DEVELOPMENT OF A COMPLIANT QUALITY MANAGEMENT SYSTEM UTILIZING THE ANSI/ASQC Q9001 - 1994 CRITERIA

by

Kevin S. Massie

Paper submitted to the Faculty of the
Virginia Polytechnic Institute and State University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

in

Systems Engineering

APPROVED:

Dr. K.P. Triantis, Chairman

E.S. Kinzer

Prof. B.S. Blanchard

November, 1995
Falls Church, Virginia

c.2

DEVELOPMENT OF A COMPLIANT QUALITY MANAGEMENT SYSTEM UTILIZING THE ANSI/ASQC Q9001 - 1994 CRITERIA

by
Kevin S. Massie
K. Triantis, Ph.D., Chairman
Industrial & Systems Engineering

ABSTRACT

ISO 9000 is a series of quality standards providing requirements and guidelines for both Quality Assurance and a Quality Management System. All customers, domestic and foreign, are looking for assurance that there is a monitored quality system in place, and that the results will be the delivery of products and services in a repeatable and consistent manner.

Throughout the United States and abroad, many companies are seeing new business Request For Proposals (RFPs), as well as active contracts adding requirements specifically mandating compliance or registration to one of the three ISO 9000 specifications. In an effort to reduce the cost of defense systems, the Department of Defense (DoD) is looking to take greater advantage of the nation's commercial technology base as a part of Defense Secretary Perry's blueprint for change, as the Government is looking for a replacement to MIL-Q-9858A and an answer to the Commercial-Off-The Shelf (COTS) transition.

Companies that have targeted the European Community (EC) for potential new business opportunities are discovering that registration to ISO 9000 has become a virtual necessity for competing at the international level and is a critical component of any business unit intending to pursue Foreign Military Sales (FMS).

With the sudden interest in rapidly achieving ISO 9000 registration, consultants have appeared attempting to assume the role of "facilitator." One reason for this is the lack of data available to the public which documents efforts taken to become a registered company.

This document is the result of a 12 month study detailing the effort to become registered to the ANSI/ASQC Q9001 - 1994 criteria. The implementation process, tools

developed, and lessons learned through this study are contained in this document to assist any type of company in pursuit of quality system compliance or registration to one of the three ISO 9000 standards.

ACKNOWLEDGEMENTS

I wish to acknowledge a number of individuals who have made a special contribution to the development of this paper. To Dr. Konstantinos P. Triantis, who taught the class that was the inspiration behind this paper, I thank for your assistance, guidance, and patience with me throughout this process. Your wisdom shared is truly appreciated.

A special thanks goes to the Quality Assurance department at Loral Federal Systems-Manassas, especially Paul Shimp and Dana Roper. Paul's energy and creativity are second to none. Without his help and leadership, registration to Q9001 absolutely would not have happened. Dana was the rational voice of reason within the group. He was always there to listen and offer his assistance whenever it was required. Both have become very good friends of mine over the last year, something for which I am very lucky.

To Elizabeth Stuart (Stu) Kinzer, the Director of TQM, I owe much more than I can ever place in a simple paragraph. She has given me opportunities over the course of my career that most people don't get in a lifetime. She has been both a good friend and confidant, whose sage words of wisdom I hope to never stop receiving. Thank you Stu.

Finally, I wish to dedicate this paper to my family. To my mother and father, Mary Lou Massie and Keith Luman Massie, I thank them for their love and guidance through the course of my life. They were the very best parents anyone could possibly have had. To my wonderful sister, Denise Lynn Massie, I thank for baby-sitting my daughter and pushing me to meet my self-imposed deadlines. Last, but not least, I wish to thank my lovely wife and daughter, Kimberly Eckler Massie and Alexis Marie Massie, who have taught me what life is all about. They have become, and forever will be, the center of my life. My strength and will to succeed come from them.

Kevin S. Massie

November, 1995

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

List of Tables

List of Figures

1.0 OBJECTIVES, SCOPE, AND METHODOLOGY

1.1 INTRODUCTION

ISO 9000 is the name of the international series of quality management and quality assurance standards providing requirements and guidelines for both quality assurance and a Quality Management System. There are three standards to which a company may become registered:

- ISO 9001 - Model for Quality Assurance in Design/Development, Production, Installation and Servicing;
- ISO 9002 - Model for Quality Assurance in Production and Installation;
- ISO 9003 - Model for Quality Assurance in Final Inspection and Test.

The Loral Federal Systems-Manassas (LFS-M) facility has chosen to register to ANSI/ASQC Q9001-1994, the ANSI/ASQC version of ISO 9001, due to the fact that it covers design and development, and is the most comprehensive in scope of the three standards. Reference to the standard made in this document are to "ISO 9001" and "Q9001," both of which are to be considered synonymous. Background data on the entire family of standards can be found in Chapter 2.0. This document looks at the implementation process employed, and tools developed at LFS-M over a 12 month period, while documenting the lessons learned preceding registration to the ISO 9001 standard.

1.1.1 The Need for an Effective QMS

An effective Quality Management System (QMS) should be the very foundation of any company. It provides valuable insight into the health and status of processes employed that ultimately produce a finished product, be it service, hardware or software. Customers, domestic and foreign, are looking for assurance that there is a monitored quality system in place, and that the results will be the delivery of products and services in a repeatable and consistent manner.

1.1.2 Customer Requirements Driving ISO 9000 Registration

The ISO 9000 Standards have developed as the model for Quality Assurance throughout the European Community (EC). Companies that have targeted the EC for potential new business opportunities are discovering that registration to ISO 9000 has become a virtual necessity for competing at the international level and is a critical component of any business unit intending to pursue Foreign Military Sales (FMS).

In the United States, the move towards ISO 9000 did not catch on as quickly as it had in the EC, but the momentum has accelerated as the merits of compliance to the standard have become known. In an effort to reduce the cost of defense systems, the Department of Defense (DoD) is looking to take greater advantage of the nation's commercial technology base as a part of Defense Secretary Perry's blueprint for change. New business Request For Proposals (RFPs) and active contracts have now added requirements specifically mandating compliance or registration to the ISO 9000 standard as the Government is looking for a replacement to MIL-Q-9858A, and an answer to the transition towards a Commercial-Off-The Shelf (COTS) environment.

1.2 RESEARCH OBJECTIVES

The primary research objective of this document is to implement a QMS and document the results of attaining registration to the ANSI/ASQC Q9001 - 1994 standard.

1.2.1 The Documentation of a QMS Implementation Approach

The QMS implementation approach employed leading to Q9001 registration will be thoroughly documented. This document is the result of a comprehensive 12 month study which started in September of 1994, and ended in September of 1995. Any type of company interested in becoming registered to one of the three ISO standards will find this document both interesting and valuable. Results have been summarized, and lessons learned during the project will be highlighted and explained as part of this process.

1.2.2 The Development of a Gap Analysis Tool

Many companies that have decided to pursue registration are now faced with the question of just how far from compliance to the standard is their existing Quality Management System. This delta must be understood prior to the next question of how much manpower, resources, and funding are required to close the gap. In order to give the user some assistance in better understanding this delta, a Gap Analysis Tool has been developed. This tool consists of a self-assessment spreadsheet containing a rating system and weighting scheme which, when completed, gives the user an idea of the approximate level of work required to obtain registration. The tool will aid in the determination of a timeframe for the effort, and does not consider cost due to the wide variability that exists in potential approaches.

The data that is generated from the use of the Gap Analysis Tool serves as a baseline for continual improvement. The baseline may serve as a measure for the status of the QMS, until the next checkpoint is established. This may occur as part of the Internal Quality Audit program, or another self-assessment from using the Gap Analysis Tool again. It serves as a useful way of displaying the data in an effort to communicate progress being made against the 20 elements of the ISO standard (see Chapter 2.0).

1.2.3 The Development of an Internal Quality Audit Checklist

The Internal Quality Audit system exists as a mechanism that allows for continual improvement to the current QMS. The audit system is discussed in much greater detail in Chapters 4.0 and 5.0. An Internal Quality Audit Checklist has been developed for use as the basis of the Internal Quality Audit program, and has been included in the Appendix as Section A-3. The Checklist was developed by breaking down each sub-element of the standard and then creating questions designed to solicit responses that will enable the auditor to more readily determine compliance to the element in question. In order to assist each functional area in preparing for an Internal Quality Audit, a matrix has been developed (see Table 1), which maps

Table 1: Functional Mapping - ISO 9001 criteria mapped to all functional elements contained within the QMS, with primary and secondary responsibilities identified for each.

Para	Description	Configuration Management	Data Management	Contracts	Education	Hardware Development	Software Development	Systems Engineering	Finance	Government Property Control	Integrated Product Support	Marketing	Metrology	Manufacturing Operations	Personnel	Production Control	Shipping & Stock Room	Receiving & Inspection	Procurement	Program Management	Quality Assurance	Reliability	Test Engineering
4.1	Management Responsibility																						
	4.1.1 Quality Policy	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	4.1.2 Organization	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	4.1.3 Management Review																				P		
4.2	Quality System																						
	4.2.1 General																				P	S	
	4.2.2 Quality System Procedures																				P	S	
	4.2.3 Quality Planning																				P	S	
4.3	Contract Review																						
	4.3.1 General			P																S			
	4.3.2 Review			P																S			
	4.3.3 Amendment to Contract			P																S			
	4.3.4 Records			P																S			
4.4	Design Control																						
	4.4.1 General					P	P	P						P						S			
	4.4.2 Design & Dev. Planning					P	P	P						P									
	4.4.3 Org. & Technical Interfaces					P	P	P						P									
	4.4.4 Design Input					P	P	P						P									
	4.4.5 Design Output					P	P	P						P									
	4.4.6 Design Review					P	P	P						P									
	4.4.7 Design Verification					P	P	P						P									
	4.4.8 Design Validation					P	P	P						P									
	4.4.9 Design Changes					P	P	P						P									
4.5	Document and Data Control																						
	4.5.1 General	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	4.5.2 Approval & Issue	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	4.5.3 Doc. & Data Changes	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
4.6	Purchasing																						
	4.6.1 General																		P				
	4.6.2 Evaluation of Subs																		P				
	4.6.3 Purchasing Data																		P				
	4.6.4 Verification of Purch. Prod.																		P				
4.7	Control of Cust.-Supplied Product									P													

Table 1: Functional Mapping - ISO 9001 criteria mapped to all functional elements contained within the QMS, with primary and secondary responsibilities identified for each.

Para	Description	Configuration Management	Data Management	Contracts	Education	Hardware Development	Software Development	Systems Engineering	Finance	Government Property Control	Integrated Product Support	Marketing	Metrology	Manufacturing Operations	Personnel	Production Control	Shipping & Stock Room	Receiving & Inspection	Procurement	Program Management	Quality Assurance	Reliability	Test Engineering
4.8	Product Ident. & Traceability	P	P			P	P	P		P	P		P	P		P	P	P					
4.9	Process Control													P							P		
4.10	Inspection and Testing																						
	4.10.1 General					P	P	P						P									
	4.10.2 Rec. Inspection & Testing					P	P	P										P					
	4.10.3 In-Process Insp. & Testing					P	P	P						P									
	4.10.4 Final Insp. & Testing					P	P	P						P									
	4.10.5 Insp. & Test Records					P	P	P						P									
4.11	Control of Insp., Meas., & Test E.																						
	4.11.1 General					S	S	S					P	S			S	S					
	4.11.2 Control Procedure					S	S	S					P	S			S	S					
4.12	Inspection and Test Status					P	P	P					P	P			P	P					
4.13	Control of Nonconforming Prod.																						
	4.13.1 General					S	S	S		S	S		S	P			S	S			P		
	4.13.2 Rev. & Disposition of NCP					S	S	S		S	S		S	P			S	S			P		
4.14	Corrective & Preventive Action																						
	4.14.1 General	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	P	S	S
	4.14.2 Corrective Action	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	P	S	S
	4.14.3 Preventive Action	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	P	S	S
4.15	Hand., Stor., Pack., Pres., & Del.																						
	4.15.1 General																P						
	4.15.2 Handling																P						
	4.15.3 Storage																P						
	4.15.4 Packaging																P						
	4.15.5 Preservation																P						
	4.15.6 Delivery																P						
4.16	Control of Quality Records	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
4.17	Internal Quality Audits																				P		
4.18	Training	S	S	S	P	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S
4.19	Servicing										P												
4.20	Statistical Techniques																						
	4.20.1 Identification of Need													P							P		
	4.20.2 Procedures													P							P		

the ISO elements to the varying functional areas within an organization. This helps the individual functional areas understand how the ISO standard applies to them specifically.

The Checklist may also be helpful when using the Gap Analysis Tool. The rating for each of the elements is determined by using the either the ISO 9000 standard or the Checklist as a guide in understanding what is required for that specific element. Once the analysis has been completed for an element, the rating is then determined from the six available options discussed later in Chapter 4.0.

1.2.4 The Documentation of the Lessons Learned

Lessons learned during the registration process will be collected, summarized, and discussed in Section 5.0 of this document. This section contains valuable pieces of information that have been collected from several months of study during the implementation process. All of the lessons learned should be reviewed by organizations considering registration so that mistakes are not duplicated. It is through this sharing of information that true progress is made.

1.3 OVERVIEW OF THE METHODOLOGY

1.3.1 ISO 9001 QMS Elements

The ISO 9001 model consists of 20 elements that specify the minimum requirements for a Quality Management System. The 20 elements are listed below and will be discussed in detail in Section 3.1 of this document:

1) Management Responsibility
2) Quality System
3) Contract Review
4) Design Control
5) Document and Data Control
6) Purchasing
7) Control of Customer-Supplied Product
8) Product Identification and Traceability
9) Process Control
10) Inspection and Testing
11) Control of Inspection, Measuring, and Test Equipment

12) Inspection and Test Status
13) Control of Nonconforming Product
14) Corrective and Preventive Action
15) Handling, Storage, Packaging, Preservation, and Delivery
16) Control of Quality Records
17) Internal Quality Audits
18) Training
19) Servicing
20) Statistical Techniques

1.3.2 Relevance to Systems Engineering

In the pursuit of ISO 9001, which covers the design and development aspects of an organization, it is essential to have an engineering background in order to effectively implement the QMS. The successful design, development, and implementation of any system, be it a QMS or submarine combat weapons system, follows the classic System Life-Cycle Process. This process involves a sequence of steps performed in a logical manner, which is focused on the development of an effective and efficient product or system. The application of the System Life-Cycle Process in the development of an ISO 9001 compliant QMS has been detailed in Figure 1.

At LFS-M, the Quality organization has focused on bringing in personnel with engineering backgrounds as part of an effort to enhance the current skills base of the group. Experience has proven that the Systems Engineer is well suited for this task as the user has a broad background concerning the product life-cycle, giving the engineer the ability to communicate and implement corrective actions across all aspects of the engineering community. The Quality auditor that is unable to understand the material before him or her, is relatively ineffective.

1.4 SCOPE OF RESEARCH

This paper examines the process of registering to ISO 9001. Due to the fact that ISO 9001 also includes ISO 9002 and ISO 9003, organizations seeking registration to any one of these three standards would be able to benefit from this research.

