ,71 ,69	,88
Knowledge/ Skills	Factor 2	2,5	6,4%	Improved Human Resources Improved Accounting Practices Improved Safety	,72 ,65 ,78	,87
Market Benefits	Factor 3	2,2	6,1%	Increased Market Sustain Market	,70 ,72	,80
Documentation	Factor 4	1,6	4,4%	Improved Documentation Improved Order Processing Improved Response	,73 ,69 ,70	,82
Market	Factor 5	1,5	4,0%	Improved Export Access Improved Domestic Market	,64 ,62	,80

TABLE 15

FINAL SYSTEM BENEFITS FACTOR LOADINGS					
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Reduction of Non Conformities	.78				
Reduction of Production Cost	.75				
Improve Delivery Time	.75				
Improve Production Efficiency	.73				
Improve Customer Satisfaction	.68				
Improve Customer Awareness	.65				
Improve Customer Service	.62				
Improve Human Resources		.82			
Improve Accounting Practices		.81			
Improve Safety		.72			
Market Increase			.73		
Sustain Market			.70		
Improve Documentation				.79	
Improve Order Processing				.72	
Improve Response to Customer				.52	
Improve Export Access					.78
Improve Domestic Market					.62

Factor 1 - System Effectiveness

Factor 1 represents an overall measure of system effectiveness with such variables as cost improvement, efficiency, delivery time, customer satisfaction, reduced non-conformities, and improved customer service. In total, two items were dropped, improving the reliability to .9010. The items dropped were improved employee morale and job satisfaction, both of which were highly crossed loaded. This factor is consistent with literature on effectiveness measures of Quality Assurance systems as well as Total Quality Management systems (Nagal and Bhargava, 1991; Ross, 1995; Feigenbaum, 1983). The benefit of an effective system is also proposed as the key outcome of ISO 9000 implementation (Sayle, 1994; Schlickman, 1998; Voehl et al, 1994). ISO 9000 is a system oriented standard which focuses on system improvement. System effectiveness improvement, of course, must precede actual performance improvements (Voehl et al, 1994; Surkovic and Handfield, 1996). Implementation of ISO 9000 will directly improve the effectiveness of the Quality Assurance system (Sayle, 1994). Furthermore, feedback on system effectiveness is used in the ISO model for continuous improvement and improved quality performance (Ross, 1995; Voehl et al, 1994). System effectiveness, as developed in this factor

analysis, is the outcome component of the proposed Quality Assurance model.

Factor 2 - Knowledge/Skills

Factor 2 loaded on improvements in human resources planning, accounting practices, safety programs, job skills, product design, and job performance. Reliability analysis showed no improvement in reliability by dropping items. Knowledge and job skills are another benefit of ISO 9000 that is supported by the literature (Surkovic and Handfield, 1996; Stamates, 1996).

Factor 3 - Market Benefits

Factor 3 represents market benefits, in particular, sustaining and increasing market share. A total of five items loaded on this factor. After eliminating cross loaded items and applying reliability analysis, the reliability coefficient improved to .88. This factor is suggested as a performance indicator of ISO 9000 in the literature (Voehl et al, 1994; Chowdhury and Zimmer, 1996). The survey measured this benefit directly in a later scale.

Factor 4 - Documentation

Factor 4 represents the direct benefit of improved documentation. While the scale is supported in the literature, it had a reliability coefficient which could only be improved to .82 by dropping two cross loaded items. Some of the problems of this scale might be that

it is a benefit that is best measured in other results. Documentation is an immediate benefit or improvement that can be a direct result of ISO implementation (Voehl et al, 1994).

Factor 5 - Market Access

Four items loaded on this factor with an eigenvalue of 1.46 and an initial reliability of .72. Dropping cross loaded items improved the reliability to .80. Factor 5 (Market Access), like Factor 4, can be considered an intermediate benefit which leads to other results.

7.4 CONCLUSION

System certification measures both compliance to ISO elements as well as system effectiveness. In the next chapter, system effectiveness will be modeled and tested as the feedback component in a Quality Assurance system. Furthermore, the relationship between system effectiveness and performance will be studied.

CHAPTER EIGHT

MODEL TESTING

8.1 INTRODUCTION

Based on theory and exploratory factor analysis, two models have been developed. The Quality Assurance model hypothesizes the relationships between the model components of System Management, Process Quality Management, Ancillary Services, Product Design, and System Effectiveness. The performance model addresses the research question related to the benefits of an implemented Quality Assurance system. In particular, the relationship between performance and effectiveness is studied. In this chapter, Structural Equation modeling will be used to test the model fit and path significance.

8.2 ISO MODEL ANALYSIS

To test the proposed model for a Quality Assurance system model (Figure 7), and the performance model (Figure 8), structural equation modeling was chosen. Structural modeling provides a method of dealing with multiple relationships while providing statistical efficiency. Statistical efficiency is further gained by reducing the causal paths to the smallest number of paths that can be theoretically justified (Stevens, 1996). The use of a

system component model and a separate performance model improves efficiency by reducing overall model paths.

8.3 NORMALITY ASSUMPTIONS

The maximum likelihood method of estimation used by LISREL is very sensitive to departures from multivariate normality. Lack of multivariate normality can substantially inflate the chi-square, overestimating the goodness of fit. In practice, the assumption of multivariate normality is seldom realized. One test of multivariate non-normality is to test for univariate normal distributions.

To test for univariate normality, Kolmogorov-Smirnov statistics were calculated for each measure. The results shown in Table 16 confirm the variables are normal. Based on the results, the use of the maximum likelihood estimation was not constrained by normality considerations.

8.4 INTRODUCTION TO TESTING

As discussed, the reliability and construct validity of the variables in the model were assessed in earlier chapters. The reliability of each of the model components was .80 or better, using the Cronbach alpha as a measure. These reliabilities are well above the research benchmarks of .8 for tested scales, and .7 for exploratory work (Nunnally, 1978). Reliable scales are a necessity in properly applying LISREL methodology, using multi-item variables. For the multi-item variables, the scores were

standardized and the mean used in the subsequent predictive model. Based on the model components and hypothesized relationships, LISREL methodology was used for structural analysis.

LISREL uses the covariance matrix of observed variables based on maximum-likelihood estimation procedures. The sample size of 213 falls well within acceptable limits for the use of structural equation modeling (Hair et al, 1991). In addition, the assumption of normality was tested, as noted earlier. Once the assumptions are tested, LISREL can be used to evaluate the overall fit of the proposed model and evaluate the individual constructs and hypotheses. The use of LISREL allowed for the study of relationships and made the transition from exploratory to confirmatory analysis.

8.5 CAUSAL MODEL

The development and testing of a causal model assumes a strong theoretical or empirical base. Theories and the resulting causal models were based on one or more of the following theoretical principal sources: (1) prior empirical research, (2) other theories and analysis, and (3) experiences and observations (Hair et al, 1991). The theoretical basis of the primary causal model was presented in Chapter 2.

TABLE 16

KOLMOGOROV-SMIRNOV ANALYSIS FOR NORMALITY			
Variable	K-S Value	P-Value	Conclusion
Quality Assurance Management	.982	.450	Normal
Ancillary Services	.681	.721	Normal
Process Quality Management	.821	.412	Normal
Product Design	.88	.445	Normal
System Effectiveness	.691	.710	Normal
Internal Performance	.786	.692	Normal
External Performance	.812	.589	Normal

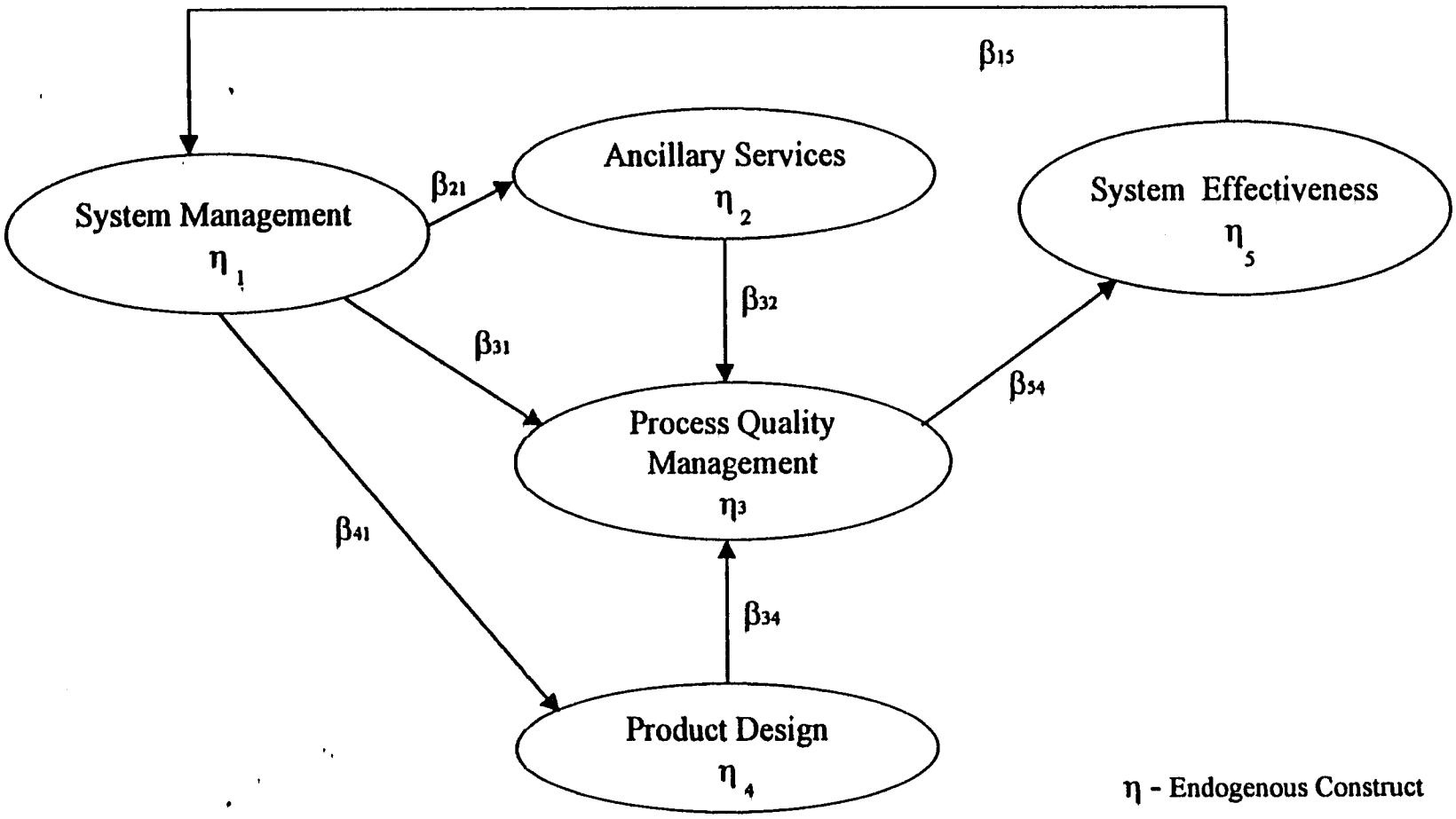
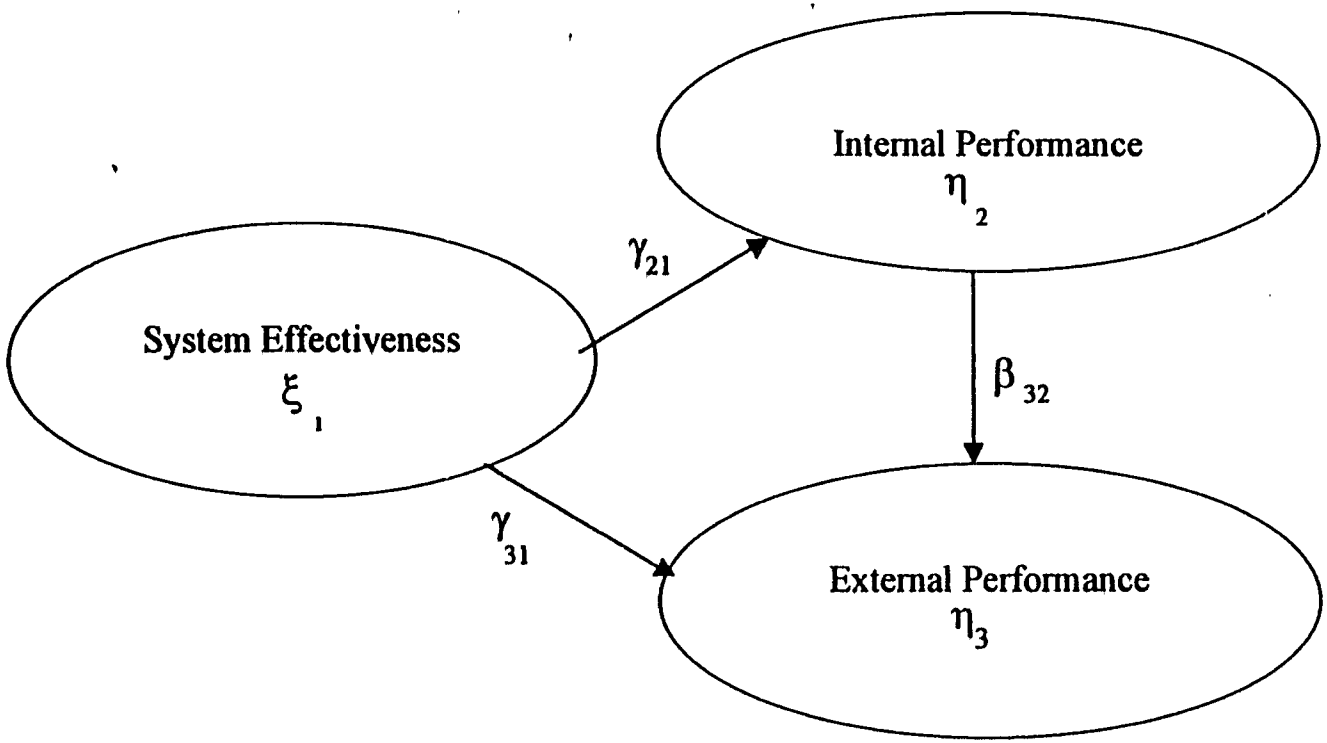