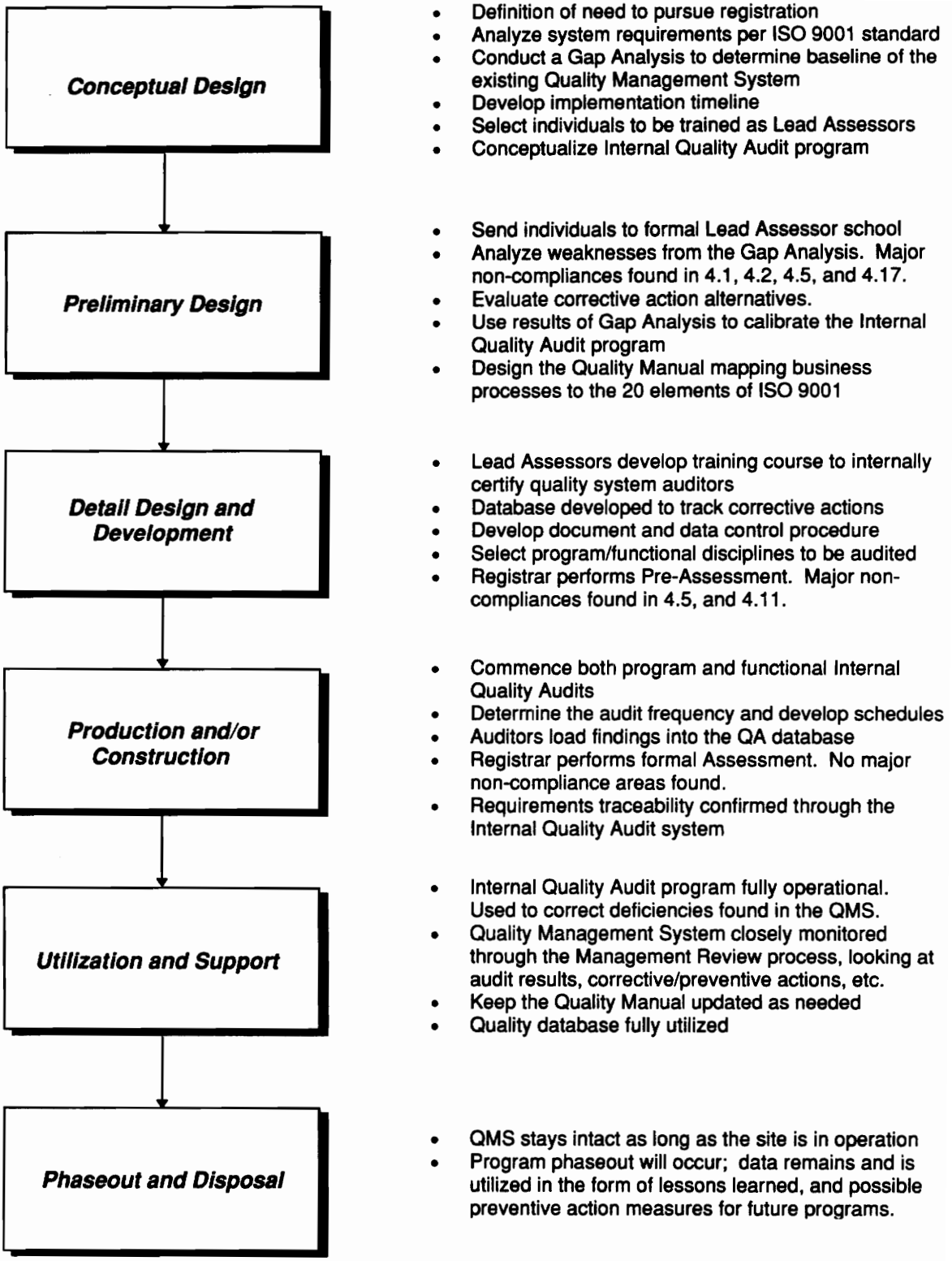


Figure 1: System Life-Cycle Process - This figure shows the steps followed in utilizing the System Life-Cycle Process in developing an ISO 9001 compliant Quality Management System.

The ISO standards apply to both commercial and military programs, in both domestic and Foreign Military Sales. Companies currently utilizing ISO as a tool to evaluate their Quality Management System range from small service organizations, to large corporations performing a multitude of functions.

1.5 IMPORTANCE OF RESEARCH

The ISO 9000 series of standards look to be the logical replacement of MIL-Q-9858A as a requirement in domestic RFP's throughout the military. Commercial business units have a need due to current and potential business being pursued in foreign markets. Due to the high volume of interest in registration to the standard, many companies have been formed with high hopes of reaping the financial benefits through being "facilitators." These facilitators come in the form of registrars, lead assessors, lead assessor courses, "how to" books giving tips on registration, etc. The point is that there are millions of dollars being spent each month on ISO in some form, without much practical guidance on the subject. LFS-M will be documenting the 12 month effort, and sharing the tools, lessons learned, cost saving measures, strategies, etc., with other companies that intend to pursue the implementation of a Quality Management System, specifically the utilization of the ISO standards themselves.

It is through the sharing of ideas that companies can learn from each other's mistakes. It is the opinion of the author that a large amount of money spent on the implementation of ISO today is unnecessary to obtain the desired result, that being registration. This is not to say that the cost of implementing ISO is trivial by any means, in fact ensuring you have a compliant Quality Management System can run a company into the thousands of dollars. However, industry can do a better job of documenting their efforts, as well as taking the time to listen and read these documents prior to embarking on their own efforts in order to save time and money.

1.6 DOCUMENT ORGANIZATION

Chapter 1 - This chapter is structured to give some insight into the research objectives, scope, and the methodology behind the Q9001 standard. It covers key elements of this document at a very high level.

Chapter 2 - This chapter moves into the origin of the standards, how the differing specifications are structured, and a comparison of the three standards. This chapter also compares the ISO 9000 standards to the Malcolm Baldrige National Quality Award criteria at a high level, due to the widely differing elements contained within each. Lastly, the importance of the research is discussed, and why it is critical to share this information with other companies around the world who are either thinking about or in the process of registering to one of the three specifications.

Chapter 3 - This chapter examines each of the 20 elements of the ISO 9001 standard and discusses important points of each. During the discussion of each element, three separate items are discussed. First, what is required by each of the elements is broken out in detail. Second, observations made during the implementation process are collected. Finally, at the end of each section, a discussion of how LFS-M handled compliance to this element of the standard was included. A second section of this chapter was included which explains the different types of non-compliances that can be written by an assessor, with examples provided for each.

Chapter 4 - This chapter looks at the implementation process from the initial Gap Analysis through the formal Assessment performed by the registrar. A Master Schedule has been included as part of the discussion which shows the timeline employed by LFS-M in obtaining registration. Also included are the criteria used in the selection of a registrar, as well as a discussion of internally developed tools that were used to facilitate registration efforts. These tools could be used by anyone seeking registration.

Chapter 5 - This chapter covers the results of the Gap Analysis, Pre-Assessment, Assessment, and Internal Quality Audit program. The results of each are discussed in detail,

with emphasis on the major non-compliance areas. Lessons learned were collected from the beginning in order for others to avoid the same traps that were experienced by LFS-M.

Chapter 6 - The final chapter covers a summary of the completed project, and a discussion of areas within the analysis of a QMS that need further research.

The Appendix is structured in the following manner:

A-1: Acronym Listing

A-2: Definitions

A-3: Quality Management System Checklist

A-4: Gap Analysis Tool Spreadsheet

2.0 BACKGROUND INFORMATION

LFS-M has provided the U.S. government and its prime contractors with high quality products for more than 25 years. Population is currently approximately 1,600 people. The site supports hundreds of federal contracts, providing applications and services for both military and civilian programs. Solutions provided range from custom designed military hardware, to the integration of substantial Non-Developmental Items (NDI) and Commercial-Off-The-Shelf (COTS) products. The site's main capabilities lie in the area of Systems Engineering, Software Development, Systems Integration, Integrated Logistics Support, and Program Management. The major business areas consist of Simulation and Training programs, Systems Integration and Services, Advanced Applications, Surveillance and Maritime Systems, and Navy Shipboard and Trainer programs.

The LFS-M facility has received numerous awards from the Navy, the federal government, and industry for the quality of its product and services. These awards include:

- The Navy's Willoughby Award in 1990 in recognition of a decade of "dedicated commitment, design engineering excellence, error-free manufacturing, and maintenance simplicity;"
- The TRW Award for our Continuous Quality Improvement Process in 1991;
- The U.S. Senate Productivity Award for Virginia in 1992.

These awards are a direct result of LFS-M's commitment to continuous process improvement. The site also has a long history of involvement with the Malcolm Baldrige National Quality Award criteria.

2.1 BACKGROUND INFORMATION ON ISO 9000

2.1.1 Origin

The International Organization for Standardization (ISO) is the name of an agency based in Geneva, Switzerland. Their purpose is to promote the development of international standards and related activities to facilitate the global exchange of goods and services. Their membership includes over 90 countries, of which the American National Standards Institute

(ANSI) is the United States representative. (Many people believe that the acronym "ISO" in the term ISO 9000 actually is a reference to the organization itself, when in fact it is a Greek word meaning "equal").

ISO 9000 is the name of the international series of quality management and quality assurance standards. The ISO 9000 series are a set of standards that describe and clarify the distinctions and interrelationships among quality concepts, and provide guidelines for selecting and using these quality system standards. The standards focus on the relationships between both the supplier and the customer, providing a set of general guidelines and contractual agreements to evaluate the capability of suppliers to meet specified quality requirements.

The ISO 9000 series standards are used throughout the world by organizations known as "registrars" to evaluate the quality systems of organizations. Companies that successfully complete these evaluations are granted a certificate of registration, which demonstrates to customers and other interested parties that the facility's Quality Management System meets international standards.

Companies that export products and/or services anywhere within the EC Common Market should be concerned with ISO 9000 registration due to contractual and possible regulatory requirements. ISO 9000 is widely used within the EC to provide a framework for a Quality Management System. Some people within a wider international community have expressed concern that the ISO 9000 standards could be used as a barrier to trade. However, no objective evidence exists to support this viewpoint.

The evolution leading to the current 1994 version of the standard can be viewed in Table 2. The different names contained within the table (ISO 9001, EN 29001, ANSI/ASQC Q9001-1994 and BS EN ISO 9001) are in fact all the same standard. The Americanized version of ISO 9000, ANSI/ASQC Q9000-1994, is identical to the EC version and is being used as a replacement for MIL-Q-9858A in most military procurements taking place today. This creates a domestic and an international need for the pursuit of registration to the standard.

Table 2: ISO 9000 Evolution - The table displays the evolution of the ISO 9000 series of standards from MIL-Q-9858, which was first released in the year 1959.

STANDARD	DATE
MIL-Q-9858	1959
MIL-Q-9858A	1963
AQAP-1 (NATO)	1968
DEF STAN 05-08 (MoD)	1970
BS 5750	1979
ISO 9000	1987
ISO 9000/BS 5750/EN 29000	1987
ANSI/ASQC Q90	1987
ISO 9000/BS9000/EN 29000	1994
ANSI/ASQC Q9000	1994

2.1.2 Definitions and Structure of the Standard

2.1.2.1 Definitions

A listing of definitions that are helpful for reference purposes have been included as Appendix A-2 of this paper. There are three that have been included in this section due to their importance in the discussion which follows:

- *Recognition Authority: That body which provides evaluation and recognition to the accreditation level (Government body).*
- *Accreditation Authority: That body which evaluates and accredits testing laboratories, Certification Bodies or Quality Systems Registrars (a public or private organization).*
- *Certification Authority: That body which assesses the actual conformity of a product or an organization (an independent third party).* [1]

1 Inchcape Testing Services, ISO-9000/Q9000 Training Courses, Revision 6, Release Date December, 1994.

In the case of LFS-M, the recognition authority is the United Kingdom and the accreditation authority is the National Accreditation Council for Certification Bodies (NACCB). The NACCB was viewed as a critical accreditation authority to have due to a large amount of business dealings with the United Kingdom.

The registrar chosen for this effort will not be directly named, but will be referred to as either the "registrar," or "assessor."

2.1.2.2 Structure of the ISO 9000 Standards

The basic structure of the ISO 9000 series of standards is shown in Figure 2. ISO 9000 is a reference to the entire family of standards. ISO 9001, 9002, and 9003 are the specifications to which a company can actually register, with ISO 9004 being a guidelines document. As is shown in Figure 2, ISO 9002 encompasses all elements of ISO 9003, with the addition of production, installation and servicing. ISO 9001 encompasses all elements of ISO 9002 and ISO 9003 with the addition of design and development, making it the broadest of the three specifications.

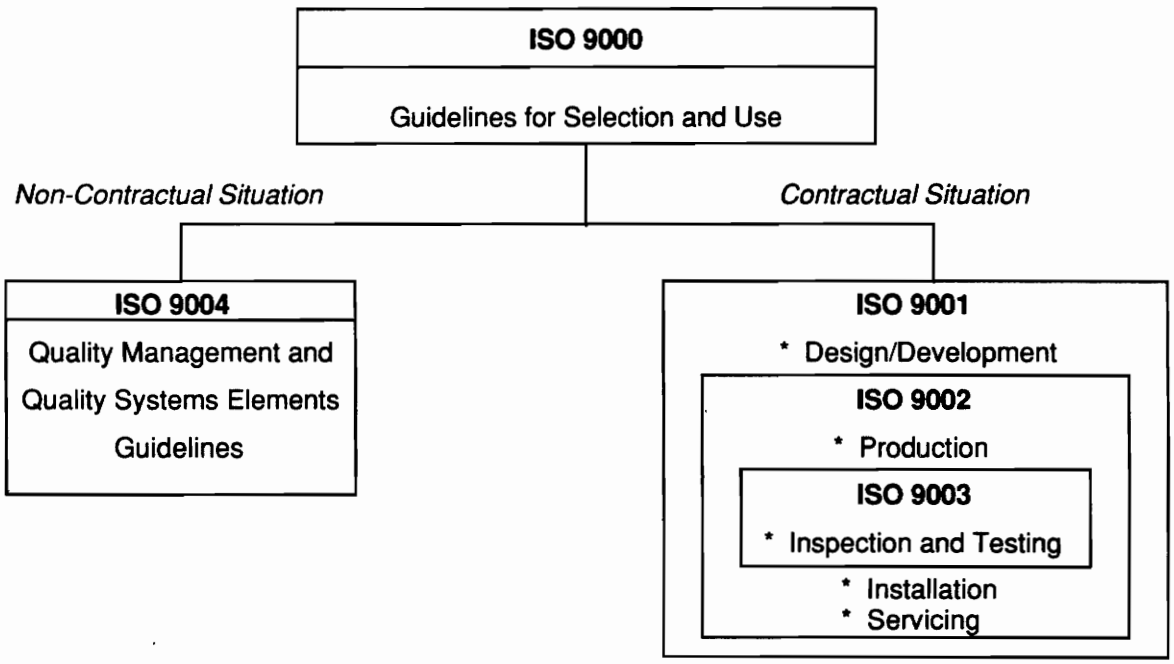


Figure 2: Structure of the ISO 9000 Standards - This figure contains the basic structure for all three of the standards within the ISO 9000 series.

The relationship between the three specifications is displayed in Table 3, and helps to better understand both the common and uncommon elements that exist. As seen in the Table, each one of the 20 elements of the standard are applicable to ISO 9001. ISO 9001's scope covers design, development, production, installation, and servicing. When covering ISO 9002, 19 of the elements are applicable, with the scope covering production, installation, and servicing. The only element that is not covered under ISO 9002 is Design Control (4.4). ISO 9003 covers 16 elements of the standard with Design Control (4.4), Purchasing (4.6), Process Control (4.9), and Servicing (4.19) not being applicable since the scope of the standard only covers final inspection and test.

Table 3: Relationship Table - The table contains a comparison of requirements for all three of the standards within the ISO 9000 series.

ISO 9001	ISO 9002	ISO 9003	SUBJECT
4.1	*	*	Management Responsibility
4.2	*	*	Quality System
4.3	*	*	Contract Review
4.4	N/A	N/A	Design Control
4.5	*	*	Document and Data Control
4.6	*	N/A	Purchasing
4.7	*	*	Control of Customer Supplied Product
4.8	*	*	Product Identification and Traceability
4.9	*	N/A	Process Control
4.10	*	*	Inspection and Testing
4.11	*	*	Control of Inspection, Measuring and Test Equipment
4.12	*	*	Inspection and Test Status
4.13	*	*	Control of Nonconforming Product
4.14	*	*	Corrective and Preventive Action
4.15	*	*	Handling, Storage, Packaging, Preservation & Delivery
4.16	*	*	Control of Quality Records
4.17	*	*	Internal Quality Audits
4.18	*	*	Training
4.19	*	N/A	Servicing
4.20	*	*	Statistical Techniques

2.2 COMPARISON TO MALCOLM BALDRIGE NATIONAL QUALITY AWARD

The Malcolm Baldrige National Quality Award (MBNQA) was created by public law 100-107 in 1987 with the goal being to promote the improvement of quality in the United States. The award was named after the late Secretary of Commerce, Malcolm Baldrige, who was killed while he was serving office in 1987.

The MBNQA addresses much broader criteria than those of the ISO 9000 Series Standards. The basic process entailed in the pursuit of the award starts with an application that is written by the business unit seeking the award. Specific criteria is provided that each company must address in a written application normally restricted in page count to approximately 85 pages. There a total of seven categories that must be covered, detailing all aspects of the companies business:

- *1.0 Leadership (90 points)*
  - *1.1 Senior Executive Leadership (45 points)*
  - *1.2 Leadership System and Organization (25 points)*
  - *1.3 Public Responsibility and Corporate Citizenship (20 points)*
- *2.0 Information and Analysis (75 points)*
  - *2.1 Management of Information and Data (20 points)*
  - *2.2 Competitive Comparisons and Benchmarking (15 points)*
  - *2.3 Analysis and Use of Company-Level Data (40 points)*
- *3.0 Strategic Quality Planning (55 points)*
  - *3.1 Strategy Development (35 points)*
  - *3.2 Strategy Deployment (20 points)*
- *4.0 Human Resource Utilization (140 points)*
  - *4.1 Human Resource Planning and Evaluation (20 points)*
  - *4.2 High Performance Work Systems (45 points)*
  - *4.3 Employee Education, Training, and Development (50 points)*
  - *4.4 Employee Well-Being and Satisfaction (25 points)*
- *5.0 Process Management (140 points)*
  - *5.1 Design and Introduction of Products and Services (40 points)*
  - *5.2 Process Management: Product and Service Production and Delivery (40 points)*
  - *5.3 Process Management: Support Services (30 points)*

5.4 Management of Supplier Performance (30 points)

6.0 Business Results (250 points)

6.1 Product and Service Quality Results (75 points)

6.2 Company Operational and Financial Results (130 points)

6.3 Supplier Performance Results (45 points)

7.0 Customer Satisfaction (250 points)

7.1 Customer and Market Knowledge (30 points)

7.2 Customer Relationship Management (30 points)

7.3 Customer Satisfaction Determination (30 points)

7.4 Customer Satisfaction Results (100 points)

7.5 Customer Satisfaction Comparison (60 points) [2]

Once the written application has been completed covering all seven of the categories listed, the evaluation then proceeds in a four-stage process:

- *Stage 1 - An independent review and evaluation is performed by at least five members of the Board of Examiners;*
- *Stage 2 - A consensus review and evaluation is performed for applications that score well in the first stage;*
- *Stage 3 - Site visits to applicants that score well in the second stage;*
- *Stage 4 - The judges give their review and recommendations.* [2]

For purposes of this document, only high level comparisons will be made between the two methodologies due to their diverse nature. The following are observations made while comparing the two approaches:

1) The MBNQA only allows for a finite set of "winners." Since it is a "contest," someone with an effective Quality Management System could be excluded from the recognition they rightly deserve. This can, if effect, do more damage than good through the loss of morale, buy-in, and overall support for the Quality Management System in place. ISO, on the other hand, can be achieved by many parties

2 United States Department of Commerce, The Malcolm Baldrige National Quality Award (National Institute of Standards and Technology, 1995), p. 20.

simultaneously. This is not to imply that the ISO criteria are more easily satisfied, just that the competition is not with other companies, simply against the criteria itself.

2) ISO 9000 is strictly achieved on a pass/fail basis, while the MBNQA is scored on a possible total of 1000 points. The MBNQA requires a scoring system, since it is a "contest" between different companies. Either way, both provide an effective means of evaluating the Quality Management System in question, because they allow for an organization to track continual improvement.

3) The ISO 9000 model measures only the state of your processes, not your products. The MBNQA examines both, with added focus on customer satisfaction (comprises 25% of the MBNQA scoring system, with ISO having 0%), strategic planning and development, human resource development and management, and business results.

4) Perhaps the biggest difference between the two is that the MBNQA is prescriptive in nature, while ISO 9000 is a descriptive model that only asks that you live to your own procedures. ISO has a very simple approach that is best stated in the following three phrases:

   - Say What you Do;
   - Do What You Say;
   - Prove it.

   This allows for the company to design its own Quality Management System to which it operates. By not being so stringent in its requirements, ISO can be less costly to implement, based on the assumption that the approach taken in pursuing registration is effective and efficient. It only asks that you define what your quality requirements will be, then prove that you follow those self-imposed requirements.

5) There are common elements that exist between the two different approaches:

   Leadership - Both MBNQA and ISO place the same weight on this element of a QMS. Leadership is considered a key item for a successful QMS by both models.

Management of Process Quality - Both approaches have this element in their evaluation models, however ISO weighs their measure of processes to a much higher degree than that of the MBNQA model.

Quality and Operational Results - MBNQA and ISO consider this an important element of an effective QMS, especially in the areas of product and service results, and supplier performance.

3.0 DEFINITION OF THE QMS

3.1 DETAILED ELEMENT DISCUSSION

The detailed element discussion that follows looks at each one of the 20 elements required by ISO 9001. First, the requirements of the specific element are stated. Second, observations collected during the implementation process are noted, including changes from the 1987 version of the standard, and the approach that the LFS-M facility took in becoming compliant to the element in question.

3.1.1 Management Responsibility (ISO 9001 Element 4.1)

Requirements

- The quality policy and it's objectives must be documented;
- The policy must be relevant to the organizational goals, the needs of your customers, and in easy to understand language;
- Management must demonstrate commitment to utilizing the ISO 9001 criteria as the model for their Quality Management System;
- The policy must be implemented throughout the organization;
- The company needs to define the organizational authority, responsibilities, and interrelationships of all personnel;
- Adequate resources must be provided for management, performance of work, and verification activities;
- A management representative must be assigned for making sure the requirements of the standard are met and maintained;
- The management representative must be member of management with executive authority;
- A management review must be held against the quality policy and objectives set for the organization;
- The management review must include results of internal audits, customer complaints, and other quality system data;
- Records must be kept of the management review as objective evidence.

Observations

There are changes in the current 1994 version of the standard that were not a part of the 1987 version. One of the changes was that Element 4.1.1 (Quality Policy) was changed to require that the quality policy be measured through the accomplishment of organizational goals

and the fulfillment of customer needs. Another change resulted in Element 4.1.2.2 (Resources) requiring that the company provide personnel and equipment to meet specified requirements.

An important rule to remember is to keep the quality policy as brief as possible. For example, the LFS-M quality policy is "Loral Federal Systems-Manassas (LFS-M) is committed to achieving the highest possible level of quality in meeting all customer and corporate requirements." An even shorter quality policy would have been perfectly acceptable, but it was determined that this policy worked best for the organization.

The management review held at LFS-M is performed at quarterly intervals. Each of the 20 elements of the standard are covered, with all executives in attendance. Management commitment is the most important step to achieving registration to any of the ISO 9000 standards. Without it, the registration effort certainly WILL FAIL.

3.1.2 Quality System (ISO 9001 Element 4.2)

Requirements

- All procedures relating to the 20 elements of ISO 9001 must be documented;
- A quality manual documenting supporting processes and procedures must be established;
- The quality manual must be implemented. This means that it is a living, breathing document that contains the current set of procedures in use by the organization. It cannot just be a set of documents which are written and put on a shelf;
- Quality planning needs to be evident and documented.

Observations

The documented quality system can take on many forms. Even if it doesn't look like what the assessor views as a "traditional structure," it is still compliant if it meets all of the requirements of the standard.

An addition to the 1994 version of the ISO standard is the requirement of a quality manual. The quality manual is a document that contains the quality policy, and describes the quality system of an organization. Element 4.2.3 now states that quality planning shall be consistent with all other requirements of the quality system, and be documented in a format to suit the supplier's method of operation.

The quality system at LFS-M was a compliant MIL-Q-9858A system. It already possessed many of the attributes required of a successful ISO 9001 system. The additions required as a result of the decision to pursue ISO 9001 registration were the following:

- A site-wide document data and control procedure was developed;
- A quality manual covering the 20 elements of ISO 9001 and the method of meeting the requirements of the standard was developed;
- An Internal Quality Audit program, auditing against the 20 elements of ISO 9001 was established;
- A quality policy was created and management representative assigned;
- A procedure for preventive action was developed;
- A procedure for servicing was developed to fill the requirement imposed by element 4.19.

There are five different types of documents, as displayed in Figure 3, that an organization must produce to address the required aspects of the standards. The quality policy

Figure 3: Traditional Documentation Structure - The five tier approach to documenting the quality system is used to depict the different types of documents that an organization must produce to address the required aspects of the standards.

is usually a one line statement reflecting the intentions of the organization. The quality manual is the map from the 20 elements of the standard to existing processes and procedures. The processes and procedures describe the what, when, where, and who performs given tasks. Work instructions are the detail required in performing a task, with quality records being the objective evidence that the system is in full use.

3.1.3 Contract Review (ISO 9001 Element 4.3)

Requirements

- There must be a documented procedure;
- Make sure you understand what your customer needs;
- Contracts must be complete and unambiguous;
- Any differences between you and your customer must be resolved;
- You must have the ability to meet all requirements stated in the contract;
- Document how amendments are handled;
- Document how you address verbal orders;
- Records of contract reviews must be maintained.

Observations

The changes from the 1987 standard are mainly the addition of a requirement for identifying how contract amendments are made and effectively communicated. Many functions within a company review specification requirements. It is much easier to establish one owner for contract review, most likely the Contracts organization. Necessary functions needing to review requirements should be referenced from the primary contract review procedure.

The LFS-M Contracts organization already had existing procedures under which they operated. As a result of the first formal visit by the assessor, there was some verbiage added to the procedure which spoke to how verbal orders from the customer were handled. This was identified as a potential weak area in the Contracts function, and promptly corrected.

3.1.4 Design Control (ISO 9001 Element 4.4)

Requirements

- There must be a documented procedure;

- May need to design the processes used to produce a product, as well as the product itself;
- Design and development sub-element requires a plan:
  - Requires a list of activities and who will perform them;
  - Must be assigned to qualified personnel.
- Need to know the organizational and technical relationships among the functions, and how information is accurately transmitted and reviewed;
- Design input requirements must be identified, reviewed, and documented;
- Incomplete, ambiguous, or conflicting requirements must be resolved;
- Must address statutory and regulatory issues;
- Design output must be documented in a form that can be verified to design input requirements and validated;
- Design output shall:
  - Meet the design input requirements;
  - Contain or reference acceptance criteria;
  - Meet regulatory requirements;
  - Identify safety issues;
  - Review prior to release.
- Design review must be held with all functions concerned represented and used to identify problems, as well as propose solutions. Records of design reviews must be kept;
- Must perform design verification - make sure that design output meets design input. Can be done via design reviews, peer reviews, qualification testing or demonstrations, alternative calculations, or through a comparison to a known proven design;
- Records of measures must be kept;
- Design validation ensures that the product meets the user requirements as defined in the contract;
- Must have procedures in place to handle, review, and approve design changes.

Observations

The changes from the 1987 standard were many. Element 4.4.5 (Design Output) now requires a separate, redefined, and formal review process. In addition, a new requirement for design validation and examination of the product to ensure customer satisfaction was incorporated, and a requirement stating that design changes have to be reviewed and approved before their realization.

An important tip in remembering the difference between verification and validation is that design verification is checking to see if you built something right (Does it work the way it is designed?). On the other hand, design validation is checking to see if you built the right thing (Does it do what the user wants it to do?).

The design control section of the standard does not say anything about how to perform a design. Therefore, arguments that it stifles creativity are usually from someone that doesn't understand the intent of the standard. Many important characteristics come from the design phase, thus it is necessary to pay attention to all facets of design (e.g. functionality, performance, safety, dependability, etc.).

LFS-M met the intent of this element of the standard through an Integrated Process Group (IPG) library. The IPG library consists of a complete set of documented engineering processes and procedures, used by the engineering community in the design and development of products (hardware and software). The library aided the successful evaluation of this element as it gave the engineers a central documentation repository to point towards when questioned about the processes they follow in the performance of their jobs. Future plans are in place to incorporate all other existing site processes as well.

3.1.5 Document and Data Control (ISO 9001 Element 4.5)

Requirements

- There must be a documented procedure;
- Must include all documents and records required by the standard;
- External documents are covered under this requirement, as applicable;
- Review and approve before using;
- Documents available where needed;
- Remove obsolete documents;
- Control changes;
- Must establish some way of knowing if the user of the document has the latest revision (master list or equivalent procedure).

Observations

One of the most often asked questions is "what has to be documented?" A general rule of thumb is if more than one person does a job, and it is essential that they all do it the same way, write it down. However, if it is something that anyone with the necessary training would intuitively knows how to do, don't write it down. If only one person knows how to do it, and the world would stop if that person gets hit by a truck, or wins the lottery, write it down.

Unwritten document control requirements include the following: document number; revision number; release/effective date; and page control number. When copies of an electronic document can be produced, the master should contain the disclaimer "For Reference Use Only." This lets the user know that the copy being used may not be the latest revision available.

LFS-M developed a site-wide document and data control procedure that governed all documentation across the site. The procedure was placed on-line, making it accessible to all employees. The Internal Quality Audit program was used to correct document and data control violations throughout the site.

3.1.6 Purchasing (ISO 9001 Element 4.6)

Requirements

- There must be a documented procedure;
- Records of acceptable subcontractors must be maintained;
  - How does someone get on the Approved Supplier List?
  - How/When do they get off?
- Subcontractors must be chosen based on their capabilities;
- Purchase orders must be reviewed and approved prior to release;
- Supplier verification performed at the subcontractor's facility must be included in the purchasing documents;
- Customer verification performed at the subcontractor's facility must be included in the customer's contract.

Observations

The changes incorporated from the 1987 standard are that requirements were added specifying verification arrangements, and the method of product release (means by which product is released after successful acceptance) in purchasing documents.

The LFS-M Procurement function has been audited on a regular basis for many years. They already had processes in place that were used to govern all aspects of their work.

3.1.7 Control of Customer Supplied Product (ISO 9001 Element 4.7)

Requirements

- There must be a documented procedure;
- You are responsible for the product, so treat it as though it is your own;
- The customer is responsible for supplying you with acceptable product.

Observations

Some examples of customer supplied product that fall under the purview of this element of the standard are Government Furnished Material and Equipment, and Customer Furnished Material and Equipment.