FIGURE 7 PRIMARY CAUSAL MODEL FOR
AN ISO 9000 QUALITY ASSURANCE SYSTEM



ξ - Exogenous Construct

η - Endogenous Construct

β - Endogenous to endogenous relationship

γ - Exogenous to endogenous relationship

FIGURE 8 PRIMARY CAUSAL MODEL FOR ISO SYSTEM PERFORMANCE

To move from a theoretical model to a causal model requires the causal structure of the theoretical variables to be identified. All variables or constructs in a causal model fall into two classes: exogenous and endogenous. Exogenous variables, or independent variables, are not predicted or caused by any other variables in the model. Endogenous variables are predicted by other variables in the model. Endogenous variables can be used to predict other endogenous variables. The distinction between endogenous variables is based on the review of theoretical principal sources.

Based on the hypothesized model in Chapter 3, the variables, System Management, Ancillary Services, Process Quality Management, Product Design, and System Effectiveness, are all endogenous variables (see Figure 7). Figure 8, as noted earlier, is a causal model for system performance, showing system effectiveness as exogenous and the two performance variables as endogenous. The theoretical model discussed stated no causal relationships between these variables as null hypotheses. The development of a path diagram to be used for structural equation testing requires the nature of the causal relationship between variables to be defined (Stevens, 1996). A path diagram is, therefore, used to represent these causal relationships in the model. To do this, we need to restate the hypotheses in Chapter 4 as alternative hypotheses.

8.6 HYPOTHESES FOR THE QUALITY ASSURANCE SYSTEM

Alternate Hypothesis 1

There is an overall positive relationship between quality assurance system management and process quality management.

Alternate Hypothesis 2

There is an overall positive relationship between system management and ancillary services.

Alternate Hypothesis 3

There is an overall positive relationship between system management and product design.

Alternate Hypothesis 4

There is an overall positive relationship between ancillary services and process quality management.

Alternate Hypothesis 5

There is an overall positive relationship between product design practices and process quality management.

Alternate Hypothesis 6

There is an overall positive relationship between process quality management and system effectiveness.

Alternate Hypothesis 7

There is an overall positive relationship between system effectiveness and system management.

8.7 ALTERNATE HYPOTHESES FOR SYSTEM PERFORMANCE

Alternate Hypothesis 8

There is an overall positive relationship between system effectiveness and external performance.

Alternate Hypothesis 9

There is an overall positive relationship between system effectiveness and internal performance.

Alternate Hypothesis 10

There is an overall positive relationship between internal performance and external performance.

8.8 STRUCTURAL ANALYSIS METHODS

Using LISREL, a path diagram can readily be translated into structural equations to be tested. These structural equations are similar to multiple regression equations, in that the hypothesized effect is put into an equation of endogenous variables which are predicted by exogenous, or other endogenous variables with a prediction error. The predictor variables also have a structural coefficient.

The measurement model is assessed first, using the goodness of fit of the data to the hypothesized underlying constructs. Poor goodness of fit suggests poor model specification and a limited data base (Stevens, 1996). Unfortunately, there is no single direct measure of goodness of fit for structural modeling. In LISREL, various measures are used to assess goodness of fit and describe the strength of the structural model's prediction. Three types of these measures are commonly used: measures of absolute fit, measures of incremental fit, and measures of parsimonious fit (Hair et al, 1991).

Measures of absolute fit determine the degree to which the measurement and structural model predict the observed covariance. LISREL provides three measures of absolute fit: Chi Square, GFI, and the root mean square residual.

Incremental fit measures compare the model to the null model. Finally, parsimonious fit measures compare the fit of the model to the number of estimated coefficients needed to achieve that level of fit. LISREL has two measures of parsimonious fit: AGFI and normed chi-square.

In this study, all of the available LISREL measures are used to evaluate the overall model fit and the acceptability of the hypothesized constructs.

8.9 MODEL FIT

The values for model fit of the ISO Quality Assurance system model are shown in Table 17. Table 18 shows the values for the ISO

performance model.

The size of the study suggests chi square is not appropriate (Stevens, 1996). Unlike chi square, the goodness of fit index (GFI) is independent of sample size and is robust against even departure from normality. The CFI evaluates all of the model parameters. It is a non statistical measure ranging in value from 0 to 1 (with 1 being a perfect fit). Minimum level of acceptability is .90 (Stevens, 1996). Both the Quality Assurance system model and the performance model being evaluated meet this minimum requirement.

Adjusted goodness of fit index (AGFI) is similar to GFI, except it is adjusted for the degrees of freedom in the hypothesized models. The .90 is the minimum acceptable level (Hair et al, 1991). Both of the models meet this minimum.

For incremental fit, normal-fit-index (NFI) and comparative-fit-index are used. Again, .90 is considered a threshold value (Joseskorg and Sorbom, 1986). Both hypothesized models met these criteria. In summary, both the ISO system Quality Assurance model and the ISO performance model show evidence of good fit. Next, the t values of the gamma and beta coefficients are used to test the research hypotheses.

8.10 LISREL TESTING OF CAUSAL RELATIONSHIPS IN THE MODEL

The results of the LISREL analyses of the causal models are given in Table 19. Figures 9 and 10 also show the final t values for the individual model paths. The nature of relationships are

discussed in the Conclusions. The results of all ten hypotheses show t values greater than 2.00, indicating statistical significance at .05 level. In all ten model hypotheses, the null hypothesis is rejected and the alternative accepted.

8.11 CONCLUSIONS

In this chapter, we showed the model fit and through path analysis supported the ten hypotheses. After confirming the two research models, contextual variables will be examined for their role in explaining the system effectiveness and performance. Of particular interest are the impact of firm size (sales volume, company size), exporting to Europe, and exporting in general. The next chapter uses MANVOA to test contextual variable hypotheses.

TABLE 17

STATISTICS FOR STRUCTURAL EQUATION MODEL ISO QUALITY ASSURANCE MODEL		
Goodness of Fit Measure	**Value**	**Recommended Value***
Chi-Square	471	Not Significant
Chi Square Degrees of Freedom	1.80	< 3.0
Goodness of Fit (GFI)	.98	> .90
Adjusted GFI	.94	> .90
Non Normal Fit	.95	> .90
Comparative Fit (CFI)	.98	> .90

*Stevens, 1996

TABLE 18

STATISTICS FOR THE STRUCTURAL EQUATION MODEL THE PERFORMANCE MODEL		
Goodness of Fit Measure	**Value**	**Recommended Value***
Chi-Square	490	Not Significant
Chi Square Degrees of Freedom	1.82	< 3.0
Goodness of Fit (GFI)	.98	> .90
Adjusted GFI	.93	> .90
Non Normal Fit	.94	> .90
Comparative Fit (CFI)	.96	> .90

TABLE 19

CAUSAL MODEL RESULTS			
ISO QUALITY ASSURANCE SYSTEM MODEL			
Hypothesis	LISREL Coefficient	t-Value	Significant at .05?
1	.52	10.29	Yes
2	.41	7.51	Yes
3	.40	7.27	Yes
4	.19	4.21	Yes
5	.14	3.16	Yes
6	.48	2.50	Yes
7	.27	3.66	Yes
ISO PERFORMANCE MODEL			
8	.19	2.93	Yes
9	-.38	-6.82	Yes
10	-.32	-5.33	Yes

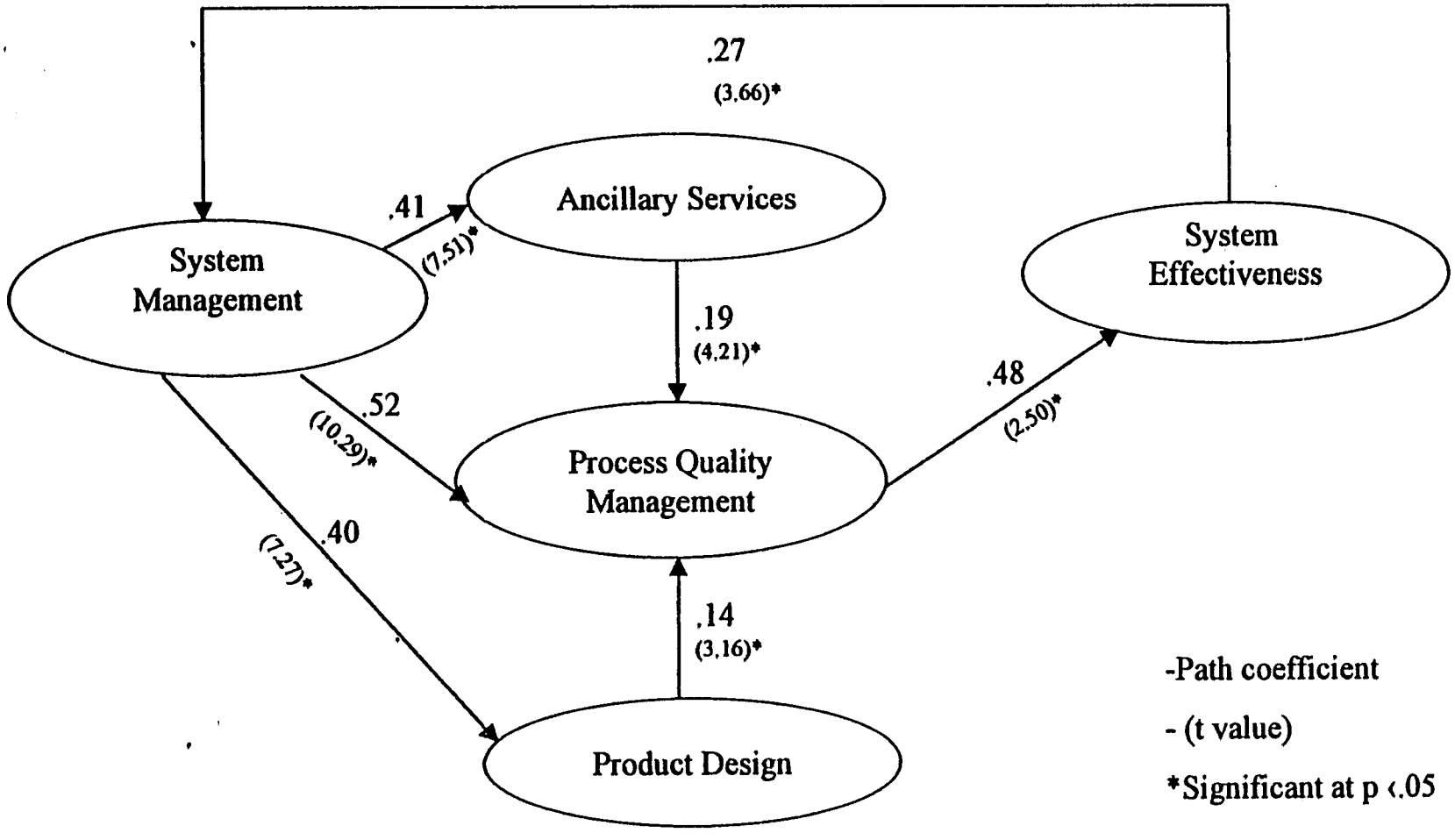
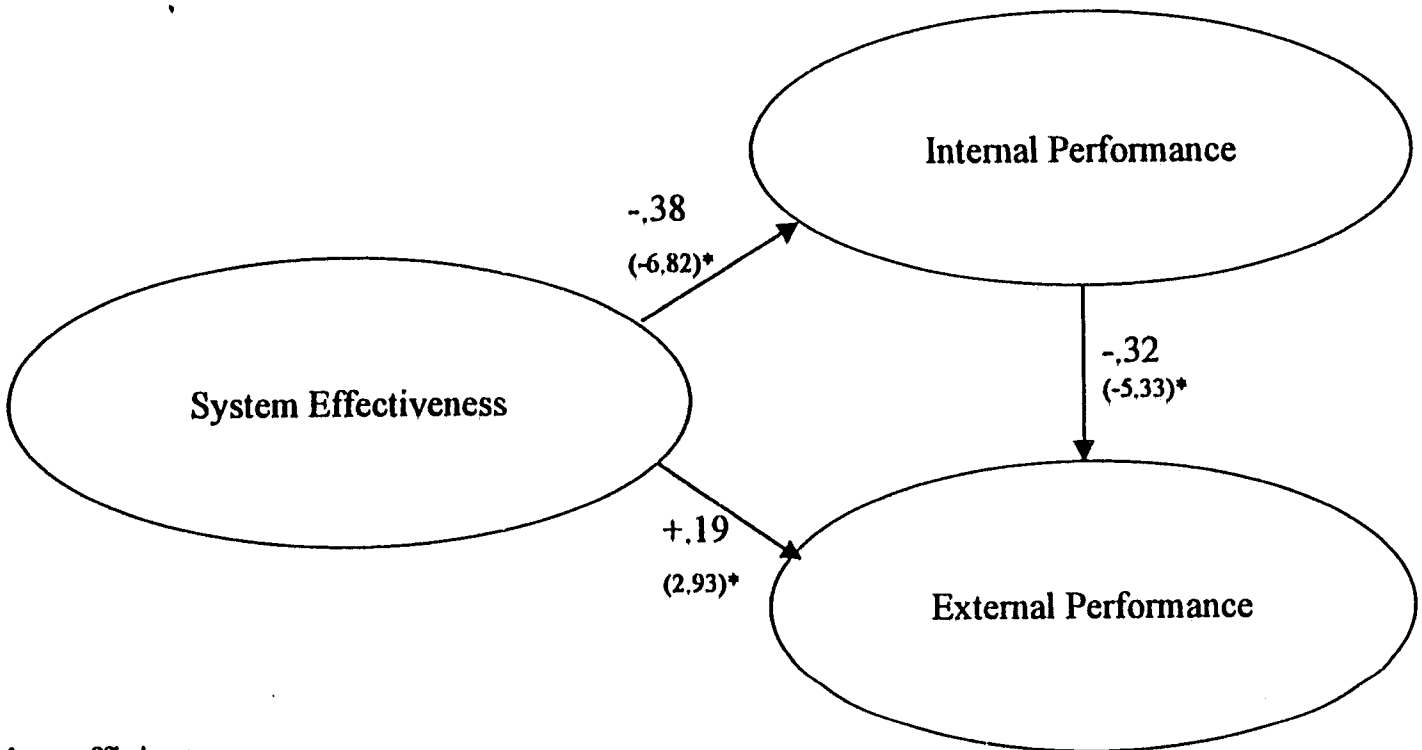