LFS-M had procedures in existence which control customer supplied product. There were many violations discovered in the internal audits, mainly cases where customer equipment was not located where the master property control listing said that it could be found. All noted discrepancies were corrected in a timely manner prior to the formal Assessment.

3.1.8 Product Identification and Traceability (ISO 9001 Element 4.8)

Requirements

- Users must know what they are working with at all stages of production, delivery, and installation (parts, assemblies, batches, etc.);
- Traceability requirement generally comes from a specification within a contract;
- Must have the ability to do a product re-call, should a part that was released early due to an urgent production need become identified as being a piece of a bad lot at a later time.

Observations

LFS-M met the requirements of this element of the standard as existing procedures were in use throughout the site. This element applies to raw materials, work in progress, and finished goods.

3.1.9 Process Control (ISO 9001 Element 4.9)

Requirements

- Processes that affect quality must be controlled:
  - Documented where absence would affect quality;
  - Equipment, environment are included as well;
  - Product/process monitoring;
  - Workmanship criteria;
  - Training;
  - Equipment maintenance.
- Special processes:
  - Can't be fully verified without destroying product (e.g. solder joint or loctite of a screw);
  - Require continuous monitoring;
  - Records must be maintained.

Observations

The changes from the 1987 standard are the addition of servicing and equipment maintenance requirements. Also specified are the "qualified operators" used in special process requirements.

LFS-M was found to be compliant with this element of the standard because Statistical Process Control (SPC) has been used at the facility for many years. Although usage on some programs has diminished due to a decrease in production, there were still several business areas that used SPC on a regular basis as a tool to reduce defects.

3.1.10 Inspection and Testing (ISO 9001 Element 4.10)

Requirements

- There must be a documented procedure;
- Receiving inspection and testing sub-element requires that verification be performed against a purchase order or quality plan;
- Item may be released only after verification;
- Must be traceable if released prior to verification for recall purposes;
- In-process inspection and testing must be done in accordance with procedures;
- Processes need to be monitored;
- Hold until verification is complete, or traceability established;
- Identify non-conforming material;
- All quality plan requirements must be complete;
- Records of final test complete the body of evidence that the product complies with the stated requirements;
- Maintain records showing what was tested, and what the results were;
- Be sure to consider regulatory requirements and product liability issues;
- Identify the person who "accepts" the product.

Observations

A new addition to the 1994 version of the standard accounts for the allowance of urgent production release of product.

LFS-M has procedures in place detailing all steps required for the proper inspection and testing of any unit and/or system to be delivered. A process also was in place covering the requirement for the potential occurrence of an urgent production release of product.

3.1.11 Control of Inspection, Measuring, and Test Equipment (ISO 9001 Element 4.11)

Requirements

- There must be a documented procedure;
- Calibration:
  - Must be documented procedures, and done at appropriate intervals;
  - Traceable to national standards (NIST)
  - Covers all equipment requiring accuracy and precision;
  - Records must be maintained;

- Assess previous results, if out of calibration;
- Assure suitable environment, handling, and storage;
- Guard against "user adjustments";

- Test hardware (fixtures, templates) and test software must be verified prior to use.

Observations

LFS-M had procedures in place governing all aspects of this element of the standard. However, lack of discipline in following those procedures resulted in a major non-compliance. There was a tremendous amount of work performed through the internal audits in order to get the facility ready for the formal Assessment. It is important to note that this element applies to ALL equipment (e.g. personal, customer, etc.).

3.1.12 Inspection and Test Status (ISO 9001 Element 4.12)

Requirements

- System for knowing, at all times, status of product:
  - Routings, travelers, stamps, physical location, etc.
- Document methods for showing status.

Observations

LFS-M was found to be compliant with the requirements of this element of the standard. Stringent controls were in place and already a part of the QMS at LFS-M due to years of operation in a MIL Standard environment. This made the explanation of how the site performed this activity a much easier task.

3.1.13 Control of Non-Conforming Product (ISO 9001 Element 4.13)

Requirements

- There must be a documented procedure;
- Define who can review and disposition items in question;
- Clearly identify to prevent accidental use;
- Must report concessions to customer if in contract;
- Must re-inspect reworked goods using standard inspection and test procedures.

Observations

There are several possible dispositions which include rework, repair, use-as-is by concession, re-grade for different application, and reject or scrap.

LFS-M met the requirements of this element of the standard by having a procedure in place. However, following those procedures within the lab areas was questionable. Many of the labs had non-compliance findings written against them, such as bad product being inter-mingled with good product, and product that was not properly identified. All labs across the site were audited on a periodic basis following the Pre-Assessment, until upper management felt comfortable that proper corrective action had been administered.

3.1.14 Corrective and Preventive Action (ISO 9001 Element 4.14)

Requirements

- There must be a documented procedure;
- Take action to a degree that is appropriate to the magnitude of the problem;
- Implement and record changes to documented processes/procedures;
- Include customer complaints, and product non-conformities;
- Investigate, record, and eliminate the cause of problem;
- Check to see if changes are effective;
- Applies to the entire quality system;
- Use all sources of data to find potential problems;
- Determine what needs to be done;
- Include as part of the management review performed at prescribed intervals.

Observations

Changes to the 1994 standard include the addition of "effective handling" to customer complaint procedures, and a requirement for recording results of analyses and investigations. Also, corrective and preventive action were separated for clarification.

LFS-M met the requirements of this element of the standard with minor corrections. A procedure was added for preventive action. Once this was in place, the intent of the standard was met.

3.1.15 Handling, Storage, Packaging, Preservation and Delivery (ISO 9001 Element 4.15)

Requirements

- There must be a documented procedure;
- Need to provide methods to prevent damage, deterioration, loss of identification (including age control);
- Must designate storage areas;
- Shall control packing, packaging, and marking processes;
- Must apply appropriate methods for preservation and segregation;
- Condition of product in stock shall be assessed (at defined appropriate intervals);
- Shall ensure protection of product after final inspection and test;
- Applies to raw materials, work in progress, finished goods.

Observations

There a couple of important tips to remember that apply to this element of the standard: 1) "Handling" applies to things which are in motion, or being worked on, and 2) "Storage" refers to things at rest anywhere in the process - not just in the storage area.

LFS-M met the requirements of this element of the standard as procedures were already in place and in use.

3.1.16 Control of Quality Records (ISO 9001 Element 4.16)

Requirements

- There must be a documented procedure;
- Quality records are your objective evidence;
- Records must be:
  - Legible;
  - Identifiable to the product involved;
  - Readily retrievable;
  - Stored in a suitable environment.
- Retention times must be stated;
- Available for review when in a contract.

Observations

Quality records required by the standard are called out within the document itself.

Those elements referencing quality records specifically are:

- 4.1.3, Management Review;
- 4.3, Contract Review;
- 4.4.6, Design Review;
- 4.4.7, Design Verification;
- 4.6.2, Acceptable Subcontractors;
- 4.7, Customer Supplied Product;
- 4.8, Product Traceability;
- 4.9, Qualified Processes;
- 4.10.1, Inspection and Testing Records;
- 4.10.2.3, Urgent Production Release;
- 4.10.5, Inspection and Test Data, plus Authority for Release;
- 4.11.1, Inspection and Test Hardware and/or Software;
- 4.11.2.e, Inspection and Test Equipment;
- 4.13.2, Nonconforming Product Concessions;
- 4.14.2.b, Corrective Action;
- 4.16, Any records necessary to demonstrate conformance to specified requirements and quality system operation;
- 4.17, Internal Quality Audits;
- 4.18, Training.

LFS-M satisfied the auditors during their examination of this element of the standard. The proper handling and storage system for keeping quality records was questioned. However, a quality record can be anything from meeting minutes, to delivered customer documents, so there can be any range of acceptable methods for storage.

3.1.17 Internal Quality Audits (ISO 9001 Element 4.17)

Requirements

- There must be a documented procedure;
- Must assess the overall quality system;
- Verify that the quality system is effective;
- Internal Quality Audits must be scheduled on the basis of status, and importance;

- Audits must be performed by "independent" personnel (has no direct responsibility for the activity being monitored);
- Results must lead to timely corrective action;
- Audit results must be included in the management review.

Observations

The Appendix contains a set of questions developed to test conformance to the ISO 9001 criteria during Internal Quality Audits, and can be found in Section A-3. These audit questions should be used as a checklist for performing functional Internal Quality Audits.

The Internal Quality Audit program is the backbone of continuous process improvement. The three core elements of continuous process improvement are Internal Quality Audits, Corrective and Preventive Action, and Management Review.

LFS-M met the requirements of this element of the standard with the addition of a procedure for performing Internal Quality Audits, the establishment of a program which audited the QMS to the 20 elements of ISO 9001, and an auditor training program.

3.1.18 Training (ISO 9001 Element 4.18)

Requirements

- There must be a documented procedure;
- Must evaluate the staff, and identify training needs;
- Provide training to all whose activities affect quality;
- Training records must be maintained;
- People can be qualified based on their education, training, and/or experience.

Observations

The only changes from the 1987 standard to the 1994 version was that the term "documented" was added as it applies to training.

LFS-M had a process in place meeting the intent of the standard. The only additional work required was that the training process needed to be formally documented via a released procedure. The real exposure to passing this element of the standard was that management was

not as familiar with the process as they should have been. This was fixed by preparing a one page "white paper," detailing the training process, and disseminating it to all managers on site.

3.1.19 Servicing (ISO 9001 Element 4.19)

Requirements

- There must be a documented procedure;
- Applies upon delivery, when specified by contract.

Observations

LFS-M met the requirements of this element of the standard through the addition of a site-wide procedure for servicing. It is also important to note that field work is covered under this element.

3.1.20 Statistical Techniques (ISO 9001 Element 4.20)

Requirements

- There must be a documented procedure;
- If used to control a process, you must have documented procedures;
- If used, the technique must be adequate for the intended purpose.

Observations

It is not mandatory to perform statistical techniques. However, 4.9.d (Process Control) could be found non-compliant by failing to use statistical techniques, if an auditor feels that these techniques to improve product quality could have been employed.

LFS-M satisfied the requirements of this element of the standard through the existence of internal processes, and tools available to perform different types of statistical analysis. Again, SPC had been in use for many years, so there was a great deal of objective evidence available to support usage of the statistical techniques.

3.2 Categorizing Non-Compliances

When a registrar conducts an audit of a company's Quality Management System, the objective is to determine whether or not it is compliant to the standard being utilized. When an item is not in compliance with the intent of the standard, it is referred to as a "finding" or "non-compliance." Non-compliances can be written against any and all elements of the standard, if necessary, and are categorized as either an observation, minor non-compliance, or a major non-compliance. An observation is an observed condition that could affect quality, but is not a clear violation of written procedures. A minor non-compliance is defined as "*a non-compliance finding which is indicative of a system deficiency, but poses no immediate hazard to product quality. It must however be rectified within a defined time limit,*" or "*a single observed lapse in a procedure.*" The last finding, a major non-compliance, is the most severe rating. It is defined as "*a non-compliance finding which is indicative of a system deficiency that may hazard or put at risk (potential degradation of current level of quality) product quality, and must be rectified before approval is considered,*" or "*the absence of a required procedure or the total breakdown of a procedure.*" [3] Good examples of the difference between major and minor findings would be the following:

- Major - A significant percentage of the measuring instruments are outside valid calibration status;
- Minor - A micrometer in use was found to be just overdue for calibration.

- Major - Several instances noted of informal and unapproved changes to work instructions;
- Minor - A single drawing in use found to be marked up with unauthorized changes to non-critical design tolerances.

- Major - A failure to establish documented procedures for contract review or design verification;
- Minor - A failure to keep records of a contract review or design verification on one project only.

3 Inchcape Testing Services, ISO-9000/Q9000 Training Courses, Revision 6, Release Date December, 1994.

During the closing meeting of an audit by a registrar, a summary of all findings will be discussed and given to the site focal point for corrective action. A number of minor non-compliances listed against the same requirement can represent a total breakdown of a system, and thus be considered a major non-compliance. Registration will not be considered until corrective action has been implemented for all reported major non-compliances. However, minor non-compliances would not prevent registration from proceeding, and would be followed up for effective corrective actions at the next surveillance visit. Generally, most registrars will not consider giving any type of recommendation for registration given any type of major non-compliance in any area of the standard.

The gathering of objective evidence is critical prior to the determination of whether an element of a Quality Management System is non-compliant. Objective evidence is defined as "information which can be verified, based on facts and obtained through observation, measurement, test or other means." Without objective evidence to back a finding, there is no finding. Always remember, "the process is correct until proven otherwise."

When writing a non-compliance against an element of the standard, it is important to remember the following:

- *If a potential non-compliance is observed, take note of all the relevant facts, corroborated by the company guide, for later discussion with the lead auditor, and possible inclusion in a non-compliance report;*
- *If the answers given are unsatisfactory, pursue your investigation until you have established factual evidence in order to clarify the situation, but watch your time;*
- *Never attempt to write non-compliance reports while in the middle of an investigation. Good report writing needs careful thought and time;*
- *Draft the non-compliance using, as far as possible, phrases from the system standards. This provides a disciplined framework for writing, and adds authority to the statements of*

noncompliance. It also aids the client to recognize what needs to be done to gain compliance with the standard. [3]

There is some historical data available that gives some insight into areas most commonly found to be non-compliant. Figure 4 displays a percentage of system non-compliances registered against ISO 9001 as compiled by Lloyd's Register Quality Assurance Ltd. (LRQA). The chart highlights each of the 20 elements of the ISO standard in the rank order that they have been found by LRQA as primary reasons for not recommending a company's registration to a standard after they have performed audits. As evidenced by the chart, the number one reason that most companies fail to achieve registration is due to problems in the area of element 4.5, Document and Data Control. It is interesting to note that 60% of all problems with registration are associated with the following five elements of the standard:

1. Document and Data Control;
2. Design Control;
3. Purchasing;
4. Inspection and Test;
5. Process Control.

Another interesting point which can be included in any company's planning cycle, is the fact that 70% of all companies have to apply some type of corrective action before registration is approved the first time around.

3 Inchcape Testing Services, ISO-9000/Q9000 Training Courses, Revision 6, Release Date December, 1994.

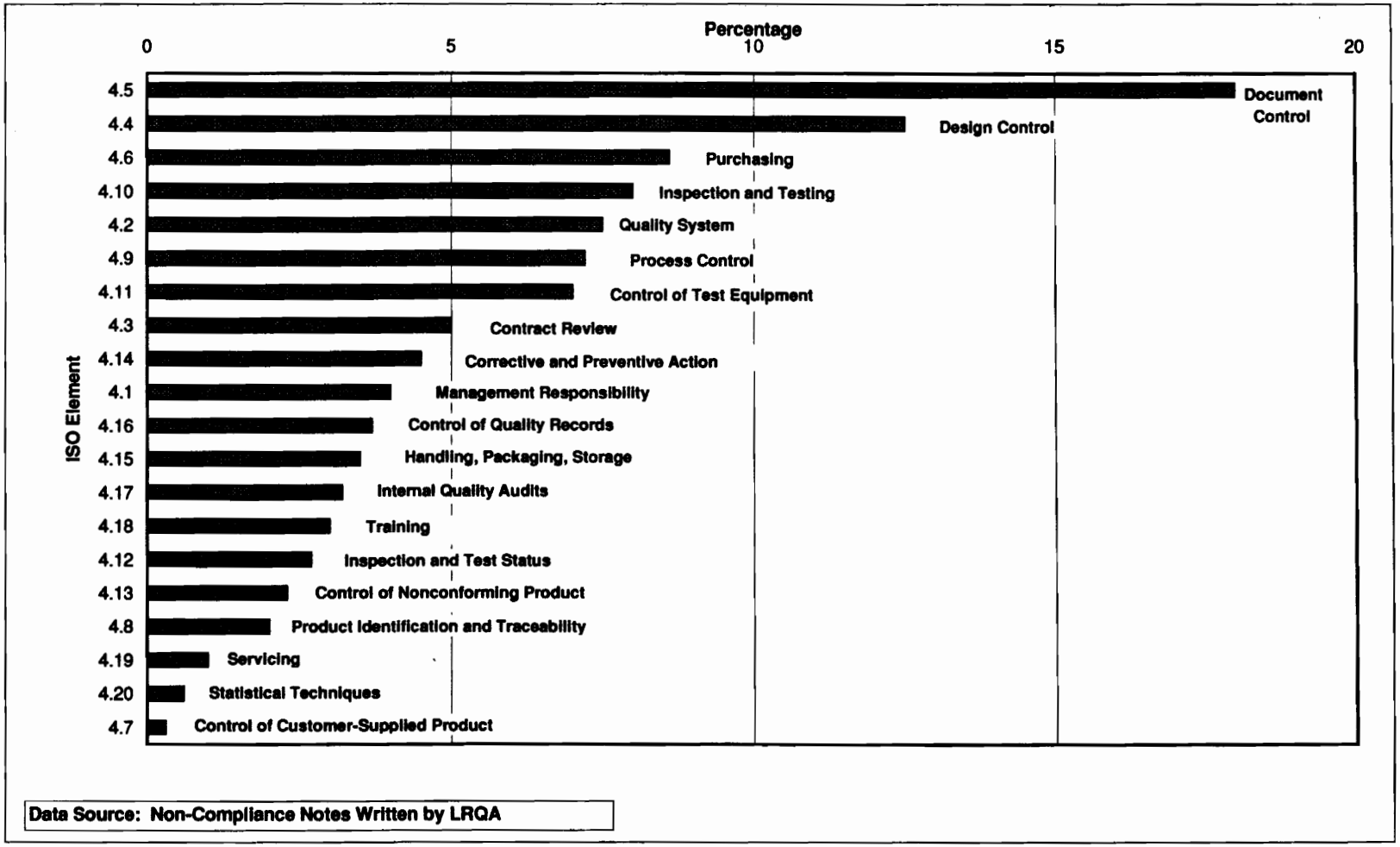


Figure 4: System Non-Compliances - The percentage of system non-compliances registered against ISO 9001 (1987 version) is shown. Data was collected by LRQA of the United Kingdom.

4.0 IMPLEMENTATION

4.1 IMPLEMENTATION DISCUSSION

Implementation has been broken down into eight logical steps that an organization would have to exercise properly in order to successfully obtain ISO 9001 registration. The different steps toward registration are shown in the ISO 9001 Implementation Schedule, included as Figure 5, which displays the actual timeline to which the LFS-M facility operated[4]. Although at first the schedule may seem somewhat aggressive, it is the belief of the author that the fact that LFS-M was already a MIL-Q-9858A facility, certainly gave the site a good foundation upon which to build. That does not imply that the site was already compliant with the ISO 9001 standard, just that the maturity of the existing Quality Management System enabled an accelerated timeline. However, one of the biggest mistakes that an organization can make in their pursuit of ISO registration is starting with a preliminary schedule that stretches the effort out two to three times longer than it should actually require. Usually the scope doesn't even cover an entire site, only a production program or line, simply for fear of failure. The axiom "start with a small project first" can too often be used as an excuse for not taking an adequate and appropriate risk in today's business environment, when total success can be so readily achieved.

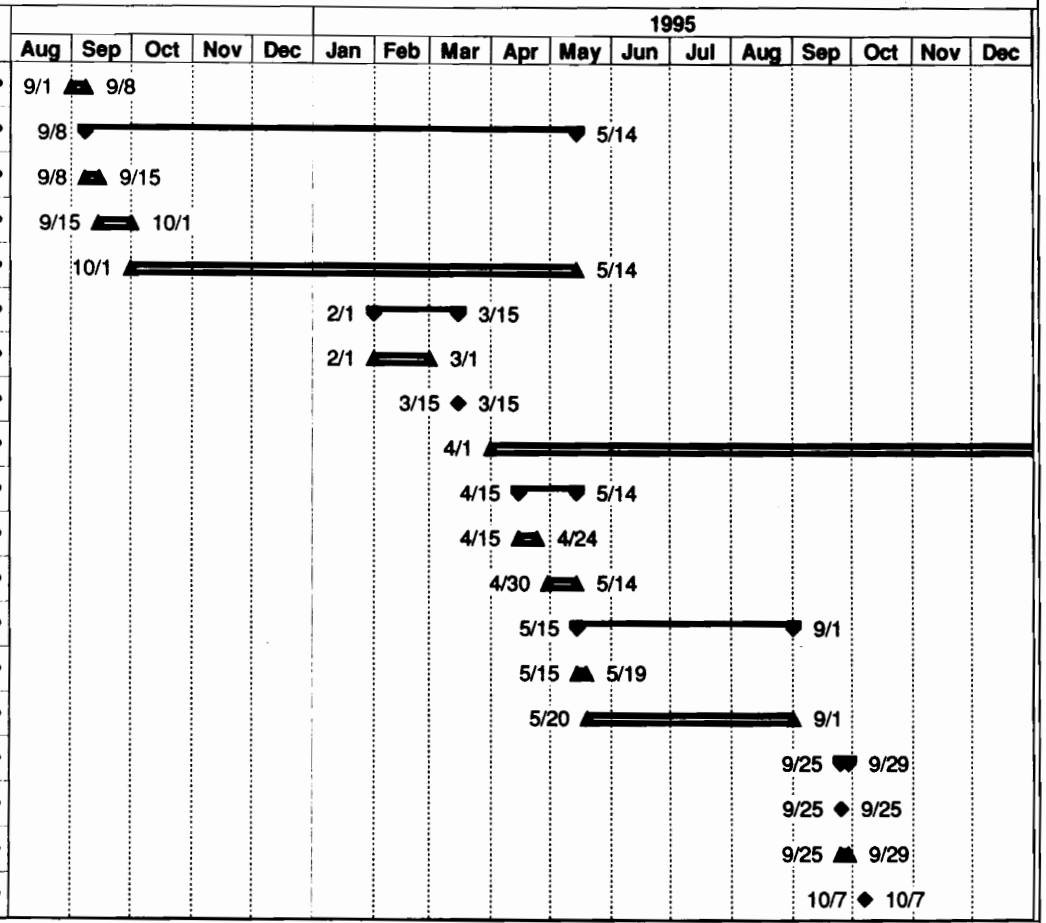
4.1.1 Determination of Need

The first step to ISO 9001 registration begins with the determination of need. Organizations are pursuing registration today for many different reasons. New business RFP's, and active contracts have suddenly become sprinkled with phrases like the fairly innocuous "shall be compliant with ISO 9001," to the ever feared "shall be registered to ISO 9001." Some simply are looking for a Quality Management System to employ at their company and want to use the ISO 9001 criteria to improve the way they do business on a day to day basis. Whatever the reason, a little bit of homework is required at this point in time. A good place to start would be to poll some of the business area managers in order to discern whether they are seeing

4 Note: The Master Schedule, Figure 5, does not show an end date for the Internal Quality Audit program as this is a continuous process throughout the remainder of organizational operation.

ISO 9001 Implementation Schedule

ID	Name	% Comp
1	**STEP 1 - DETERMINATION OF NEED**	**100%**
2	**STEP 2 - ESTABLISH BASELINE**	**100%**
3	Select and Train Implementation Team	100%
4	Perform Audit of Quality Mgmt. System	100%
5	Work Findings from Audit	100%
6	**STEP 3 - REGISTRAR SELECTION**	**100%**
7	Perform Comparative Analysis	100%
8	Application Submission	100%
9	**STEP 4 - INTERNAL QUALITY AUDITS**	**100%**
10	**STEP 5 - DOCUMENTATION REVIEW**	**100%**
11	Submit Quality System Documentation	100%
12	Work Findings from Document Review	100%
13	**STEP 6 - PRE-ASSESSMENT**	**100%**
14	Actual Pre-Assessment by Registrar	100%
15	Work Findings from Pre-Assessment	100%
16	**STEP 7 - ASSESSMENT**	**100%**
17	Address Pre-Assessment Findings	100%
18	Actual Assessment by Registrar	100%
19	**STEP 8 - REGISTRATION**	**100%**



Project: ISO 9001 Implementation
Date: 10/26/95

Critical — **Milestone** — **Summary**
Noncritical — **Summary**
Progress — **Rolled Up**

Figure 5: ISO 9001 Implementation Schedule - The schedule displays the ten month ISO 9001 implementation timeline utilized by the LFS-M team.

requirements show up in their RFPs, or if their customer has verbally expressed an interest in the company's future plans to become an ISO registered facility. The point is to thoroughly understand the main drivers behind the decision to pursue registration as it will most likely be challenged at some point in the implementation phase by parties that don't share the same thought process.

Once the decision to pursue registration has been made, it is imperative that senior management be committed to the process from the beginning. It is best to get all executive decision makers in the same room, and obtain concurrence as a team that each and every one of them will fully support the effort. There are many critical steps in the registration process, but there is none more important than gaining and keeping full management commitment.

4.1.2 Establish Baseline

The only way to determine just how much work is required to become compliant with all 20 elements of the standard is through the development of a quality system baseline. This is best accomplished through the performance of a Gap Analysis, or simply measuring the distance between your current Quality Management System capabilities, and what would be required to be a registered company.

LFS-M performed a Gap Analysis, as indicated on the implementation schedule, early on in the process after the need for registration was decided. LFS-M was fortunate to enlist the services of Mr. Charles Abney, Loral Western Development Laboratories, to guide the team through the Gap Analysis. Mr. Abney is an ISO 9000 expert who spent a week with the team, consisting of a couple of days of intensive training, followed by a few days of internal auditing across the site testing compliance to the ISO 9001 standard. It is highly recommended to have a consultant present who is able to teach the team how to interpret each element of the standard. This helps everyone on the team obtain a mutual understanding of each paragraph in the standard, leaving little to each individual's own interpretation. This prevents confusion in the long run, and establishes a core set of individuals who could eventually become quality system auditors at some point in the future.

The results of the Gap Analysis performed during the consultant's visit are covered in Section 5.1.1 of Chapter 5.0, Project Results. These results indicated that registration could be obtained within a seven to ten month timeframe, depending on the effort put forth.

The results of the Gap Analysis are extremely useful in that the process identified the primary focus areas for the team over the next few months. The plan was to close the major non-compliance areas, as well as all minors, prior to bringing in a third party assessor to perform a Pre-Assessment of the Quality Management System.

4.1.3 Registrar Selection

The selection of a registrar is a critical step in the implementation process. There are many important attributes in a potential registrar that need to be evaluated as part of the selection process. Exactly what those attributes are can only be determined and prioritized by the company that is pursuing registration, but may include such criteria as accreditations of the registrar, cost charged for the Pre-Assessment and Assessment activity, frequency of verification audits, willingness and ability to work with companies, etc.

The criteria utilized in the selection of a registrar for the LFS-M facility can be viewed in Figure 6. An analysis of seven different registrars was performed over a one month period. The initial list of potential registrars was gathered largely from input received through the Loral Corporate ISO 9000 Working Group meetings held on a quarterly basis designed to facilitate communication among the many different divisions throughout the United States. The LFS-M registrar was chosen for several reasons:

1) They were accredited by the National Accreditation Council for Certification Bodies (NACCB). An NACCB accreditation was viewed as the primary criteria for registrar selection due to the extent of the division's business dealings with the United Kingdom.
2) The registrar was utilized heavily by many sister divisions, and had a reputation as being a very tough, but fair third party registrar with whom to do business. It was felt that the Quality Management System would get the most benefit by selecting a stringent evaluator, as LFS-M would benefit in the long run.

Registrar	Appl. Fee & Doc. Review	Pre-Assess Cost	Assess Cost	Total Non-Rec. Cost	Annual Recurring Cost	Re-cert Freq.	Accred. Boards	Notes & Pass/Fail Criteria
Registrar 1	$1,300	$5,200	$21,450	$27,950	$10,400 (for 2)	6 months	RvC RAB INMETRO	Flexible in major non-compliances. Recommended by John Doe from xxxx Re-cert every six months at $5,200 each.
Registrar 2	$1,300	$7,800	$18,200	$27,300	$15,600	1st 3 mths., then at 6 mnth. inter.	NACCB RAB ANSI	No major non-conformances in any category accepted, number of minors may also constitute a major.
Registrar 3	$2,850	$0	$12,650	$15,500	$7,800	N/A	APAVE SOCOTEC	Does not have RvC or NACCB accreditation.
Registrar 4	$0	$0	$5,000	$5,000	$2,950	6 months	RvC	Registration must first be agreed upon by xxx, who has the option to audit the site again themselves.
Registrar 5	$1,300	$15,000	$25,000	$41,300	$6,000	9 months	RvC RAB	Re-cert every nine months
Registrar 6	$1,300	$10,000	$18,000	$29,300	$10,000	Annually	RvC RAB	Re-certify annually
Registrar 7	$1,300	$8,300	$19,100	$28,700	$3,098	Annually	RvC RAB ANSI, SCC	Re-certify annually

Accrediting Boards

ANSI - American National Standards Institute
APAVE - France
INMETRO - Brazilian agency
NACCB - United Kingdom
RAB - Registrar Accreditation Board (U.S.)
RvC - Raad voor de Certificatie (Dutch Council for Certification)
SCC - Standards Council of Canada
SOCOTEC - France

Note: Six accrediting boards signed a mutual recognition agreement, two of the six were NACCB & RvC

Figure 6: Registrar Selection Criteria - This figure displays the registrar selection criteria considered in the selection of the LFS-M assessor (Actual data may not be shown for legal reasons).

3) The registrar was competitive from a cost standpoint, with travel expenses being minimal. They were willing to negotiate cost to some extent, giving a couple of extra assessment days (when taken to task) free of charge.

4) The registrar had performed many audits with companies that had a similar scope of registration, especially in the area of systems integration. A large amount of LFS-M's work is in the area of software development, and the registrar produced impressive credentials in this critical area.

There are several pieces of information that can be readily obtained through phone interviews with the candidate registrars. Questions that might be useful to ask each of them could include the following: Do you have a list of references for companies that are similar in scope? What are your current and planned accreditations? What training and skills do your auditors possess that qualify them to perform assessments on companies with the same scope of registration? What type of complaint resolution process does the company employ if an issue arises where the company feels an auditor is being unprofessional or unfair? Under what circumstances would/could the registrar withdraw registration? How soon can a pre-assessment and/or assessment be performed? Upon successful registration, is the company allowed to use the logos of the accrediting organizations in marketing publications and/or new business proposals?

This is not an all inclusive set of questions, but does represent a minimum sample that should be asked prior to teaming with any assessor, as the company will be required to work with this same group of people for many years to come. The selection process should never be taken too lightly.

4.1.4 Internal Quality Audits

An effective Internal Quality Audit program is essential to continual process improvement. Continual process improvement comprises three basic elements; 1) Internal Quality Audits utilized to identify areas of non-compliance within the Quality Management System, 2) results of the audits are then used to develop effective corrective actions in order to eliminate the causes of the non-compliance, and 3) management reviews, which are held in order to communicate the status of the Quality Management System, and take additional action where needed in order to gain total system compliance. However, it starts with the establishment of an effective Internal Quality Audit program, and is the most important of the three elements mentioned.