FIGURE 9 PRIMARY CAUSAL MODEL FOR ISO 9000 QA SYSTEM



Path coefficient

- (t value)

- *Significant at p < .05

FIGURE 10 PRIMARY CAUSAL MODEL FOR ISO SYSTEM PERFORMANCE

CHAPTER NINE

ANALYSIS OF CONTEXTUAL VARIABLES

9.1 INTRODUCTION

The literature review suggested that the performance and effectiveness of the system are impacted by a number of contextual variables. This chapter explores the dependent variables of effectiveness and performance with two levels of independent variables - sales volume, number of employees, exporting, and European business.

9.2 CONTEXTUAL VARIABLES

The literature review on ISO 9000 clearly identified that the performance model of ISO 9000 would be affected by some key contextual variables (Sayle, 1994; Schlickman, 1998). Several of these, such as company size and exports, are discussed in detail.

9.2.1 Company Size

Company size is identified in the literature as a key contextual variable for any ISO model (Surkovic and Handfield, 1996). Several authors have noted that small companies realize more benefits and larger increases in performance measures (Stamates, 1996; Voehl et al, 1994). The reasons for this are many. First, small companies tend not to have well

developed Quality Assurance systems in place prior to ISO 9000 implementation (Voehl et al, 1994). Also, large companies would have progressed further towards an overall TQM system, prior to the acceptance and implementation of ISO 9000 system. Further, smaller companies tend to have more to gain commercially from ISO certification compared to their better known larger competitors (Stamates, 1996). Finally, small companies tend to focus more on the ISO implementation objective while it is one of several objectives in the larger organizations (Zuckerman, 1996).

9.2.2 Exports

The rapid growth of ISO 9000 as an international standard has been spurred by the growth of exports. Originally, ISO offered a means to assure quality among the thirteen European countries, thus, bringing down barriers to an economic European union. At the same time, ISO 9000 offered a trade barrier to those outside the European Union, resulting in a world wide movement toward ISO certification. Exporting, in this respect, was part of the drive towards implementing a Quality Assurance system to the ISO 9000 standard. The assumption was that ISO certification would increase the exports of the company, and thus lead to increased business. The link between exporting and improved performance, however, has never been clearly demonstrated (Stamates, 1996).

9.3 MULTIVARIATE ANALYSIS

There are two dependent variables which are the result of ISO 9000 system implementation: quality system effectiveness and quality performance. System effectiveness is the evaluation of the Quality Assurance system. The literature survey posits a strong relationship between system effectiveness and performance (Schlickman, 1998). Because of the possible dependence among the two dependent variables, MANOVA is used. The multivariate approach also allows for testing a stronger overall research question involving two dependent variables simultaneously. The use of fragmented univariate tests can greatly overstate the type I error.

9.4 ASSUMPTIONS OF MANOVA

In testing the multivariate null hypothesis, there are three assumptions: a) Independence of the observations, b) Multivariate normality, and c) Equality of the covariance matrices.

Independent observations is the most serious potential violation. MANOVA is fairly robust to violations of normality (Kachigan, 1991). MANOVA is also robust to violations of equal covariance matrices.

9.4.1 Normality

The multivariate normality was tested earlier and found to be satisfactory. Furthermore, deviations from multivariate normality have only a very small effect on Type I error.

9.4.2 Independence of Observations

While this could be a very serious violation, it is not common in business survey research. Research has shown that whenever the survey is individually administered, observations are independent (Stevens, 1996).

9.4.3 Homogeneity of Covariance

The assumption of equal covariance can be restrictive. However, a number of tests are available to evaluate this assumption. SPSSX offers an assessment test for homogeneity of covariance matrices. This is the Box-M test. One precaution is needed in applying it. The Box test is sensitive to violations of multivariate normality. If multivariate normality has been demonstrated, as in this research, then the Box test is a fairly clean test of homogeneity of covariances (Stevens, 1996). For both contextual variables, the Box test was not significant, thus assuring homogeneity (.05 level). Having met the basic assumptions of MANOVA, we can proceed to hypothesis development.

9.5 HYPOTHESES FOR CONTEXTUAL VARIABLES

Hypotheses were developed for four independent variables - sales volume, employee size, European business, and existence of exporting. All these variables were measured at two levels. The

dependent variables of interest are system effectiveness and quality performance.

9.5.1 Hypothesis A. The system effectiveness and realized performance from ISO 9000 are influenced by the sales volume of the company (size).

The literature survey strongly supports the impact of company size on the benefits and performance of ISO 9000 companies. Several authors have suggested that sales volume is the key size factor (Sayle, 1994; Schlickman, 1998). Studies suggest a break in sales of twenty-five million dollars as the cut-off between small and large (Kaplan and Norton, 1995). This cut-off of twenty-five million dollars in sales volume was used to test the dependence of system effectiveness and performance on company size based on sales volume.

9.5.2 Hypothesis B. The system effectiveness and performance from ISO 9000 are influenced by the number of employees (size).

Hypothesis B explores the impact of size, using number of employees as the size factor. Again, two groups were used. The decision here was to use 250 employees as the break point. Some authors would hold that less than twenty employees makes a better cut-off between small and large (Chase et al, 1983). Other authors of corporate studies choose a higher cut-off

between small and large corporations (Bonaccossi and Lipparini, 1994). The selection, less than and greater than 250, was made to best fit the research data and meet the homogeneity of covariance assumption which requires a well balanced sample size (Stevens, 1996).

9.5.3 Hypothesis C. The system effectiveness and performance from ISO 9000 are influenced by European business of the company.

Historically, the original drive to ISO 9000 certification evolved from the European Community. Initially, the large US industries with European marketing interests moved toward ISO 9000 (Beohling, 1990). Since it is likely these companies realized additional sales and ultimately performance improvement, this needs further exploration. Hypothesis C offers a means to further explore this dependence. In the survey, responses were divided into two categories according to a 'yes/no' response.

9.5.4 Hypothesis D. The system effectiveness and performance from ISO 9000 are influenced by export marketing of the company.

A similar argument to Hypothesis C can be made for exporting, except it suggests a broader scope. ISO 9000 has moved rapidly from the early 1990s as a European requirement to an international business requirement it is today.

Clearly, the motivation for ISO 9000 certification is the hope of increased export opportunities (Stamates, 1996). It is hypothesized that export activity influences the system effectiveness and performance achieved.

9.6 HYPOTHESIS TESTING

Before calculating the test statistics for the groups, the Bartlett's test for sphericity was used to assess the appropriateness of the use of MANOVA. Bartlett's test specifically looks at whether the dependent measures are significantly correlated, which is the basis for using multivariate MANOVA. SPSSX tests the significance of the Bartlett test. For the population data, Bartlett's test of sphericity was 22.8 with six degrees of freedom and a significance p-value of .000. Since the observed significance level is small, the hypothesis that the population correlation matrix is an identity matrix is rejected. That is, we can assume that system effectiveness and performance are correlated and can proceed.

Group sizes for hypotheses must be reviewed to assure the necessary assumption of equality of covariances. The group sizes are near equal, well within the suggested 1.5 ratio. Having previously established multivariate normality, the Box test was applied for equality of covariance for data sets for the four hypotheses. The Box test confirmed the equality of covariance in all four cases at the .05 level.

9.6.1 Hypothesis A

Table 20 shows the results of the MANOVA for Hypothesis A on sales volume for the dependent variables, effectiveness, and performance. The multivariate Hotelling T^2 and Wilk's Lambda are significant at the .05 level, supporting Hypothesis A, in addition to univariate significance for both dependent variables. The interaction is not significant, indicating the main effects can be interpreted directly. It can be concluded that company size, as measured by sales volume, has effect on both system effectiveness and performance of certified companies. Here we see that small companies gain more in benefits and performance. The rationale for this result is probably related to the fact that smaller companies have immature quality systems prior to adopting ISO 9000 structure. Larger corporations usually have quality systems in place prior to ISO 9000, and the effort can be more of a documentation effort than quality improvement (Sayle, 1994).

9.6.2 Hypothesis B

Table 21 shows the results of the MANOVA for Hypothesis B on the number of employees on the dependent variables, system effectiveness and performance. The multivariate Hotelling T^2 and Wilk's Lambda are significant at the .05 level supporting Hypothesis B. There is univariate significance for both dependent variables as well. The

interaction is not significant, allowing the main effect to be directly interpreted. It can be concluded that the size of the company, as measured by employees, has an impact on the system effectiveness and performance achieved. The reasons again are similar to those suggested in the analysis of Hypothesis A.

9.6.3 Hypothesis C

Table 22 shows the results of MANOVA for Hypothesis C on European business, and effectiveness and performance results. The multivariate Hotelling T^2 and Wilk's Lambda are significant at the .05 level, supporting Hypothesis C. There is univariate significance as well. The interaction is again not significant, allowing for direct analysis of the main effect. It can be concluded that European marketing influences benefits and performance of ISO certified companies. The initial historical motivation of many companies was to improve their European business, which may account for better results of companies with European links.