The first step in the establishment of an Internal Quality Audit program is to have a few select individuals extensively trained. The preferred method would be to have these representatives attend a lead assessor course from a qualified registrar, if financial constraints allow such an investment. These training courses generally last about one week and are offered by several accredited registrars throughout the country. The course is expensive, and rather intensive, however the experience gained is invaluable to both the company and attendees. Sending at least one person is highly recommended, if at all possible. The attendees leave with a complete understanding of the standard from a registrar's viewpoint, and have the ability to perform a complete first, second, and third party quality system audit. Should funding be unavailable to send even one person to the course, you will have to obtain additional training through some other medium, or be forced to rely solely on the training received from the subject matter expert present during the performance of the Gap Analysis.

The second step is to develop an internal training course for certifying a select set of auditors from different functional areas within the company. This establishes a pool of auditors from which to draw upon when performing internal audits. LFS-M sent three auditors to a week long lead assessor course taught by a well known registrar. Once complete, the knowledge was brought back and used to develop a training course for certifying the internal assessors. If the

content of the internal course developed is accurate and detailed, the only reason to send other personnel to be trained from an accredited registrar would be if the individual needs to obtain official lead assessor certification status from an accrediting body.

The third step is to develop an audit schedule. Since the registrar audits the LFS-M facility at six month intervals, Internal Quality Audits are performed at the mid-point of this six month period. This allows for two thorough Internal Quality Audits annually, which provides for a good assessment of the Quality Management System. The frequency and level of auditing that occurs on a program or functional area should be based on prior audit findings. If audit findings indicate that a major non-compliance exists in the area of design control, then more time should be spent in the design and development areas than in others requiring audits, such as Procurement, Contracts, Integrated Logistics Support, etc. A registrar will look to see if Internal Quality Audits are scheduled on the basis of the status and importance of the activity to be audited, and that the personnel performing the audit are independent of the area being audited. LFS-M achieved auditor independence by having Quality Assurance, who reports directly into the President, perform the Internal Quality Audits on all programs and functional areas.

The last step is to have an adequate database from which to track all actions to closure. The database does not have to be elaborate, simply functional. The data contained within the database will be tested, since it is objective evidence, for its effectiveness in the implementation of corrective and preventive action.

4.1.5 Documentation Review

The document review process usually occurs about one month prior to the formal Pre-Assessment by the registrar. The documentation can either be reviewed on site or at the assessors central office. Usually, most assessors prefer to perform the review on site since they are able to have questions answered real time. LFS-M sent the documentation to the lead assessor, but given the chance to do it over again, would have brought them into the facility. A face to face meeting clears up any confusion with the documentation and gives the company a chance to get the assessor familiar with the site's processes. LFS-M paid the price in spending

most of the first day of the Pre-Assessment getting the auditors up to speed, when they should have been auditing the quality system.

The assessor will want to review the quality manual, procedures referenced in the quality manual, and work instructions. Once the review is complete, the assessor generates a report requiring corrective action plans of all non-compliances noted. Once the non-compliances have been closed, the Pre-Assessment may take place.

4.1.6 Pre-Assessment

The Pre-Assessment is an option that most experienced registrars will highly recommend. The reason for this is that it greatly increases the chances of passing a formal Assessment, because the Quality Management System has already been thoroughly "scrubbed" by the assessor. If the option for the Pre-Assessment is exercised, the organization will know exactly what is needed in order to pass an audit, as opposed to being surprised during the formal Assessment. In the case of LFS-M, it was discovered that the interpretation of what was and was not a major non-compliance item differed from the registrar's viewpoint. LFS-M was then able to appropriately tailor the Internal Quality Audit program and action plans based on the data received from the Pre-Assessment. LFS-M would not have passed a formal Assessment without it.

The Assessment process is displayed in Figure 7, and is used during both the Pre-Assessment and the formal Assessment. The length of the Assessment varies with the organization's size and complexity, and with the auditor's practices.

The Pre-Assessment starts with the team meeting held with the assessors, prior to visiting the facility to be audited. They will discuss problems that they may audit as a result of the document review, and formulate an audit plan based on their knowledge to date of the facility in question. During the Pre-Assessment, the auditors have the choice between allocating functional areas to each of them to audit against the 20 elements of the standard, or allocating parts of the 20 elements to each auditor.

Once the auditors arrive at the facility, an opening meeting is conducted. This meeting is very brief, and covers the introductions of the audit team, describes the scope of the audit, assurances of confidentiality, background of registrar, accreditations, and lastly, the audit process to be employed during the course of the week. Once this meeting is finished, the audit will commence.

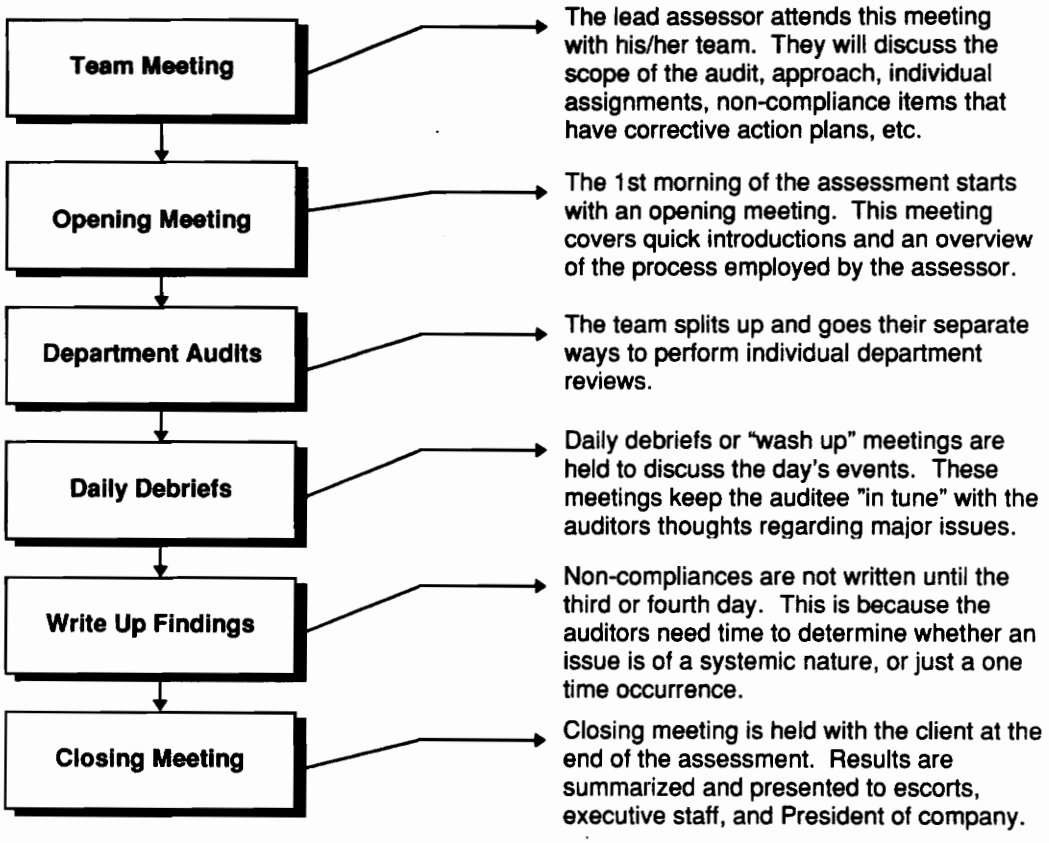


Figure 7: The Assessment Process - This figure displays the Assessment process that is employed by the registrar during both the Pre-Assessment and the formal Assessment.

The audit starts with the assessors going their separate ways to perform individual department level audits throughout the facility. Assessors must be escorted at all times from the time they arrive, to the moment they leave. It is normal practice for the assessors to cover different areas of the standard so as to not duplicate efforts. This also allows the Assessment team to increase the sample size of the population, ensuring a complete analysis of the quality system. Department level audits often lead to a program audit in that the auditor wants the freedom to follow a "thread" if necessary. A good example would be if while visiting the Contracts organization, auditor A wanted to see how a specific program generated and communicated its requirements to engineering. Following this thread would quickly lead to the originator of the generated requirement, most likely Program Management, who could then be audited as to how they received their requirement for that program. This happens quite often and makes scheduling a site visit itinerary a difficult task as it is usually obsolete after the first five minutes.

Each day of auditing ends with what is called a "daily debrief." Attendees include the audit team, company quality representative, and other key personnel that wish to be present. This meeting is utilized to cover several aspects of the Assessment activity:

- Non-compliances uncovered during the course of the day are reviewed in order to ensure everyone involved understands the nature of the non-compliance;
- Relations are monitored between the assessor and guide if conflicts exist. Sometimes during the course of the Assessment, tensions run high and personalities tend to clash. These situations need to be resolved immediately;
- Questions regarding any part of the Assessment can be asked and resolved at this point;
- Progress of the Assessment is monitored to ensure that an adequate sample of the quality system is checked. Should the process run behind schedule, efforts can be made to quicken the pace of the audits;
- Timeframes for corrective actions in response to non-compliance findings are agreed upon.

It is through these daily debriefs that the management representative and other team members get a good idea of what non-compliances the assessors are finding in the quality system, and whether they fall into the minor or major category.

Assuming the audit is over a period of one week, findings will not be generated until the third or fourth day. This gives the auditor a chance to determine whether the issue is systemic in nature, or a one time occurrence. Findings will fall into one of three categories:

- Observation - an observed condition that could affect quality, but is not a clear violation of written procedures;
- Minor non-compliance is defined as "*a non-compliance finding which is indicative of a system deficiency, but poses no immediate hazard to product quality. It must however be rectified within a defined time limit*," or "*a single observed lapse in a procedure;*"
- Major non-compliance is the most severe rating. It is defined as "*a non-compliance finding which is indicative of a system deficiency that may hazard or put at risk product quality, and must be rectified before approval is considered*," or "*the absence of a required procedure, or the total breakdown of a procedure.*" [4]

All non-compliances must be corroborated by objective evidence, and require a corrective action plan to be submitted within a specified period of time.

4.1.7 Assessment

The formal Assessment follows the same basic format used for the Pre-Assessment that is shown in Figure 7. The main difference is that this Assessment will end with a closing meeting in which the auditor and staff will make a recommendation for or against registration. Normally, most assessors will not recommend an organization for registration with a major non-compliance in any one of the 20 elements of the ISO standard. Assuming the organization passes with only minors, corrective action plans are again required to be submitted within a set timeframe.

4 Inchcape Testing Services, ISO-9000/Q9000 Training Courses, Revision 6, Release Date December, 1994.

4.1.8 Registration

If the outcome of the formal Assessment is a recommendation for registration, the organization will receive a certificate in approximately one month. The big mistake that many organizations make is to stop improving their processes once the goal is achieved. This is why assessors have follow-on visits to ensure that the organization fixes prior non-compliance areas in certain elements, and doesn't let the Quality Management System deteriorate over time. These follow-on visits are normally every six months, but can vary from registrar to registrar.

A recertification is usually required after some period of time. The LFS-M registrar does not require a recertification after a period of time, saving the organization the cost of a fully staffed assessment.

4.2 TOOLS DEVELOPED

There are two tools that were developed in order to facilitate the implementation effort that are transferable to other organizations. The tools are the Internal Quality Audit Checklist, and the Gap Analysis Tool which are discussed at length in the next two sections.

4.2.1 Internal Quality Audit Checklist

In order to conduct an Internal Quality Audit program, a Checklist has to be developed which an internal quality auditor can use to test the quality system for compliance to the standard being assessed. Given that the Checklist is comprehensive, it can be used as a guide in auditing any program or functional area. The Internal Quality Audit Checklist developed and used by LFS-M has been included as Appendix A-3. Each element of the standard has specific requirements that an organization must address, and were covered in detail and discussed in Chapter 3. The Checklist, developed by the LFS-M team, considers each of these requirements, and how to best create questions that could test the system for compliance. Any functional area can select those elements of the standard that they feel are applicable to their group. In order to assist those functional areas in determining which elements are applicable, each of the 20 elements were mapped to varying functional areas within an organization.

This Checklist was used in the LFS-M Internal Quality Audit program to audit each functional area. The hard copy documents were filled out and kept in a database for objective evidence, which the assessors examined and determined to satisfy the requirements of the ISO standard.

4.2.2 Gap Analysis Tool

The performance of a Gap Analysis prior to beginning any work in attempting to achieve registration is very important. The objective of the exercise is to give the company a point of reference with regard to future progress, as well as indicate how much work needs to be done in order to pass an audit by a registrar. Due to this importance, a Gap Analysis Tool was developed in order to hopefully facilitate, focus, and prioritize the efforts by any company in its initial stage of seeking registration to any one of the three ISO 9000 standards.

The Gap Analysis should be performed by one or two individuals who have a working knowledge of the company's processes currently in use. The tool first involves examining the ISO criteria at the sub-element level (e.g. 4.1.1, 4.1.2, 4.1.3, etc.). The ISO standard should be used as the requirements guide, or the Internal Quality Audit Checklist could be used. Both methods would satisfy the requirement of the exercise, which is to evaluate requirements and score each sub-element of the ISO standard. The evaluation is performed by using the criteria as a guide in determining which of the following element ratings best describe the current state of the specific sub-element in question. There are six possible states from which to choose, ranging from a rating of "0" to "5." A six point scale was selected due to its ease of use and because it was felt that it covers all possible ranges of compliance; from no attempt to comply at all (or 0% complete), to full implementation (or 100% complete). The differences in the point system are shown below, with an example to help the user better understand the rating described:

0 - No attempt has been made to comply with the stated requirements of the standard. 0% of the final effort has been completed. (e.g. No records of acceptable subcontractors exist, and plans have not been put in place to create such a database.)

1 - Planning stages to meet the requirements of the standard, however the system has not yet been implemented. 1% to 25% of the final effort completed. (e.g. Plans are in place to develop the database, however it has not yet been implemented.)

2 - Implementation of a compliant solution to meet the requirements of the standard has commenced. 26% to 50% of the final effort completed. (e.g. The database has been developed, users trained, and format has been specified.)

3 - System has been implemented, yet many areas of non-compliance across the company remain. 51% to 75% of the final effort completed. (e.g. The database is now in use, but only by a few programs across the site.)

4 - Much progress has been made towards compliance to the requirements of the standard, minor work remains. 76% to 99% of the final effort completed. (e.g. The database is in full use, but a handful of programs still need to comply with the requirement.)

5 - Element meets the requirements of the standard and is fully compliant. 100% of the final effort completed. (e.g. The database is in full use, and each program audited can produce objective evidence proving 100% usage of the subcontractor database.)

Once a rating has been selected, the resulting score is placed in the Gap Analysis Tool spreadsheet, displayed as Table 4. The rating score would be placed in the appropriately labeled column. Once the rating score has been inserted, the process is repeated until an analysis has been performed on the entire Quality Management System.

A personally developed weighting scheme is utilized in order to compute a score for each element. The weights were developed giving higher consideration to those areas of the standard of high importance, such as a requirement to have established procedures. The weighting scheme is subjective, however it has helped LFS-M in prioritizing its focus in the closure of areas that were found to be non-compliant. Registrar feedback, during both the Pre-Assessment and formal Assessment, was used as a method of calibrating the weighting scheme of the model.

Table 4: Gap Analysis Tool - This tool can be used to quantify the status of each element within a quality system. This table contains the actual LFS-M Gap Analysis data collected.

	ANSI/ASQC Q9001 - 1994 Element	Rating	Weight	Score
4.1	**MANAGEMENT RESPONSIBILITY**			
	4.1.1 Quality Policy	0	0.30	0.00
	4.1.2 Organization			
	4.1.2.1 Responsibility and authority	5	0.10	0.50
	4.1.2.2 Resources	3	0.05	0.15
	4.1.2.3 Management representative	0	0.15	0.00
	4.1.3 Management review	1	0.40	0.40
	Total Score for Element 4.1			**1.05**
4.2	**QUALITY SYSTEM**			
	4.2.1 General	0	0.30	0.00
	4.2.2 Quality-system procedures	5	0.40	2.00
	4.2.3 Quality planning	3	0.30	0.90
	Total Score for Element 4.2			**2.90**
4.3	**CONTRACT REVIEW**			
	4.3.1 General	5	0.35	1.75
	4.3.2 Review	4	0.25	1.00
	4.3.3 Amendment to contract	4	0.25	1.00
	4.3.4 Records	5	0.15	0.75
	Total Score for Element 4.3			**4.50**
4.4	**DESIGN CONTROL**			
	4.4.1 General	4	0.20	0.80
	4.4.2 Design and development planning	5	0.10	0.50
	4.4.3 Organizational and technical interfaces	4	0.10	0.40
	4.4.4 Design input	5	0.10	0.50
	4.4.5 Design output	5	0.10	0.50
	4.4.6 Design review	3	0.10	0.30
	4.4.7 Design verification	3	0.10	0.30
	4.4.8 Design validation	3	0.10	0.30
	4.4.9 Design changes	4	0.10	0.40
	Total Score for Element 4.4			**4.00**
4.5	**DOCUMENT AND DATA CONTROL**			
	4.5.1 General	0	0.40	0.00
	4.5.2 Document and data approval and issue	3	0.30	0.90
	4.5.3 Document and data changes	3	0.30	0.90
	Total Score for Element 4.5			**1.80**
4.6	**PURCHASING**			
	4.6.1 General	5	0.40	2.00
	4.6.2 Evaluation of subcontractors	3	0.20	0.60
	4.6.3 Purchasing data	4	0.20	0.80
	4.6.4 Verification of purchased product			
	4.6.4.1 Supp. verification at subcontractor's premises	3	0.10	0.30
	4.6.4.2 Customer verification of subcontracted prod.	4	0.10	0.40
	Total Score for Element 4.6			**4.10**

Table 4: Gap Analysis Tool - This tool can be used to quantify the status of each element within a quality system. This table contains the actual LFS-M Gap Analysis data collected.

	ANSI/ASQC Q9001 - 1994 Element	Rating	Weight	Score
4.7	CONTROL OF CUSTOMER-SUPPLIED PRODUCT	4	1.00	4.00
	Total Score for Element 4.7			4.00
4.8	PRODUCT IDENTIFICATION AND TRACEABILITY	4	1.00	4.00
	Total Score for Element 4.8			4.00
4.9	PROCESS CONTROL	4	1.00	4.00
	Total Score for Element 4.9			4.00
4.10	INSPECTION AND TESTING			
	4.10.1 General	4	0.35	1.40
	4.10.2 Receiving inspection and testing			
	4.10.2.1 Incoming product	4	0.05	0.20
	4.10.2.2 Amount and nature of receiving inspection	4	0.05	0.20
	4.10.2.3 Urgent production release	0	0.05	0.00
	4.10.3 In-process inspection and testing	5	0.15	0.75
	4.10.4 Final inspection and testing	5	0.15	0.75
	4.10.5 Inspection and test records	4	0.20	0.80
	Total Score for Element 4.10			4.10
4.11	CONTROL OF INSPECTION, MEASURING, & TEST EQUIPMENT			
	4.11.1 General	4	0.50	2.00
	4.11.2 Control procedure	4	0.50	2.00
	Total Score for Element 4.11			4.00
4.12	INSPECTION AND TEST STATUS	4	1.00	4.00
	Total Score for Element 4.12			4.00
4.13	CONTROL OF NONCONFORMING PRODUCT			
	4.13.1 General	5	0.55	2.75
	4.13.2 Review and disposition of nonconforming product	4	0.45	1.80
	Total Score for Element 4.13			4.55
4.14	CORRECTIVE AND PREVENTIVE ACTION			
	4.14.1 General	3	0.40	1.20
	4.14.2 Corrective Action	4	0.30	1.20
	4.14.3 Preventive Action	4	0.30	1.20
	Total Score for Element 4.14			3.60
4.15	HANDLING, STORAGE, PACKAGING, PRES., & DELIVERY			
	4.15.1 General	3	0.25	0.75
	4.15.2 Handling	4	0.15	0.60
	4.15.3 Storage	3	0.15	0.45
	4.15.4 Packaging	4	0.15	0.60
	4.15.5 Preservation	4	0.15	0.60
	4.15.6 Delivery	4	0.15	0.60
	Total Score for Element 4.15			3.60
4.16	CONTROL OF QUALITY RECORDS	4	1.00	4.00
	Total Score for Element 4.16			4.00

Table 4: Gap Analysis Tool - This tool can be used to quantify the status of each element within a quality system. This table contains the actual LFS-M Gap Analysis data collected.

	ANSI/ASQC Q9001 - 1994 Element	Rating	Weight	Score
4.17	INTERNAL QUALITY AUDITS	1	1.00	1.00
	Total Score for Element 4.17			**1.00**
4.18	TRAINING	4	1.00	4.00
	Total Score for Element 4.18			**4.00**
4.19	SERVICING	3	1.00	3.00
	Total Score for Element 4.19			**3.00**
4.20	STATISTICAL TECHNIQUES			
	4.20.1 Identification of need	3	0.40	1.20
	4.20.2 Procedures	4	0.60	2.40
	Total Score for Element 4.20			**3.60**

Key to Compliance Ratings

0 - No attempt has been made to comply with the stated requirements of the standard. 0% of the final effort has been completed. (e.g. No records of acceptable subcontractors exist, and plans have not been put in place to create such a database).

1 - Planning stages to meet the requirements of the standard, however the system has not yet been implemented. 1% to 25% of the final effort completed. (e.g. Plans are in place to develop the database, however it has not yet been implemented).

2 - Implementation of a compliant solution to meet the requirements of the standard has commenced. 26% to 50% of the final effort completed. (e.g. The database has been developed, users trained, and format has been specified).

3 - System has been implemented, yet many areas of non-compliance across the company remain. 51% to 75% of the final effort completed. (e.g. The database is now in use, but only by a few programs across the site).

4 - Much progress has been made towards compliance to the requirements of the standard, minor work remains. 76% to 99% of the final effort completed. (e.g. The database is in full use, but a handful of programs still need to comply with the requirement).

5 - Element meets the requirements of the standard and is fully compliant. 100% of the final effort completed. (e.g. The database is in full use, and each program audited can produce objective evidence proving 100% usage of the subcontractor database).

Once each sub-element's score has been calculated, the final element score is derived by simply adding up each sub-element score. Table 4 contains the actual Gap Analysis data that was collected during the initial audit of LFS-M's Quality Management System. Generally, any element with a score below a "3" should be considered a potential major non-compliance which, in the event of an audit by a registrar, could prevent any company from obtaining registration (The cutoff point of "3" was determined by utilizing past quality audit data to test the model, and compare it to the rating given the element at that point in time by a third party registrar). A score in the "3" to "4" range could get a major, but most likely would get by on a minor non-compliance. A score of "5," of course, would mean that the element is 100% compliant to the standard in question, and could surpass an audit by any registrar.

The results of the Gap Analysis can be used in any way that the user feels would be the most beneficial. In the case of LFS-M, the data was used as a baseline measurement from which continual improvement was made. A blank copy of the Gap Analysis spreadsheet has been included as Section A-4 in the Appendix.

5.0 PROJECT RESULTS

5.1 AUDIT RESULTS

In order to examine the results of this project, this section of the document will be presented in the following order: Gap Analysis, Pre-Assessment, Assessment, and finally Internal Quality Audit results. The Internal Quality Audits occurred in 04/95 and 08/95. The reason for their placement at the end of this discussion is that it is difficult to have an "apples to apples" comparison given the different viewpoints involved. The organizational viewpoint is usually a more critical view of the Quality Management System than that of the assessor, assuming the personnel performing the internal audits are aggressive, and knowledgeable.

The Gap Analysis was also performed by the internal team, however these results establish a baseline for the quality system, and are placed at the front of this section.

5.1.1 Gap Analysis

The LFS-M Gap Analysis was performed during September of 1994. The consultant that was brought in to facilitate the effort was Mr. Charles Abney from Loral Western Development Labs. Chuck led a multi-disciplined group through a week long session which involved a two day discussion of how to interpret the ISO 9001 standard, followed by a couple of days of intensive internal quality auditing of a few selected programs across the site. The results of the Gap Analysis are displayed in Table 5. As can be viewed in the table, four major non-compliances were cited:

1) 4.1 Management Responsibility - This element failed because a policy for quality had not been documented to ensure effective implementation at all levels, the quality system was not reviewed by executive management, a management representative was not clearly defined, and a charter for the management representative had not yet been executed. Corrective action consisted of the creation of a quality policy

Table 5: Gap Analysis Results - This table shows the results of the Gap Analysis performed on the LFS-M Quality Management System. As shown in the table, four major non-compliance areas were identified during the site-wide audit.

Requirement Category	Majors	Minors	Obs.
4.1 Management Responsibility	1	1	1
4.2 Quality System	1	3	0
4.3 Contract Review	0	0	0
4.4 Design Control	0	9	0
4.5 Document and Data Control	1	11	2
4.6 Purchasing	0	0	1
4.7 Control of Customer-Supplied Product	0	0	0
4.8 Product Identification and Traceability	0	0	0
4.9 Process Control	0	1	1
4.10 Inspection and Testing	0	0	0
4.11 Control of Inspection, Measuring, and Test Equipment	0	0	0
4.12 Inspection and Test Status	0	1	0
4.13 Control of Non-Conforming Product	0	0	0
4.14 Corrective and Preventive Action	0	2	2
4.15 Handling, Storage, Packaging, Preservation, and Del.	0	0	1
4.16 Control of Quality Records	0	3	2
4.17 Internal Quality Audits	1	3	0
4.18 Training	0	5	1
4.19 Servicing	0	0	0
4.20 Statistical Techniques	0	2	0
TOTALS	4	41	11

and the assignment of the Director of Total Quality Management as the focal point. A plan to hold a management review with the President and the executive staff on a quarterly basis was put in place. Meeting minutes are taken as objective evidence of this review.

2) 4.2 Quality System - This element failed because a quality manual covering the requirements of the ISO 9001 standard did not exist. The quality system in place was fairly mature, otherwise the work involved to comply with this element of the standard would have been enormous. Corrective action was to simply create the quality manual, which describes how the site complies with each element of the ISO 9001 standard. This manual was placed on the site-wide internal mail system in order for everyone to be able to peruse when necessary.

3) 4.5 Document and Data Control - This element failed because the site had not yet established unique policies/procedures to map ISO 9001 to its business activities, and

had not established or maintained documented procedures to control all documents that related to the standard. Corrective action included the development of a site-wide document and data control procedure governing all internally produced documents. This met the requirement for having a procedure, but did little to mitigate the exposure throughout the site. This exposure was far more difficult to correct than estimated at this point in the process. This point wasn't realized until after the results of the Pre-Assessment were received.

4) 4.17 Internal Quality Audits - This element failed because an Internal Quality Audit system had not yet been established to determine the effectiveness of the quality system, and some areas were not being audited by independent personnel (i.e. Quality). Corrective action implemented was the establishment of a site-wide Internal Quality Audit program, using individuals from across several functional disciplines. These individuals were used to perform audits on their own areas, with QA verifying results to ensure independence. The Internal Quality Audit Checklist, discussed in Section 4.2.1, was used in each of these audits, with the hard copy serving as objective evidence that the audit was performed.

The results of the Gap Analysis were used to focus the efforts of the Internal Quality Audit program across the site, as well as to sensitize every individual through department meetings, communications of various types, etc. It is interesting to note that in the area of document and data control, more time was spent being concerned with the control of documents that could be found on someone's desk, as opposed to the procedures located on walls and machinery within the manufacturing and laboratory environments. This was simply a result of not understanding the total applicability of the standard, which lends more credence to the argument that an organization needs to get the assessor into the facility as soon as possible to let them give their interpretation as to what is, and is not an issue.

Table 6: Formal Pre-Assessment Results - This table shows the results of the Formal Pre-Assessment performed on the LFS-M Quality Management System. As shown in the table, two major non-compliance areas were identified during the site-wide audit.

Requirement Category	Majors	Minors	Obs.
4.1 Management Responsibility	0	0	0
4.2 Quality System	0	0	0
4.3 Contract Review	0	1	0
4.4 Design Control	0	0	1
4.5 Document and Data Control	1	2	1
4.6 Purchasing	0	2	1
4.7 Control of Customer-Supplied Product	0	0	1
4.8 Product Identification and Traceability	0	0	1
4.9 Process Control	0	4	0
4.10 Inspection and Testing	0	0	0
4.11 Control of Inspection, Measuring, and Test Equipment	1	0	2
4.12 Inspection and Test Status	0	2	0
4.13 Control of Non-Conforming Product	0	2	1
4.14 Corrective and Preventive Action	0	0	0
4.15 Handling, Storage, Packaging, Preservation, and Del.	0	1	2
4.16 Control of Quality Records	0	0	0
4.17 Internal Quality Audits	0	0	1
4.18 Training	0	2	0
4.19 Servicing	0	0	0
4.20 Statistical Techniques	0	0	0
TOTALS	**2**	**16**	**11**

5.1.2 Formal Pre-Assessment

The formal Pre-Assessment was performed from May 15th through May 19th of 1995 by the registrar. There were three assessors present at the site for a period of four days, due to the LFS-M facility employing approximately 1,600 people. The organization felt significant progress had been made, however there was a concern over a possible erroneous interpretation of the standard. As it turned out, LFS-M was not too far off base, except for a couple of areas which will be discussed in detail. The results of the Pre-Assessment can be viewed in Table 6.

The results of the formal Pre-Assessment indicated a lack of discipline across the site's laboratories. The assessors felt that the site had very good documentation from a process standpoint, however were "using the labs as an engineering playground." There were two major non-compliances that resulted from the audit:

1) 4.5 Document and Data Control - The registrar noted several instances of non-compliance to this element of the standard. It was viewed as a site-wide issue, however the primary area of concern were the number of violations found within the labs across LFS-M. The registrar summarized their findings in bulletized format as displayed below:

- Uncontrolled procedures found in several areas;
- Out of date procedures found in use;
- Reference documents required to perform activities found on walls throughout the site;
- Test procedures and forms not consistently controlled;
- Instances where work was being performed to a draft copy of a procedure;
- Use of drawings that were out of date;
- Red-lined procedures with no approval authority or date of red-line;
- White out correction tape in use on a procedure.

All of these combined issues constituted a "potential breakdown in the document and data control system." Since this is the number one reason preventing companies from becoming registered, this did not catch everyone by surprise. What the Pre-Assessment did do was pin-point exactly what was, and wasn't a document and data control issue. The registrar was primarily concerned with the exposures contained within the production environments, those that directly affected product quality. The corrective action taken to close this area of non-compliance was to increase lab audit activity, as well as heighten awareness across the site as to the interpretation of this element of the standard. Each lab on site was audited over a period of weeks following the May Pre-Assessment until the site felt comfortable in closing the issue. Several "Reference Use Only" stamps were procured, which were used to fix exposures immediately during internal audits. By having a document titled "Reference Use Only," the user of the document knows that he or she could potentially have a down level document, and that they should check to see what is the latest revision level. This is a fix that is easy to implement, as well as cost effective.