9.6.4 Hypothesis D

Table 23 shows the results of MANOVA for Hypothesis D on exports; and system effectiveness and performance results. The multivariate Hotelling T^2 and Wilk's Lambda are significant at the .05 level supporting Hypothesis D. The interaction was not significant, allowing study of the main

effect. It can be concluded that exporting has an effect on effectiveness and performance results of certified companies. As with European business, exporting companies were some of the earliest to adopt ISO 9000 because of potential market benefits.

TABLE 20

MULTIVARIATE ANALYSIS OF VARIANCE OF PERFORMANCE AND EFFECTIVENESS BASED ON COMPANY SIZE (SALES VOLUME)

MATRIX OF MEANS

	Independent Variables	
Dependent Variables	Small Companies	Large Companies
Effectiveness	3.98	3.46
Performance	3.92	3.52
N	108	92

MULTIVARIATE ANALYSIS

Test Name	Value	F Value	P
Wilk's Lambda	.81	18.81	.031*
Hotelling	4.33	8.92	.018*

*Multivariate tests show significance at .05 Level

UNIVARIATE F TESTS

Variable	SS	MS	Error	F	P
Effectiveness	24	17	.799	20.42	.012*
Performance	29	31	4.11	7.16	.013*

*Significant at .05

TABLE 21

MULTIVARIATE ANALYSIS OF VARIANCE
OF PERFORMANCE AND EFFECTIVENESS BASED ON COMPANY SIZE
(NUMBER OF EMPLOYEES)

MATRIX OF MEANS

	Independent Variables	
Dependent Variables	Small Companies	Large Companies
Effectiveness	4.11	3.63
Performance	4.01	3.24
N	108	98

MULTIVARIATE ANALYSIS

Test Name	Value	F Value	P
Wilk's Lambda	.76	12.81	.011*
Hotelling	3.21	9.37	.011*

*Multivariate tests show significance at .05 Level

UNIVARIATE F TESTS

Variable	SS	MS	Error	F	P
Effectiveness	19	18	.7899	22.76	.022*
Performance	34	35	3.22	6.93	.003*

*Significant at .05

TABLE 22

MULTIVARIATE ANALYSIS OF VARIANCE OF PERFORMANCE AND EFFECTIVENESS BASED ON EUROPEAN BUSINESS

MATRIX OF MEANS

	Independent Variables	
Dependent Variables	European Business	Non European
Effectiveness	3.73	3.24
Performance	3.59	3.22
N	82	104

MULTIVARIATE ANALYSIS

Test Name	Value	F Value	P
Wilk's Lambda	.77	17.87	.047*
Hotelling	4.5	9.2	.042*

*Multivariate tests show significance at .05 Level

UNIVARIATE F TESTS

Variable	SS	MS	Error	F	P
Effectiveness	49.3	47.2	.87	14.73	.046*
Performance	39.1	28.6	4.99	12.49	.042*

*Significant at .05

TABLE 23

MULTIVARIATE ANALYSIS OF VARIANCE
OF PERFORMANCE AND EFFECTIVENESS BASED ON EXPORTS

MATRIX OF MEANS

	Independent Variables	
Dependent Variables	Export Companies	Non Exporting
Effectiveness	4.12	3.24
Performance	4.02	3.34
N	82	104

MULTIVARIATE ANALYSIS

	Test Name	Value	F Value	P
	Wilk's Lambda	.84	32.55	.000*
	Hotelling	3.2	24.43	.000*

*Multivariate tests show significance at .05 Level

UNIVARIATE F TESTS

Variable	SS	MS	Error	F	P
Effectiveness	43.8	37.3	.777	47.75	.000*
Performance	34.9	31.3	4.34	36.48	.000*

*Significant at .05

9.7 MANOVA SUMMARY AND CONCLUSIONS

The MANOVA results suggest a possible explanation for different performance results for ISO certified companies. Clearly, firm size, whether measured by sales volume or number of employees, affects system effectiveness and performance. Small firms report greater improvement in performance and system effectiveness. The reason is that small firms have less developed Quality Assurance systems, and ISO implementation advances the development of the overall system. Larger firms with mature Quality Assurance systems and well developed TQM systems gain less, if anything, from ISO implementation.

The result of improved system effectiveness and performance for companies involved in exporting and/or European business is less surprising. Increased export and European business was the motivation of many ISO certified companies in the first few years of ISO registration. The MANOVA conclusions must be viewed in the broader context of results to be discussed in the next two chapters.

CHAPTER TEN

CONCLUSIONS

10.1 INTRODUCTION

This dissertation examines relationships among Quality Assurance system components - system management, process quality management, ancillary services, product design, and system effectiveness. In addition, the relationships between system effectiveness, internal performance, and external performance are also examined. In Chapter 8, path analysis was used to test individual hypotheses. In this chapter, the relationships in these multi-construct models are developed and discussed in some detail.

10.2 DISCUSSION OF RELATIONSHIPS

10.2.1 Quality Assurance systems management and process quality management

The fundamental focus of the research presented in this dissertation is that of ISO 9000 as a Quality Assurance system. System management is, therefore, central to the very system and its functioning. Four elements of the ISO 9000

standard are directly related to system management. These elements are management responsibility, training, corrective and preventive action, and internal quality auditing. These elements, combined as system management, have a positive relationship with process quality management as well as product design and ancillary services. From factor analysis, the ISO elements related to process quality management are inspection and testing, inspection and test status, control of non-conforming product, document control, process control, and product ID and traceability.

Process quality management is the hub of Quality Assurance programs as well as Total Quality Management programs. Our finding demonstrates the necessity of a system approach. In this case, system management is a precedent of process quality management.

From a practioner standpoint, this is an important finding. It suggests that an implementation program for ISO 9000 should focus first on the elements of system management. While many authors have suggested that the ISO element of management responsibility comes first, they have overlooked other system elements such as training, corrective action, and internal auditing as a necessary system framework. Failure to fully establish a system framework, prior to the implementation of other ISO elements, would explain the poor success and extended time frames required to certify to ISO 9000.

10.2.2 *System management and ancillary services*

The ISO elements which load on the Quality Assurance component of ancillary services are servicing, statistical process control, and control of supplied products. Ancillary services are those required by the customer, or necessary for doing business with a customer. For ISO certified companies, statistical process control is viewed as a required customer service. This is a fundamental point which differentiates Quality Assurance from the broader concept of TQM, which includes statistical process control as part of process management. It should also be noted that SPC is part of process quality management in the broader QS 9000 standard for the auto industry.

As noted in Hypothesis 1, system management is a precedent for ancillary services. The role of management is fundamental for the overall functioning of Quality Assurance and long run improvement of the system.

10.2.3 *System management and product design*

In the ISO Quality Assurance system, product design refers to traditional engineering design functions as well as the element of contract review. Contract review, in manufacturing, includes an analysis of feasibility and process capability. Hypothesis 3 shows the importance of including

product design in the overall management of a Quality Assurance system.

Hypothesis 3 states that, ultimately, management is responsible for the development of proper design procedures. Positive and proactive top management involvement in the functioning of product design activities is fundamental to a Quality Assurance system. Furthermore, system management requires an annual review of the product design function. Another part of this positive relationship is the responsibility of top management, to assure product design for corrective action is implemented for product and process problems. This finding is further supported by research into total quality management which emphasizes top management involvement and leadership in product design, process quality management, and ancillary services.

10.2.4 *Ancillary services and process quality management*

Ancillary services, which include statistical techniques and control of customer supplied product, is chiefly a customer-driven system improvement. These customer requirements have a positive impact on the process quality management. In the broader scope of Total Quality Management, statistical process control evolves into a factor under process quality management. In the basic Quality Assurance model, SPC not only improves process control, but directly

improves inspection practices. In this sense, ancillary services are the customer's representative in the functioning of the process quality management component. It reinforces the idea that a basic Quality Assurance system is the foundation to TQM.

10.2.5 *Product design practices and process quality management*

The finding here represents a stronger view of product design in process quality management. It supports the need for design considerations and manufacturing capability to be viewed as part of an overall Quality Assurance system. Good design practices are precedent to the process quality management. This conclusion is supported by Hypothesis 5 and is fundamental to Quality Assurance systems. Like ancillary services, product design represents a tie to the customer and the customer needs. More importantly, it is the basis for mutual consideration of product design and manufacturing capability. A mutual effort can strengthen the function of process quality management. Similar conclusions are seen in other manufacturing models such as concurrent engineering. The more significant tie-in of product design and customer can be seen in the growth of reliability engineering. Reliability is a long range dimension of quality which is improved by design. This factor has been part of the expansion of

inspection practices in Quality Assurance systems via process quality management.

10.2.6 *Process quality management and system effectiveness*

The process quality management component contains the ISO elements of Inspection and Testing, Inspection, Measuring, and Test Equipment, Inspection and Test Status, Document and Data Control, Process Control, and Purchasing. Process quality management is the heart of the Quality Assurance system. The component of process quality management is positively impacted by: system management (Hypothesis 1), ancillary services (Hypothesis 4), and product design (Hypothesis 5). Process quality management has a direct impact on system effectiveness. In particular, there is a very strong link to the process quality management and customer satisfaction. This conclusion reinforces the role of ISO 9000 in improved customer relations and satisfaction.

10.2.7 *System effectiveness and system management*

Hypothesis 7 supports the existence of a feedback loop in the Quality Assurance system. It is the responsibility of top management to evaluate the effectiveness of the overall system, and that corrective action as well as preventive action is necessary for long term improvement. While process

quality management can be considered a middle management function, this component lacks the overall view necessary to correct the Quality Assurance system. For this reason, the feedback from system effectiveness goes to the system management component, not directly to the process management component. This conclusion of the role of top management as the leader in Quality Assurance is also supported in broader TQM models. This cybernetic feedback is provided by management using the ISO 9000 requirement of review meetings, internal audits, corrective action plans for system problems, and system training program maintenance.

10.2.8 *System effectiveness and external performance*

System effectiveness has a direct positive effect on external performance. External performance is defined as market share improvement and delivery performance. The proper functioning of a Quality Assurance system results in improved external performance. Here again, we see a benefit of ISO 9000 certification in that verification of the effectiveness of the Quality Assurance will improve external performance. Implementation of an ISO 9000 certified Quality Assurance system can be expected to improve external performance such as delivery performance. Increased market share can also be expected by ISO implementation.

10.2.9 *System effectiveness and internal performance*

Internal performance is defined as the operational results of scrap rate, rework, customer returns and customer claims. Hypothesis 9 shows that an effective Quality Assurance system will positively improve these operational results. Implementation of an ISO 9000 Quality Assurance system results in improved internal performance. This is an important finding, since some debate still exists as to the operational benefits of ISO 9000. This study shows a significant improvement in operational results as a result of ISO 9000 implementation.

10.2.10 *Internal performance and external performance*

While internal performance deals with operational results, external performance is directly related to customer satisfaction. External measures are delivery performance, market share, and new markets. Hypothesis 10 states that an improvement in internal operational results translates into an improvement in customer satisfaction. As scrap rates and rework rates decrease, this quality improvement results in delivery performance. Delivery performance improves because the manufacturing time is shortened by the elimination of rework and re-make orders due to quality.

10.2.11 *System effectiveness and performance are influenced by sales volume*

Smaller companies, as measured by sales volume, show improved system effectiveness and performance over larger companies. This difference appears to be related to the fact that smaller companies have less developed Quality Assurance systems and, thus, ISO implementation offers improvement and growth. In larger companies, however, less is gained by ISO implementation due to better evolved Quality Assurance systems.

10.2.12 *System effectiveness and performance are influenced by European business*

While our research has shown a relationship between improved system effectiveness and performance with European business, this is probably sample related. Early ISO certified companies did so to gain or maintain European business. Whether this is a continuing trend or not needs further study.

10.3 CONCLUSION

This chapter directly answers the initial research questions. First, the ISO 9000 variables result in the development of underlying Quality Assurance system components. These hypothesized Quality Assurance components do align in a testable, functioning model. Secondly, the proposed Quality Assurance system leads to system effectiveness and, ultimately, an improvement in internal and external performance. Contextual variables of size (sales volume and number of employees) were found to negatively affect effectiveness and performance. In the next chapter, specific recommendations will be made for both the practioners and researchers on the application of the models.

CHAPTER ELEVEN

SUMMARY, RECOMMENDATIONS, AND CONCLUSIONS

11.1 SUMMARY

The literature has not been clear or unified on the functions of ISO 9000 as a Quality Assurance system. In this research, an ISO 9000 based Quality Assurance system was established. Furthermore, the basic foundation of ISO 9000 and Quality Assurance is analyzed in relationship to the broader view of Total Quality Management. This research is consistent with the research on TQM and fully describes a Quality Assurance subsystem as part of TQM.

The ISO 9000 Quality Assurance system is a cybernetic system which monitors and adjusts for system effectiveness via a system management function. The responsibility and control of the overall Quality Assurance system is with upper management. This responsibility, as detailed in ISO 9000, is to establish a company mission, review system effectiveness, maintain system training, develop corrective action, and maintain an internal auditing function. In this respect, system management interacts positively with the other components of the Quality Assurance system: product design, process quality management, and ancillary services.

The ISO 9000 Quality Assurance model developed reinforces the interaction of the customer requirements via product design and ancillary services such as SPC and contract review. The model posits that product design is an antecedent to the process quality management. This finding is more consistent with recent research on Total Quality Management while representing an evolutionary component of Quality Assurance. More importantly, this finding shows the nature of Quality Assurance as a foundation or building block to build a broader Total Quality Management system.

The strongest finding of this research is that the implementation of an ISO 9000 Quality Assurance system results in improvements in both external and internal performance. The Quality Assurance system results in internal improvements such as improved scrap rate, reduced rework, and reduced customer complaints. Thus, improved internal quality leads to improvements in external quality performance such as customer satisfaction. The implementation of ISO 9000 also is a basic foundation for Total Quality Management which offers a number of additional measurable benefits.

11.2 SYSTEM IMPLEMENTATION

The fourth research question posed in Chapter 1 deals with how to implement ISO 9000. The model developed in this dissertation can help answer that question. In the cybernetic model presented, control and monitoring is achieved by the

system component, system management. We have shown that system management is an antecedent to the other system components of product design, ancillary services, and management of process quality. ISO 9000 implementation should focus, therefore, first on the development of the Quality Assurance component of system management. Since internal auditing, corrective action loops, and training are part of the system management, these elements should be established first. In practice, ISO implementation plans, to date, have focused on ISO elements such as documentation and quality system to start with. The present research suggests that the system management framework should be established first. In the next few paragraphs, the directions for future research, as a follow-up to the current work, are described as recommendations for further research.

11.2.1 RECOMMENDATION: The model should be tested in companies that have ISO 9000 and full TQM implementation.

TQM is an evolutionary process built on a Quality Assurance foundation. This research supports that Quality Assurance is a basic subsystem needed to build TQM on. This basic ISO 9000 model should be tested in companies in various stages of TQM implementation. The evolutionary nature of the transition from Quality Assurance to TQM can then be studied. This would be of importance in the overall study of quality management.

11.2.2 RECOMMENDATION: Future Research should incorporate additional potential antecedents to system effectiveness for Quality Assurance.

The present research focused on the twenty elements of ISO 9000 as a basis for Quality Assurance. Other potential Quality Assurance elements were not considered. Factors such as employee involvement and management styles, which are known to be significant in broader TQM models, in particular, offer potential studies of Quality Assurance systems.

11.2.3 RECOMMENDATION: More performance measures should be considered for study.

Other areas of improved performance for study include safety, profitability, and reduced purchasing costs. Additional performance measures, both internal and external, should be considered for future study using the model framework proposed. In particular, measures of competitive capabilities should be included.

11.2.4 RECOMMENDATION: Future Research should conduct confirmatory factor analysis.

Linear structural modeling tests show how well a researcher's hypothesized model fits the data, and a priori

model is developed. Confirmatory factor analysis tests alternative models statistically against the sample data. Confirmatory factor analysis allows for a systematic and more rigorous test of alternative factor structures. In this respect, confirmatory studies test hypothesized measurement models against new data from the same referent population.

11.2.5 **RECOMMENDATION: Compare country and cultural differences in the use of ISO 9000 and ISO benefits.**

The nature of ISO 9000 having very deep European roots suggests possible differences in benefits and use of ISO for different countries. The MANOVA findings suggest at least a possibility that companies with European business ties got more benefits from ISO 9000 implementation. This should be explored in future research.

11.3 CONCLUSION

The growth of ISO 9000 as a quality system has been unmatched in international cooperation and national efforts. The literature, however, is lacking in a systematic research study of ISO's Quality Assurance elements as a functioning system. The purpose of this dissertation was to develop a system model of ISO 9000 to meet that deficiency. Using the

system model of ISO 9000 to meet that deficiency. Using the twenty Quality Assurance elements of ISO 9000, factor analysis was applied to develop a system framework. LISREL methodology was used to assess structural relationships in a proposed Quality Assurance model.

The proposed model and factors were subjected to a variety of reliability and validity tests. The reliabilities obtained (.87 or better) are higher than most reported in empirical research in quality and manufacturing. Model fits as measured by LISREL methodology were also relatively high (.95 or better).

The hypothesized model for the ISO 9000 Quality Assurance system offers a base for ISO implementation and evaluation. The model developed is cybernetic in nature, using system management and system feedback to improve system functioning. It further more defines the system functioning into three components: product design, ancillary services, and the process quality management. The ISO 9000 model is the foundation for a Total Quality Management system. This dissertation represents the first empirical study of the Quality Assurance subsystem. This dissertation also one of the first to use LISREL methodology to assess structural relationships in Quality Assurance.

CHAPTER TWELVE

ISO 9000 IN THE YEAR 2000

At the completion of this research, an international committee reviewing ISO 9000 proposed a broad revision of the standard. In August of 1998, ISO Committee 176 issued a draft of a new version of ISO 9000 to ultimately be published in November 2000. The draft is being circulated for comment among quality professionals via the internet. The proposed ISO 9000 draft represents a shift in terminology and content, and, to a large degree, philosophy. While the new draft moves towards an overall system model, it still has some problems. The new draft uses a clause structure to outline its requirements. The clause structure is outlined in Table 24.

12.1 New Concepts and Philosophy

The new draft of ISO 9000 can be considered a shift in philosophy. Clearly the new draft moves ISO 9000, a basic Quality Assurance system, toward a ***Total Quality Management System***. In addition, the ***overall scope is expanded*** better into both operations and service functions of a company. Both of these movements are driven by an ***emphasis on customer*** input

and output. Finally, the new draft develops a true ***system approach*** to the standard similar to that developed in this dissertation. However, an operational system model is not developed in the new draft standard.

12.2 Draft ISO 9000 as a TQM Model

The research in this dissertation has successfully modeled ISO 9000 as a Quality Assurance subsystem and foundation to TQM. In fact, in the implementation of TQM, a Quality Assurance subsystem can be considered a necessary first step (Skrabec, 1994). Many criticisms of ISO 9000 have been that it fails to meet TQM criteria (Sayle, 1994; Surkovic et al, 1996). However, ISO 9000 never claimed any scope beyond that of a Quality Assurance system. Most view Quality Assurance as the keystone of broader TQM systems (Voehl et al, 1994). The new ISO draft broadens its scope into TQM. Table 25 shows the additional elements of the new ISO 9000 that are TQM elements. Clearly, draft ISO 9000 is targeted at being a TQM system, with a major subsection of customer related processes covering the following:

a) Identification of customer requirement
b) Review of customer requirements
c) Capability to meet defined requirements
d) Customer communication
e) Customer property
f) Customer satisfaction analysis

TABLE 24

CLAUSE STRUCTURE OF THE NEW ISO 9000 DRAFT	
Clause 1	Scope
Clause 2	Normative Reference
Clause 3	Terms and Definitions
Clause 4	Quality Management System Requirements
Clause 5	Management Responsibility 5.1 General 5.2 Customer Needs 5.3 Policy 5.4 Objectives and Planning 5.5 Quality Management System 5.6 Management Review
Clause 6	Resource Management 6.1 General 6.2 Human Resources 6.3 Other Resources
Clause 7	Process Management 7.1 General 7.2 Customer Related Processes 7.3 Design 7.4 Purchasing 7.5 Production 7.6 Control of Non Conforming Product 7.7 Post Delivery Services
Clause 8	Measurement, Analysis, and Improvement 8.1 General 8.2 Measurement 8.3 Analysis 8.4 Improvement

These new subsection additions bring ISO 9000 into the TQM fold. Draft ISO 9000 overcomes the early criticisms of the auto industry in the development of QS 9000 (Stamates, 1996). Draft ISO 9000 approaches and appears to meet QS 9000 requirements with the following exceptions:

1) SPC tools are not fully specified as in QS 9000.

2) Employee teams are not fully specified as in QS 9000.

3) There are no industry specific requirements.

For practioners, QS 9000 companies could be considered draft ISO 9000 compliant but not vice versa.

12.3 Comparison of Draft ISO 9000 to the Research Model

Draft ISO 9000 represents a basic TQM system while the research model developed in this dissertation is for a Quality Assurance subsystem. As presented in this dissertation, Quality Assurance is the basic building block of an overall TQM quality system. Table 26 shows the system components of Draft ISO 9000 and the research model.

TABLE 25

ADDITIONAL TQM ELEMENTS OF THE NEW DRAFT ISO 9000	
Information Resources	6.3.1
Infrastructure	6.3.2
Work Environment	6.3.3
Quality Planning	5.4.3
Customer Related Processes	7.3
Measurement of Customer Satisfaction	8.2.1.1
Post Delivery Services	7.7
Improvement Processes	8.4.3

12.3.1 Similarities of Draft ISO 9000 and Current Research Model

A. Both models are cybernetic systems with feedback and control loops.

B. Both models emphasize management responsibility and system management performance feedback and system control.

C. Both models have a core component of process management.

12.3.2 Differences of Draft ISO 9000 and Current Research Model

A. Draft ISO 9000 presents a schematic model while the research presented in this dissertation developed a testable model.

B. The model in this dissertation clearly identifies the nature and rate of feedback as a cybernetic system model, while Draft 9000 only identifies the need of a feedback loop.

C. Draft ISO 9000 confuses the procedures of inspection with the results by viewing them together as a system component. This research separates measurement into system effectiveness and performance which provides feedback for system improvement.

12.4 The Research Model as an Operational Platform for TQM

The major conceptual differences are that Draft ISO 9000 functionally separates all product, process, and customer inspection into a measurement analysis component, while the research model has this as part of process quality management. This points to a fundamental difference. The research model integrates the process and Quality Assurance whereas Draft ISO 9000 separates them. Moreover, this research model develops a Quality Assurance subsystem as a foundation of a TQM model which is consistent with the literature.

The integration of the process and Quality Assurance is supported by the Quality Assurance and TQM literature (Ross, 1995; Schlickman, 1998). This integration is fundamental to Japanese models (Imai, 1986; Ishikawa, 1985). Draft ISO 9000 reinforces the traditional American and European approach to separate Quality Assurance systems (Saco, 1997). The advantage of quality systems integration, as proposed by this research, is more consistent with the quality philosophy of Deming.

The research model offers key advantages over Draft ISO 9000 in implementation as well. The research model is based on practical experience and empirical research. The component of system management offers a first step for implementation because it includes training, development of a corrective action loop, audit feedback, and management review. Draft ISO

9000 spreads these functions over three components, making implementation difficult. System implementation was also overlooked by ISO 9000 and has led to many approaches (Stamates, 1996). The research model offers a logical systems approach where control and feedback form a system framework on which to build.

TABLE 26

COMPARISON OF QUALITY ASSURANCE ELEMENTS IN DRAFT ISO 9000 AND CURRENT RESEARCH MODEL	
Draft ISO 9000	Current Research Model
Management Responsibility Clause 5	**Quality Assurance System Management**
4.1 Management Responsibility 4.5 Documentation 4.16 Control of Quality Records	4.1 Management Responsibility 4.14 Corrective Action 4.17 Audits 4.18 Training
Resource Management Clause 6	**Ancillary Services**
4.1 Management Responsibility 4.18 Training	4.7 Customer Product 4.19 Servicing 4.20 SPC
Process Management Clause 7	**Design of Product**
4.3 Contract Review 4.4 Design 4.6 Purchasing 4.8 Product ID 4.9 Process Control 4.12 Test Status 4.13 Non-conforming 4.15 Handling	4.3 Contract Review 4.4 Design Control
Measurement/Analysis Clause 8	**Process Quality Management**
4.10 Inspection 4.11 Test Equipment 4.13 Non-conforming 4.14 Corrective Action	4.6 Purchasing 4.9 Process Control 4.8 Product ID 4.10 Inspection 4.11 Test Equipment 4.12 Test Status 4.13 Non-conforming

Finally, the proposed research model offers a simpler and better system design than Draft ISO 9000. First, Draft ISO 9000 combines the system of measurement with measurement results. The research model more properly models measurement techniques such as the inspection elements, under the system component of process quality management, while the research model places the actual measurements in the system effectiveness component. This correctly puts system effectiveness (measurements) as a component for system management feedback. Furthermore, this research demonstrated the relationship and feedback between system effectiveness and system management (Hypothesis 7). Certainly, Draft ISO 9000 establishes a feedback loop in a system framework which goes beyond the current ISO 9000, but lacks empirical proof. The research model, however, based on empirical research, provides for incorporating feedback in a system framework.

BIBLIOGRAPHY

Anderson, J., Cleveland, G. and Schroeder, R., "Operation Strategy - A Literature Survey", Journal of Operation Management, Vol. 8, 1989, pp. 189-214.

Anderson, J., Rungtusanatham, M., Schroeder, R. and Devara, S., "A Path Analytic Model of the Theory of Quality Management", Decision Sciences, Vol. 26, No. 3, 1995, pp. 637-650.

Asanuma, B., "Manufacturer-Supplier Relationships in Japan", Journal of Japanese and International, Vol. 3, 1989, pp. 1-30.

Benson, G.P., Saraph, J.V. and Schroeder, R.G., "The Effects of Organizational Context on Quality Management: An Empirical Investigation", Management Science, Vol. 37, No. 9, September, 1991, pp. 1107-1124.

Beohling, W., "Europe 1992: Its Effect on International Standards", Quality Progress, June, 1990, pp. 29-32.

Black, J. The Design of the Factory with a Future, McGraw-Hill, New York, 1991.

Bogozzi, R. and Philips, L., "Representing and Testing Organizational Theories", Administrative Science, Vol. 27, 1982, pp. 459-489.

Bonaccossi, A. and Lipparini, A., "Strategic Partnerships in New Product Development", Journal of Product Innovation Management, Vol. 11, 1994, pp. 134-145.

Chase, Richard B. and Garvin, David A., "The Service Factory", Harvard Business Review, July-August, 1989, pp. 61-69.

Chase, Richard B., Kumar, K. Ravi and Youngdahl, William E., "Service-Based Manufacturing: The Service Factory", Production and Operations Management, Vol. 1, No. 2, Spring, 1992, pp. 175-184.

Chase, Richard B. and Tansik, David A., "The Customer Contact Model for Organizational Design", Management Science, Vol. 29, No. 9, September, 1983, pp. 1037-1050.

Chowdhury, S. and Zimmer, K., QS 9000 Pioneers, Quality Press, 1996.

Cohen, W. and Levinthal, M. "Absorptive Capacity: A New Perspective", Administrative Science Quarterly, March, 1990.

Day, G., "Continuous Learning About Markets", California Management Review, Summer, 1994.

Deming, William, Out of the Crisis, MIT, Cambridge, 1982.

DeVellis, R. Scale Development, Sage Publications, Beverly Hills, 1991.

DiBella, N. and Gould, A., "Understanding Organizations as Learning Systems", Sloan Management Review, Winter, 1995.

Doll, William and Vonderembse, Mark, "The Evolution of Manufacturing Systems: Towards the Post Industrial Enterprise", Omega, Vol. 19, No. 5, 1991, pp. 401-411.

Escoe, A., Nimble Documentation: A Practical Guide for World Class Organizations, Quality Press, 1997.

Evans, J. and Lindsay, W. The Management and Control of Quality, West Publishing Company, Minneapolis-St. Paul, 1993.

Feigenbaum, A. Total Quality Control, McGraw-Hill, New York, 1983.

Ferdows, K. and DeMeyer, A., "Lasting Improvement in Manufacturing: In Search of a New Theory", Journal of Operations Management, Vol. 9, No. 2, 1990, pp. 168-184.

Flynn, B.B., Schroeder, R.G. and Sakakibara, S., "A Framework for Quality Management Research and an Associated Measurement Instrument", Journal of Operations Management, Vol. 11, 1994, pp. 339-366.

Flynn, B.B., Schroeder, R.G. and Sakakibara, S., "Relationship Between JIT and TQM: Practices and Performance", Academy of Management Journal, Vol. 38, 1995, pp. 1325-1360.

Garvin, D., "Building a Learning Organization", Harvard Business Review, July-August, 1993.

Garvin, D., "Eight Dimensions of Quality", Harvard Business Review, November-December, 1987, pp. 101-109.

Gorsuch, R. Factor Analysis, Lawrence-Erlbaum, New Jersey, 1983.

Grell, P., "Multicriteria Approach to Concurrent Engineering", International Journal of Production Economics, Vol. 34, 1994, pp. 99-113.

Gronroos, C., "From Marketing Mix to Relationship Marketing", Management Decision, Vol. 32, No. 2, 1994, pp. 4-19.

Hair, J., Anderson, R., Tothan, R and Black, W., Multivariate Analysis, Macmillan, New York, 1991.

Handfield, R., "A Resource Dependent Perspective of Just-In-Time", Journal of Operations Management, Vol. 11, 1993, pp. 289-311.

Hayes, Robert and Lamprecht, Joseph, "Germany's World Class Manufacturers", Harvard Business Review, July-August, 1980.

Heady, R. and Smith, M., "One Empirical Study of the Topical Differences Between Total Quality Management and Quality Management", Quality Management Journal, Spring, 1995.

Imai, M. Kaizen - The Key to Japan's Competitive Success, McGraw-Hill, New York, 1986.

Ishikawa, K. Guide to Quality Control, Asian Productivity Organization, Tokyo, 1974.

Ishikawa, K. What is Total Quality Control, Prentice-Hall, Englewood Cliffs, 1985.

Joseskorg, K. and Sorbom, D., LISREL - Analysis of Linear Structural Relationships, Scientific Software, Inc., 1986.

Juran, J., "A Quality Trilogy", Quality Progress, Vol. 19, 1986, pp. 19-25.

Juran, J., "Product Quality", Management Review, June/July, 1981.

Juran, J.M. A History of Managing For Quality, ASQC Pres, Milwaukee, 1995.

Juran M. and Gryna, F. Quality Planning, McGraw-Hill, New York, 1986.

Kachigan, S. Multivariate Statistical Analysis, Radium Press, New York, 1991.

Kalwani, M. and Narayandas, N., "Long Term Manufacturing Relationships", Journal of Marketing, Vol. 59, 1995, pp. 1-16.

Kaplan, R. and Norton, D., "Balanced Scorecard - Measures that Drive Performance", Harvard Business Review, 1992, Jan., pp. 71-79.

Kerlinger, A. Foundations of Behavioral Research, McGraw-Hill, 1986.

Kuei, Char-Hua and Modu, C., "Managers Perceptions of Factors Associated with Quality Dimensions", Quality Management Journal, Spring, 1995.

Lamprecht, James, "ISO 9000 and the Service Sector", ASQC Press, 1994.

Larson, P. and Sinka, A., "The TQM Impact: A Study of Quality Manager's Perceptions", Quality Management Journal, Spring, 1995, pp. 53-60.

Layes, P. and Falkenberg, M., "Workgroups in America Today", Journal for Quality and Participation, Vol. 14, No. 3, 1991, pp. 58-69.

Lee, S. and Ebrahimpoor, M. "Analysis of Japanese Quality Systems", SAM Advanced Management, 1985, pp. 24-31.

Leong, G., Snyder, D. and Ward, P., "Research in the Process and Content of Manufacturing Strategy", OMEGA, Vol. 18, 1990, pp. 109-122.

Lewin, Arie and Minton, John W., "Determining Organizational Effectiveness: Another Look and an Agenda for Research", Management Science, Vol. 32, No. 5, May 1986, pp. 514-538.

Lipsey, M. Design Sensitivity: Statistical Power, Beverly Hills, Sage, 1990.

Luthans, F., Organizational Behavior, McGraw-Hill, New York, 1977.

MacLean, G., Documenting Quality for ISO 9000 and Other Industry Standards, Quality Press, 1993.

Mai, R. Learning Partnerships - How American Companies Implement Organizational Learning, Irwin, Chicago, 1996.

Margenau, H. The Nature of Physical Reality, McGraw-Hill, New York, 1950.

McTeer, M. and Dole, B., "How to Achieve ISO 9000 Series Registration: A Model for Small Companies", Quality Management Journal, Vol. 3, 1995.

Mears, P. and Voehl, F., Executive Guide to Implementing Quality Systems, St. Lucie Press, 1996.

Mintzberg, H., "Crafting Strategy", Harvard Business Review, July-August, 1987.

Mondon, Y., Toyota Production System, New York, AIIE, 1982.

Murakoshi, Toshihiro, "Customer-Driven Manufacturing in Japan", International Journal of Production Economics, Vol. 37, 1994, pp. 63-72.

Murphy, T., "Quality Gap", Ward's Auto World, February, 1998.

Nagal, R. and Bhargana, Piyush, "Agility: The Ultimate Requirement for World Class Manufacturing", National Productivity Review, Summer, 1991, pp. 331-342.

Nakane, J. Manufacturing Future Survey in Japan, System Science Institute, Tokyo, May, 1990.

Nemetz, P. and Fry, L., "Flexible Manufacturing Organizations", Academy of Management Review, Vol. 13, 1988, pp. 627-638.

Noble, M., "Manufacturing Strategy: Testing Cumulative Model", Decision Sciences, Vol. 26, 1995, pp. 693-704.

Nunaka, I. and Takeuchi, H. The Knowledge-Creating Company, Oxford University, 1995, New York.

Nunnally, J. Psychometric Theory, New York, McGraw-Hill, 1967.

Nunnally, J. Psychometric Theory, New York, McGraw-Hill, 1978.

Peters, T. Thriving on Chaos, Alfred Knoff, New York, 1988.

Porter, M. Competitive Advantage, Free Press, New York, 1985.

Randall, Richard, "Randall's Practical Guide to ISO 9000", Addison-Wesley Publishing, 1995.

Rao, S. Subba, Ragu-Nathan, T. S., and Solis, Luis, "Does ISO 9000 Have an Effect on Quality Management Practices?", Total Quality Management, Vol. 8, 1997, pp. 345-51.

Ross, I. Total Quality Management, St. Lucie Press, Delray Beach, 1995.

Saco, R., "The Criteria: A Looking Glass to Americans Understanding of Quality", Quality Progress, November, 1997.

Saraph, J., Benson, P., and Schroeder, R., "An Instrument for Measuring Critical Factors of Quality Management", Decision Sciences, Vol. 204, 1989, pp. 810-829.

Sayle, A., Meeting ISO 9000 in a TQM World, Quality Press, 1994.

Schlickman, J., ISO 9000 Quality Management System Design, Quality Press, 1998.

Schmenner, R., "The Merit of Making Things Fast", Sloan Management Review, Fall, 1988.

Schnoberger, J., World Class Manufacturing, Free Press, NY, 1991.

Sears, J., "Changing Role of The Quality Inspection Function", Quality Progress, July, 1983, pp. 12-17.

Sellitz, C., Wrightsman, L. and Cook, S., Research Methods in Social Relations, Holt, Rinehart and Winston, New York, 1976.

Senge, P., "The Leader's New Work: Building Learning Organizations", Sloan Management Review, Fall, 1990.

Shina, S., Concurrent Engineering and Design, Van Nostrand Reinhold, New York, 1991.

Shores, Richard., A TQM-Approach to Achieving Manufacturing Excellence, ASQC Press, Milwaukee, 1990.

Sinha, M. and Willborn, W., Management of Quality Assurance, John Wiley & Sons, 1985.

Sitkin, S., Sutcliffe, K. and Schroeder, R., "Distinguishing Control from Learning in Total Quality Management: A Contingency Perspective", Academy of Management, July, 1994.

Skinner, W., "Manufacturing the Missing Link in Corporate Strategy", Harvard Business Review, Vol. 47, 1969, pp. 136-145.

Skrabec, Q., "Customer Concern Teams", Quality Progress, June, 1994.

Skrabec, Q., "Integrating Inspection into TQM", Total Quality Review, March, 1994.

Skrabec, Q., "Ishikawa Process Classification", Quality Engineering, Vol. 3, No. 4, 1991, pp. 517-528.

Skrabec, Q., "Transition from 100% Inspection to Process Control", Quality Progress, April, 1989, pp. 35-38.

Skrabec, Q., Rao, S. Subba, Ragu-Nathan, T. S. and Bhatt, Bhal, "ISO 9000: Do the Benefits Outweigh the Costs?", Industrial Management, December, 1997.

Skrabec, Q., Rao, S. Subba, Ragu-Nathan, T. S. and Bhatt, Bhal, "The Hidden Benefits of ISO 9000", Work in Progress, 1999.

Slater, R. Integrated Process Management, McGraw-Hill, New York, 1991.

Sohal, A. and Morrison, M., "Is There a Link Between Total Quality Management and Learning Organizations", TQM Magazine, 1995.

Stamates, D., Integrating QS 9000 with your Quality System, Quality Press, 1996.

Stevens, James, Applied Multivariate Statistics for the Social Sciences, Lawrence Ehlbaun Associates, New Jersey, 1996.

Stone, E., Research Methods in Organizational Behavior, Goodyear Publishing, Santa Monica, 1978.

Sullivan, L.P., "Quality Function Deployment", Quality Progress, June, 1986, pp. 39-50.

Surkovic, S. and Handfield, R., "Use of ISO 9000 and the Baldridge Award in Supplier Quality Evolution", Journal of Purchasing and Materials Management, Vol. 32, 1996, pp. 2-12.

Takenchi, H., "Learning from the Japanese", California Management Review, Vol. 23, No. 4, 1981, pp. 4-19.

Thompson, P., Quality Circles: How to Make Them Work, AMACOM, New York, 1982.

Tokeuchi, H. and Queich, J., "Quality is More Than Making Good Product", Harvard Business Review, Vol. 61, 1983, pp. 139-145.

Varadarajin, P. and Cunningham, M., "Strategic Alliances", Journal of Academy of Marketing Sciences, Vol. 23, 1995, pp. 282-296.

Voehl, F., Jackson, P. and Ashto, D. ISO 9000, An Implementation Guide, St. Lucie Press, Delray Beach, 1994.

Von Hippel, Eric, "Lead Users: A Source of Novel Product Concepts", Management Science, Vol. 32, No. 7, July, 1986, pp. 791-805.

Von Hippel, Eric, "Successful Industrial Products from Customer Ideas", Journal of Marketing, January, 1978, pp. 39-52.

Wheelwright, S., "Restoring the Competitive Edge in US Manufacturing", California Management Review, Vol. 27, No. 3, 1985, pp. 26-29.

Whybark, D. Clay, "Marketing's Influence on Manufacturing Practices", International Journal of Production Economics, Vol. 37, 1994, pp. 41-50.

Zuckerman, A. and Hurwitz, A., "ISO-9000 as a Communication Tool", Quality Progress, July, 1996, p. 23.

APPENDIX A

SCALES

I. ISO ELEMENT MEASUREMENT SCALE

MANAGEMENT RESPONSIBILITY
QUALITY SYSTEM
CONTRACT REVIEW
DESIGN CONTROL
DOCUMENT AND DATA CONTROL
PURCHASING
CONTROL OF CUSTOMER SUPPLIED PRODUCT
PRODUCT ID AND TRACABILITY
PROCESS CONTROL
INSPECTION AND TESTING
CONTROL OF INSPECTION, TESTING AND MEASURING EQUIPMENT
INSPECTION AND TESTING
CONTROL OF NON-CONFORMING PRODUCT
CORRECTIVE AND PREVENTIVE ACTION
HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY
QUALITY RECORDS
TRAINING
INTERNAL QUALITY AUDITS
SERVICING
STATISTICAL TECHNIQUES

II. BENEFITS SCALE

ABLE TO SUSTAIN MARKET
ABLE TO INCREASE MARKET
IMPROVEMENT IN PRODUCTION EFFICIENCY
IMPROVEMENT IN CUSTOMER DELIVERY
REDUCTION IN CUSTOMER COMPLAINTS
REDUCTION IN CASES OF NON-CONFORMITY
REDUCTION IN COST OF PRODUCTION
IMPROVEMENT IN PROFITABILITY
IMPROVEMENT IN PERCEPTION
REDUCTION IN QUALITY AUDITS
IMPROVEMENT IN QUALITY AWARENESS
IMPROVEMENT IN MANAGEMENT CONTROL
IMPROVEMENT IN CUSTOMER SERVICE
IMPROVEMENT IN CUSTOMER SATISFACTION
REDUCTION IN WARRANTY CLAIMS
ACCESS TO EXPORT MARKETS
ACCESS TO DOMESTIC MARKET
IMPROVEMENT IN EMPLOYEE MORALE
IMPROVEMENT IN JOB SATISFACTION
IMPROVEMENT IN DOCUMENTATION
INTER COMPANY COMMUNICATION
COMPETITIVE ADVANTAGE
IMPROVEMENT IN SOP'S
REDUCTION IN CUSTOMER REJECTIONS
IMPROVEMENT IN PURCHASING
IMPROVEMENT IN PRODUCT DESIGN
IMPROVEMENT JOB SKILLS
IMPROVEMENT IN DELIVERY

IMPROVEMENT IN JOB PERFORMANCE
REDUCTION IN AUDIT RESOURCES
REDUCTION IN INTERNAL SCRAP
IMPROVEMENT CUSTOMER RESPONSE
IMPROVEMENT IN EMPLOYEE KNOWLEDGE
IMPROVEMENT IN SAFETY PROGRAMS
IMPROVEMENT IN ACCOUNTING PRACTICES
IMPROVEMENT IN HUMAN RESOURCES
EVERYONE IS CLEAR ON JOB

III. PERFORMANCE SCALE

REJECTION RATE
REWORK
CUSTOMER RETURNS
TRAINING EXPENDITURES
ON TIME DELIVERY
NUMBER OF CERTIFICATIONS
NUMBER OF AUDITS
NUMBER OF SUPPLIERS
EXPORT AS A PERCENT OF SALES
MARKET SHARE
NUMBER OF CUSTOMERS WITH CERTIFICATION

APPENDIX B

QUESTIONNAIRE

ISO-9000
Facilitators and Barriers
A Multi-Country Study

Dr. Subba Rao
Dr. T. S. Ragu-Nathan
Dr. Bhal Bhatt
Mr. Quentin Skrabec
College of Business Administration
The University of Toledo
Toledo, Ohio 43606-3390

General Instructions

This questionnaire is part of a study underway to document the factors which act as facilitators and barriers for the successful implementation of ISO-9000 standards in an organization and to understand what type of organizations decide to apply for this certification and why.

The questionnaire is divided into 12 sections. Most of the questions require that you choose the alternative that best fits your views on the topic. There are no correct or incorrect answers, and we are interested only in your perception. We estimate that it will take you between 25 to 30 minutes to fill the questionnaire. We would like to assure you that the information provided by you will be treated in the strictest confidence. Your response will be entered in a coded format and in no instance will a company ever be identified as having given a particular response.

Thank you for your cooperation. We believe that, with your assistance, this study will be in a position to answer some of the questions raised while deciding to apply for ISO 9000 certification. A business-reply envelope is enclosed for your use. A summary report of the findings will be mailed to you if you so desire.

If you wish to receive the summary report of the findings please provide your name and address or attach your business card.

_____

_____

_____

_____

1. Do you have knowledge about ISO 9000/QS 9000 certification ____ Yes ____ No

If your answer is No do not proceed any more and return the questionnaire with your business card so that we will not send you reminders. Thanks.

2. The position of your Company/Division ISO 9000 certification is:

____ ISO 9001 certified
____ ISO 9002 certified
____ ISO 9003 certified
____ We are not certified but plan to go for certification in the next two years
____ We are not interested in ISO/Q5 certification

3. **The following statements have been identified as reasons for seeking ISO 9000 /QS 9000 Certification in the literature. Please circle the appropriate number to indicate the strength of your agreement with these statements.**

5 = strongly agree; 4 = mildly agree; 3 = neutral; 2 = mildly disagree; 1 = strongly disagree; na = not applicable or do not know

To keep current customers	5	4	3	2	1	na
To gain customers	5	4	3	2	1	na
To improve efficiency/productivity	5	4	3	2	1	na
To improve customer service	5	4	3	2	1	na
To be considered for competitive bids	5	4	3	2	1	na
To establish base for quality improvement	5	4	3	2	1	na
To meet corporate directive	5	4	3	2	1	na
To keep up with competing firms	5	4	3	2	1	na
To improve export potential	5	4	3	2	1	na

4. **The following statements have been identified as barriers to seeking ISO 9000 /QS 9000 Certification in the literature. Please circle the appropriate number to indicate the strength of your agreement with these statements.**

5 = strongly agree; 4 = mildly agree; 3 = neutral; 2 = mildly disagree; 1 = strongly disagree; na = not applicable or do not know

Employee resistance	5	4	3	2	1	na
Lack of management commitment	5	4	3	2	1	na
Conflicting interpretation of standards	5	4	3	2	1	na
Lack of sufficient time	5	4	3	2	1	na
Lack of information	5	4	3	2	1	na
Lack of company resources (financial/personnel etc.)	5	4	3	2	1	na
Additional training requirements	5	4	3	2	1	na
Additional Procedure creation	5	4	3	2	1	na
Additional quality documentation	5	4	3	2	1	na
Non-flexible of company policies and procedures	5	4	3	2	1	na
Lack of a quality system	5	4	3	2	1	na
Limited human resources	5	4	3	2	1	na
High cost of certification and maintenance	5	4	3	2	1	na
Requirement of extensive changes to existing systems	5	4	3	2	1	na
Another set of quality standards adopted in our industry	5	4	3	2	1	na

5. The following items have been identified as the cost of ISO 9000/QS 9000 implementation in the literature. Please circle the appropriate number to indicate the strength of your agreement with these statements.

5 = strongly agree; 4 = mildly agree; 3 = neutral; 2 = mildly disagree; 1 = strongly disagree; na = not applicable or do not know

*If you are **not certified** please mark the **left side only** which asks for your perception of possible costs/benefits from ISO 9000/QS 9000 certification.*

*If you are **certified** please **mark both sides**. Left side asks for the anticipated costs/ benefits when you were deciding to get ISO 9000/QS 9000 certification and the right side measures the actual costs/benefits derived out of ISO 9000 /QS 9000 implementation.*

Anticipated Costs						*Actual Costs*					
5	4	3	2	1	na.....Clerical costs.....5	4	3	2	1	na	
5	4	3	2	1	na.....Training costs.....5	4	3	2	1	na	
5	4	3	2	1	na.....Surveillance cost.....5	4	3	2	1	na	
5	4	3	2	1	na.....Customer audit costs.....5	4	3	2	1	na	
5	4	3	2	1	na.....Processing costs.....5	4	3	2	1	na	
5	4	3	2	1	na.....Order processing costs.....5	4	3	2	1	na	
5	4	3	2	1	na.....Labor costs.....5	4	3	2	1	na	
5	4	3	2	1	na.....Temporary manpower costs.....5	4	3	2	1	na	
5	4	3	2	1	na.....Permanent employment costs 5	4	3	2	1	na	

6. The following items have been identified as the benefits of ISO 9000/QS 9000 implementation in the literature. Please circle the appropriate number to indicate the strength of your agreement with these statements.

5 = strongly agree; 4 = mildly agree; 3 = neutral; 2 = mildly disagree; 1 = strongly disagree; na = not applicable or do not know

*If you are **not certified** please mark the **left side only** which asks for your perception of possible costs/benefits from ISO 9000/QS 9000 certification.*
*If you **are certified** please **mark both sides**. Left side asks for the anticipated costs/ benefits when you were deciding to get ISO 9000/QS 9000 certification and the right side measures the actual costs/benefits derived out of ISO 9000 /QS 9000 implementation.*

Anticipated/possible benefits						*Actual benefits*					
5	4	3	2	1	na.....Able to sustain the market share.....5	4	3	2	1	na	
5	4	3	2	1	na.....Able to increase the market share.....5	4	3	2	1	na	
5	4	3	2	1	na.....Improvement in production efficiency.....5	4	3	2	1	na	
5	4	3	2	1	na.....Improvement in product delivery time 5	4	3	2	1	na	
5	4	3	2	1	na.....Reduction in customer complaints.....5	4	3	2	1	na	
5	4	3	2	1	na.....Reduction in cases of non-conformity.....5	4	3	2	1	na	
5	4	3	2	1	na.....Reduction in cost of production.....5	4	3	2	1	na	

6. Benefits of ISO 9000/QS 9000 implementation *continued.*

5 = strongly agree; 4 = mildly agree; 3 = neutral; 2 = mildly disagree; 1 = strongly disagree; na = not applicable or do not know

Anticipated benefits						*Actual benefits*					
5	4	3	2	1	na.....Improvement in profitability.....	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in perception of product quality (by customer)	5	4	3	2	1	na
5	4	3	2	1	na.....Reduction in customer quality audits.....	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in quality awareness (within the organization)	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in management control	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in customer service.....	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in customer satisfaction.....	5	4	3	2	1	na
5	4	3	2	1	na.....Reduction in warranty claims	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in access to export markets	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in access to domestic market (e.g. tenders/competitive bids)	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in employee morale	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in job satisfaction.....	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in documentation	5	4	3	2	1	na
5	4	3	2	1	na.....Improvement in inter company communication.....	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in competitive advantage...	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in standard operating procedures.....	5	4	3	2	1	na
5	4	3	2	1	na .....Reduction in customer rejections.....	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in purchasing procedures...	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in product design	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in employee job skills.....	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in job performance.....	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in product delivery time	5	4	3	2	1	na
5	4	3	2	1	na .....Reduction in audit service manpower resources.....	5	4	3	2	1	na
5	4	3	2	1	na .....Reduction in internal scrap	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in response to customer complaints and suggestions.....	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in employee knowledge of products and processes	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in safety programs	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in accounting practices	5	4	3	2	1	na
5	4	3	2	1	na .....Improvement in human resource planning.....	5	4	3	2	1	na
5	4	3	2	1	na .....Everyone's responsibility became more clear.....	5	4	3	2	1	na

7. **The following questions measure the relevance of ISO 9000/QS 9000 elements to your organization. Please circle the appropriate number to indicate the strength of your agreement with these statements.**

5 = Highly relevant; 4 = Somewhat relevant; 3 = neutral; 2 = Somewhat not relevant; 1 = Not at all relevant; na = not applicable or do not know

Management responsibility	5	4	3	2	1	na
Quality system (documentation)	5	4	3	2	1	na
Control review	5	4	3	2	1	na
Design control	5	4	3	2	1	na
Document and data control	5	4	3	2	1	na
Purchasing (control)	5	4	3	2	1	na
Control of customer supplied products	5	4	3	2	1	na
Product identification and tracability	5	4	3	2	1	na
Process control	5	4	3	2	1	na
Inspection and testing	5	4	3	2	1	na
Control of inspection, testing and measuring equipment	5	4	3	2	1	na
Inspection & testing status	5	4	3	2	1	na
Control of non-conforming product	5	4	3	2	1	na
Corrective and preventive action	5	4	3	2	1	na
Handling storage, packaging, preservation, and delivery	5	4	3	2	1	na
Control of quality records	5	4	3	2	1	na
Internal quality audits	5	4	3	2	1	na
Training	5	4	3	2	1	na
Servicing	5	4	3	2	1	na
Statistical techniques	5	4	3	2	1	na

8. **The following questions are some of the strategies for successful implementation of ISO 9000/QS 9000 in an organization. Please mark the appropriate number to indicate how important are these aspects.**

5 = highly important; 4 = some what important; 3 = important; 2 = some what unimportant; 1 = not at all important; na = not applicable or do not

Extensive education of users as to how ISO 9000/QS 9000 relates to total quality management, continuous improvement, etc	5	4	3	2	1	na.
Requiring product standard with ISO 9000/QS 9000 certification	5	4	3	2	1	na
Providing industry specific cases of effective quality management	5	4	3	2	1	na
Supporting ISO concepts with organizations' information system	5	4	3	2	1	na
Analyzing marketing needs before starting quality certification	5	4	3	2	1	na
Developing quality systems based on organizational strengths	5	4	3	2	1	na
A multi-tier / phased implementation of ISO 9000/QS 9000	5	4	3	2	1	na
Expecting the union to play a positive role in helping to achieve the objectives	5	4	3	2	1	na

9. **The following questions measure the extent of planning in your organization. Please circle the appropriate number to indicate the strength of your agreement with these statements.**

5 = strongly agree; 4 = mildly agree; 3 = neutral; 2 = mildly disagree; 1 = strongly disagree; na = not applicable or do not know

We have a mission statement which has been communicated throughout the company	5	4	3	2	1	na
Our mission statement is supported by our employees	5	4	3	2	1	na
We have a comprehensive and structured planning process which regularly sets and reviews short and long term goals	5	4	3	2	1	na
Our plans focus on the achievement of "best practice"	5	4	3	2	1	na
When we develop our plans, policies, and objectives we always incorporate customer requirements	5	4	3	2	1	na
When we develop our plans, policies, and objectives we always incorporate supplier capabilities	5	4	3	2	1	na
We have a written statement of strategy	5	4	3	2	1	na
Strategy had been agreed to by senior managers	5	4	3	2	1	na
Strategy covers all manufacturing operations	5	4	3	2	1	na
Strategy is clearly articulated	5	4	3	2	1	na
Our site's manufacturing operations are effectively aligned with the central business/corporate mission	5	4	3	2	1	na

10. Typically how <u>often do you review</u> the following in your organization. Please circle the appropriate number to indicate the strength of your agreement with these statements.

1-= Never 2 = Every year or less often 3 = every six months 4 = every quarter 5 = every month or more often

Attitudes/morale of employees	5	4	3	2	1
Time taken from receipt of an order to delivery of products	5	4	3	2	1
Number of customer complains	5	4	3	2	1
The level of customer satisfaction	5	4	3	2	1
The quality of raw materials	5	4	3	2	1
Suppliers' overall performance	5	4	3	2	1
Costs associated with poor quality	5	4	3	2	1
The cost and number of work place accidents	5	4	3	2	1
Percentage of capacity lost due to production down time	5	4	3	2	1
All or part of your cost structure	5	4	3	2	1
The effectiveness of the planning process	5	4	3	2	1

11. If you are **certified** please categorize each item by marking 1 to 5 your **performance before** you got your certification **and after** you got your certification in the **Before and After columns** on the right marked certified.

If you are **not yet certified** please mark present performance and your anticipated performance after certification in the **Non-Certified Columns.**

						Certified		Non-Certified	
Item	1	2	3	4	5	Before	After	Before	Anticipated Results
Scrap or rejection rate	0 to 0.5%	.51 to 1%	1,1 to 1,5%	1.51 to 2%	above 2%				
Rework as a percent	0 to 1%	1,1 to 2%	2,1 to 3%	3,1 to 4%	above 4%				
Customer returns or claims as a percent of sales	0 to 0.5%	0.51 to 1%	1,1 to 1,5%	1,51 to 2%	above 2%				
Training expenditures as a percent of pretax payroll	0 to 1%	1,1 to 2%	2,1 to 3%	3,1 to 4%	above 4%				
On time delivery to the customer	below 50%	50,1 to 70%	70,1 to 80%	80,1 to 90%	above 90%				
Number of customer certifications you hold	0	1 - 3	4 - 6	7 - 9	10 and above				
Number of customer audits you receive each year	0	1 - 3	4 - 6	7 - 9	10 and above				
Number of suppliers you audit each year	0	1 - 3	4 - 6	7 - 9	10 and above				
Export as a percent of sales	below 1	1 - 3	3,1 - 12	12,1 - 20	above 20				
Market share of primary business	1 - 10%	10 ,1 - 20%	20,1 - 30%	30,1 - 40%	above 40%				
Number of your customers that have 9000 certification	0	1 - 3	4 - 8	9 - 10	above 10				

12. **Thank you for your assistance in this project.**

Please give us the following information for statistical purposes.

1. Your title _____

2. If you know your SIC code then please write it down _____
(Otherwise please check the most appropriate one indicating your primary business)

____ Automotive or parts ____ Primary metals ____ Fabricated metals
____ Electrical ____ Electronics ____ Raw materials
____ Chemical and related ____ Plastics ____ Appliance
____ Government ____ General manufacturing ____ Textiles
____ Wood and wood products ____ Paper and paper products
____ Transportation and equipment ____ Food and Agriculture
____ Others (please specify): _____

3. Please indicate the number of employees in your plant

____ 1 to 50 ____ 51 to 100 ____ 101 to 250 ____ 251 to 500
____ Over 500

4. Please indicate the range of your annual sales of your plant: (in $)

____ Under 5 million ____ 5 to <10 million ____ 10 to <25 million
____ 26 to <50 million ____ 51 to <100 million ____ more than 100 million

5. How do you classify your ownership:

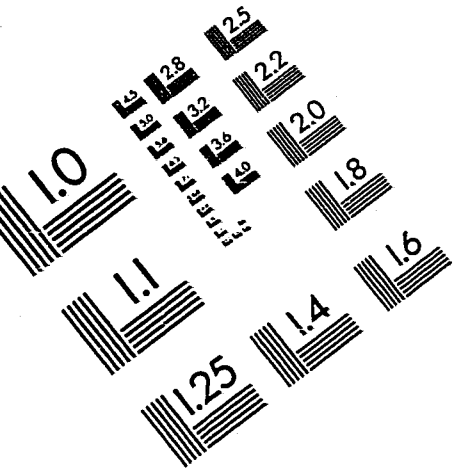
____ Domestic ____ Foreign owned ____ Multinational
____ Joint venture

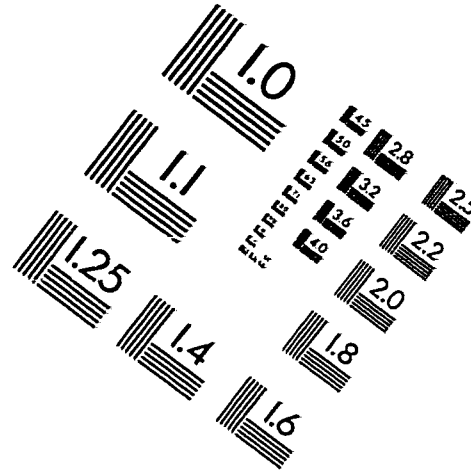
6. Do you presently export? ..... ____ Yes ____ No
7. Do you have any European sales?..... ____ Yes ____ No
8. Do you have any government contract work? .... ____ Yes ____ No
If yes, does government contract requires
you to be ISO 9000/QS 9000 certified..... ____ Yes ____ No
9. Do you do internal audits of your operations?.... ____ Yes ____ No

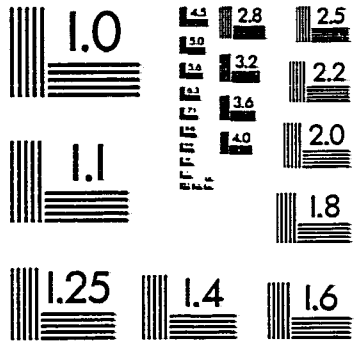
List any quality awards you received in the last 5 years

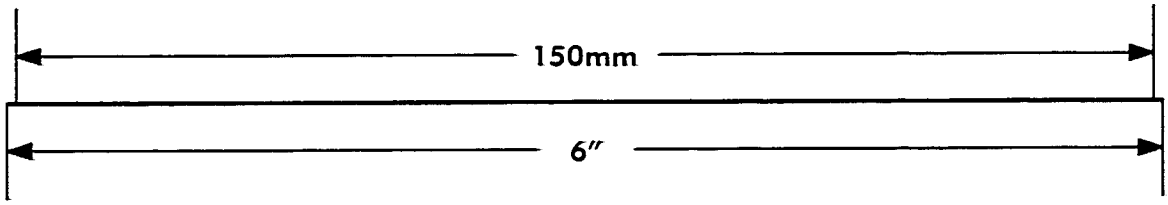
_____
_____
_____

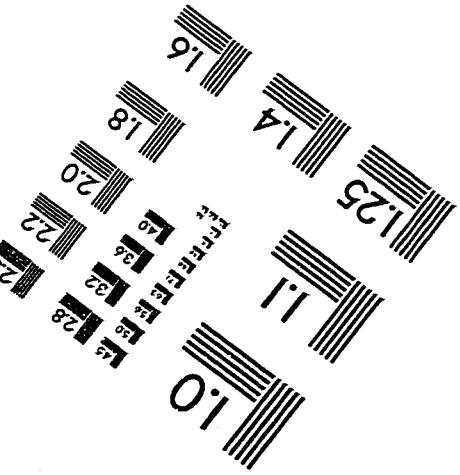
IMAGE EVALUATION
TEST TARGET (QA–3)

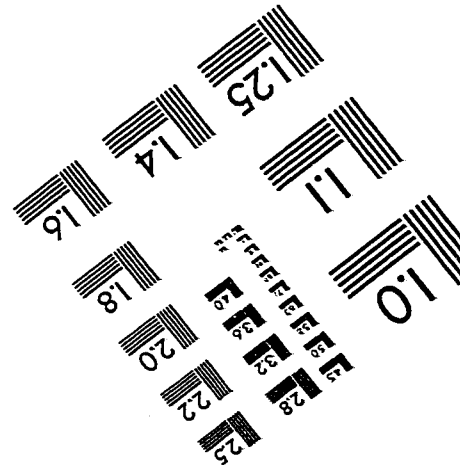












APPLIED IMAGE, Inc
1653 East Main Street
Rochester, NY 14609 USA
Phone: 716/482-0300
Fax: 716/288-5989