2) 4.11 Control of Inspection, Measuring, and Test Equipment - The major non-compliance against this element of the standard was the one that caught LFS-M completely by surprise. Once the assessor listed their findings, it was obvious that the group was simply too close to the situation to see how poorly prepared the site was in this area. The registrar's findings for this element of the standard are summarized below:

- Equipment was found in many areas that were out-of-calibration;
- Pre-stamped calibration stickers were found;
- Equipment found in labs not entered into the calibration system;
- Uncontrolled test software found in use;

This data was utilized once again in fine tuning the Internal Quality Audit program. The problem was much bigger than initially realized, and required immediate corrective action. Hundreds of pieces of equipment were tagged "out of calibration - do not use" during the Internal Quality Audits, with the responsibility of fixing the equipment placed with the lab managers.

The issue pertaining to the use of uncontrolled test software had to do with the engineering community developing their own code to perform a given test on a product. Once the coding of this test software was complete, most of the developers failed to follow through with any type of verification and control measure. Validation of test software is done by ensuring that the piece of software performs as it was intended, including the objective evidence that proves it was performed. Control is achieved by sending the original to Software Configuration Management for storage, while using a copy for testing purposes. This issue is, and always will be, LFS-M's true "Achilles' heel."

Table 7: Formal Assessment Results - This table shows the results of the Formal Assessment performed on the LFS-M Quality Management System. As shown in the table, no major non-compliance areas were identified during the site-wide audit.

Requirement Category	Majors	Minors	Obs.
4.1 Management Responsibility	0	1	1
4.2 Quality System	0	0	1
4.3 Contract Review	0	0	0
4.4 Design Control	0	0	2
4.5 Document and Data Control	0	4	1
4.6 Purchasing	0	1	1
4.7 Control of Customer-Supplied Product	0	0	1
4.8 Product Identification and Traceability	0	0	0
4.9 Process Control	0	0	0
4.10 Inspection and Testing	0	0	0
4.11 Control of Inspection, Measuring, and Test Equipment	0	2	0
4.12 Inspection and Test Status	0	0	0
4.13 Control of Non-Conforming Product	0	2	0
4.14 Corrective and Preventive Action	0	1	1
4.15 Handling, Storage, Packaging, Preservation, and Del.	0	1	0
4.16 Control of Quality Records	0	1	0
4.17 Internal Quality Audits	0	1	1
4.18 Training	0	0	0
4.19 Servicing	0	0	0
4.20 Statistical Techniques	0	0	0
TOTALS	0	14	9

5.1.3 Formal Assessment

The formal Assessment was performed from September 25th through September 29th of 1995. The site was visited by the same three auditors that performed the Pre-Assessment during the month of May in order to achieve some level of consistency. The results of the Assessment, shown in Table 7, showed that significant progress had been made over the last few months. Both major non-compliance areas noted during the Pre-Assessment received only minor non-compliance violations during this audit. Document and Data Control had been the number one priority during Internal Quality Audits, and had dramatically improved, yet the site still received four minor non-compliances. This element of the standard needs continued attention in order to prevent it from deteriorating from its current position.

During the closing meeting, the lead assessor informed LFS-M that their week long evaluation of the Quality Management System resulted in 14 minor non-compliances, and 9

observations. Based on these findings, LFS-M was informed that they would be recommended for registration. In order to officially be "registered," the organization was required to send a corrective action for all observations and minor non-compliances within 21 days to the registrar's head office. Once this paperwork was received, processing of the LFS-M registration would commence. This process normally takes about one month.

An important item surfaced during the Assessment in that the lead assessor was basically convinced that the QMS was working properly on the second day of auditing. He is primarily concerned with the core elements of continuous process improvement, which as discussed earlier consists of Management Responsibility, Corrective and Preventive Action, and the Internal Quality Audit program. Each auditor's opinions and interpretations are going to be different, but this auditor felt that these three elements needed to be audited at an extremely low level, where the other elements were audited at a higher level. Although document and data control is very important, these three elements will have the highest priority, before the January follow-on visit, as these will be the majority of the three day audit.

5.1.4 Internal Quality Audits - General Discussion

The Internal Quality Audit program results and discussion have been placed at the end due to their difference in both purpose and level of auditing. The purpose of the program is to provide for a mechanism by which to monitor the status of, and continuously improve the Quality Management System. The level of auditing is usually more detailed, therefore producing results which are more critical than those of an independent assessor. This is assuming that the internal assessors are aggressive and knowledgeable of both the standard to which the QMS is being assessed against, and of the organizational processes which are being audited.

The results of the 04/95 and 08/95 Internal Quality Audits, as well as results shown in section 5.1.1 through 5.1.3, are displayed in Figure 8. Internal audits performed by the LFS-M team are noted by the "Loral" at the top of the column, where the two formal Assessments performed by the third party auditor are noted by "REG." The registrar audits were an especially

ISO 9001 20 ELEMENTS	9/94 Loral	4/95 Loral	5/95 REG	8/95 Loral	9/95 REG	1/96 REG	COMMENTS
4.1 Management Responsibility	■	■	OK	OK	◯		Personnel in select areas were unable to identify the Management Rep.
4.2 Quality System	■	■	OK	OK	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.3 Contract Review	OK	OK	◯	◯	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.4 Design Control	◯	◯	OK	◯	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.5 Document and Data Control	■	■	■	■	◯		Uncontrolled documents, redline procedure needs work, test s/w issues
4.6 Purchasing	OK	OK	◯	◯	◯		Minor instances of not adhering to procedures
4.7 Control of Customer-Supplied Product	OK	OK	OK	◯	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.8 Product Identification and Traceability	OK	OK	OK	◯	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.9 Process Control	◯	◯	◯	◯	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.10 Inspection and Testing	OK	OK	OK	OK	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.11 Control of Insp., Meas., & Test Equip.	OK	OK	■	■	◯		Minor instances of not adhering to procedures
4.12 Inspection and Test Status	◯	OK	◯	OK	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.13 Control of Nonconforming Product	OK	◯	◯	◯	◯		Issues with control and identification of non-conforming product
4.14 Corrective and Preventive Action	◯	■	OK	OK	◯		Root cause analysis and preventive action need immediate attention
4.15 Handling, Storage, Pack., Pres. & Del.	OK	◯	◯	◯	◯		Xylene found in coating area with expiration date past due
4.16 Control of Quality Records	◯	◯	OK	OK	◯		Minor issue with handwritten changes on supplier corrective action
4.17 Internal Quality Audits	■	■	OK	OK	◯		Files of audits reveal insufficient evidence to support conclusions
4.18 Training	◯	◯	◯	◯	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.19 Servicing	OK	■	OK	OK	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard
4.20 Statistical Techniques	◯	◯	OK	◯	OK		Element found to be compliant to the ANSI/ASQC Q9001 - 1994 standard

OK Meets Standard ◯ **Minor Non-Compliance** ■ **Major Non-Compliance**

Figure 8: ISO 9001 20 Elements Status - The chart shown is used by the LFS-M Management Representative to report the health and status of the 20 elements of the Quality Management System. The meeting is attended by the President of the Division and his executive staff.

good tool for calibrating the Internal Quality Audit program. They aided in both interpretation of some of the key elements and highlighted items that were overlooked.

The Internal Quality Audit program is critical to a successful registration. It is the means by which improvement to the QMS is achieved, and driven. It was determined that much work was needed in this area, but the program was still quite effective, even though it was not as mature as it could have been. More attention needs to be given to the treatment of root cause analysis, and the effective implementation of preventive action.

5.2 LESSONS LEARNED

This section will group lessons learned during the course of this 12 month project into each of the eight different steps in obtaining registration, shown in Figure 5 of Chapter 4.0.

Determination of Need

- Understand why the decision to pursue registration has been made. Research is required to determine if one of the three ISO 9000 standards is appropriate for your organization, or possibly another QMS model that is available.
- Ensure that the organization has commitment from top management. Without this commitment, any attempt to become registered will fail.

Perform Gap Analysis

- Bring in an expert to facilitate the performance of the Gap Analysis. This process can be a great learning experience for all involved. Make the most of it.
- Avoid spending money on expensive and questionable QMS corrections thought to be required until after the Pre-Assessment has been performed. Let the assessors visit your facility and determine what needs to be fixed in order to become registered, if there is any question at all. The majority of money spent on compliance is wasted on faulty interpretations of the standard that require costly solutions, when it is later found to be totally unnecessary. Use your common sense.
- Take the time to interpret the gray areas of the standard. A few of the terms within the standard that need to be defined as to how they apply to an organization are "adequate," "as

appropriate," "suitable," "where applicable," and "independent." By defining these gray areas, an organization has a position by which to defend itself during an audit, which could preclude the receipt of a non-compliance. For example, 4.9.d (Process Control) states that controlled conditions should include "suitable maintenance of equipment to ensure continuous process capability." Here, the user should define what is "suitable." Define what types of equipment are used in the normal operation of the facility, calibration intervals of equipment, reference the preventive maintenance procedure, etc. By defining this gray area, the organization takes a proactive approach towards the ability to defend itself from a non-compliance by stating the company position. If in writing, it is now a part of the "say what you do" element of ISO, and gives the auditee a tool to easily defend itself because their interpretation of the standard is documented.

Registrar Selection

- Choose the registrar early in order to develop an alliance, and discuss the implementation timeline for the organization.
- Understand the accreditations that the organizational business needs require (e.g. RvC, NACCB, RAB, etc.) in a registrar prior to making any type of selection.
- Prioritize the drivers to be used as part of the process of selecting a registrar (e.g. cost, accreditations, existing teaming arrangements, willingness to work together, reputation. etc.).
- Be cautious of "Memorandums of Understanding" between different accrediting bodies. Investigate the details of the understanding and, where possible, check with customers to see if the MOU's are acceptable.

Internal Quality Audits

- The most valuable tool that an organization has at its disposal, if properly utilized, is the Internal Quality Audit program. Use the internal audits as a means to drive compliance across the organization.

- Ensure independence of the audits, and that the root cause of any issue found is determined in order to apply proper corrective action. Root cause analysis needs to go to the level of detail required in order to prevent the auditor from asking "but why?."

Documentation Review

- If possible, have the document review at the auditee's facility. This allows for questions to be asked and answered real time, instead of through some other less effective medium. Use the review as a chance to familiarize the assessor with the facility and organization.

Pre-Assessment

- ISO 9000 training should be given by personnel that are respected in the given functional or business areas that they represent. This will facilitate buy-in and cooperation.
- Make use of all forms of communication mediums in order to heighten awareness prior to the Pre-Assessment (e.g. posters, awareness training modules, e-mail, etc.).
- Select assessor escorts carefully, as they play a very important role in the process.
- If it is felt that there is a potential problem, now is the time to point the assessor in that direction. It is better to address the issue now, instead of taking the chance that it can be stumbled upon during the formal Assessment. Use the Pre-Assessment to improve the QMS being assessed.

Assessment

- If at all possible, work the schedule so that the same assessors are available that performed the Pre-Assessment. This way there is a predetermined understanding of hot buttons, auditing methods, and overall approach to evaluating a QMS.
- Do not give the assessors too much help. Be honest and open, but make them find issues by themselves.
- Understand the backgrounds of each assessor. There can never be enough homework done in preparation for the formal Assessment.
- Be prepared to defend a position with the assessors. Negotiation from a major to a minor non-compliance is possible, if approached in the proper manner.

- Assuming a successful formal Assessment, attempt to determine the focus of the first surveillance audit.

Registration

- Upon successful recommendation for registration, corrective actions plans are required within a given timeframe, before the processing of registration begins. The LFS-M plan was due within 21 days, but was submitted within one week due to business needs.
- Consider possible methods of marketing the registration to current and potential customers.

6.0 CONCLUSIONS/RECOMMENDATIONS

The LFS-M Division was recommended for registration to the ANSI/ASQC Q9001 - 1994 standard by the registrar on September 29, 1995. This successful achievement marked many months of effort by an outstanding team of individuals able to function together as a team.

6.1 SUMMARY

This document was developed in order to give interested organizations a user's view of the implementation process. Currently, there are millions of dollars spent each year within the QMS assessment area, and the future shows signs of nothing but continued growth. There are consulting groups offering assistance in every aspect of QMS implementation, but personal experience has led this author to question the credentials of many of these consultants. Organizations seeking registration need to be aware of a consultant's credentials prior to entering any type of business arrangement in order to gain something from the experience.

This is an analysis of the successful approach in the implementation of a QMS at a very large and diverse organization. The views and approaches expressed within this document are a result of personal research, and are not those of the Loral Corporation.

6.2 AREAS NEEDING FURTHER RESEARCH

There are a few areas that require further research. Probably the most important to customers would be the cost of quality issue. The DoD has become very interested in an organization's ability to track the cost of quality. In order to have a truly accurate measure of cost per program, two things have to happen: 1) a detailed set of metrics to collect the necessary data needs to be defined and deployed throughout the organization, and 2) the personnel using that system must be committed to entering accurate and timely information into that system. Should the latter item not be achieved, it is simply a matter of "garbage in, garbage out." The user is left with a set of measurements that mean absolutely nothing. Gaining total commitment to this concept is a tough task, but a necessary one.

More tools to facilitate the implementation process would be helpful. Areas that could use something of this nature include:

- A model developed which would enable the user to estimate total implementation cost by filling out parameters required by the main cost drivers;
- The highlighting and definition of areas that companies should focus on within the standards;
- Analyzing or ranking potential registrars based on their effectiveness. There are many registrars to choose from, but other than using recommendations, there was not much data available to perform comparisons;
- Further work in improving the reliability and consistency of the Gap Analysis Tool;
- More work in the design of a comprehensive quality information system;
- Evaluation of new or emerging standards.

Anything that helps an organization perform a task by themselves, as opposed to paying a consultant, is probably beneficial, and worthy of further investigation.

REFERENCES

ANSI/ASQC, The ANSI/ASQC Q9000-1-1994 through Q9004-1-1994 American National Standards, American Society For Quality Control, Milwaukee, WI, 1994.

Beardsley, J. and Schaefer, D., One Company's Journey to ISO 9000 Registration, Journal for Quality and Participation, March, 1995.

Blanchard, B.S. and Fabrycky, W.J., Systems Engineering and Analysis, Prentice-Hall, Inc., Englewood Cliffs, NJ, 1981.

Brumm, E.K., Managing Records for ISO 9000 Compliance, Quality Progress, January, 1995.

Department of Defense (DoD) and the National Aeronautics and Space Administration (NASA), Guidance on the Application of ISO 9000/ASQC Q90 Series Quality System Standards (MIL-HDBK-9000, NASA-HDBK-9000), DoD and NASA, February, 1994.

Garvin, D.A., Managing Quality - The Strategic and Competitive Edge, The Free Press, A Division of Macmillan, Inc., New York, NY, 1988.

Hockman, K.K., Grenville, R. and Jackson, S., Road Map to ISO 9000 Registration, Quality Progress, May, 1994.

Inchcape Testing Services, ISO-9000/Q9000 Training Course, Revision 6, Release Date December, 1994.

Juran, J.M. and Gryna, F.M., Quality Planning and Analysis: From Product Development through Use, McGraw-Hill, Inc., New York, NY, 1993.

Kerridge, B., ISO 9000 Standard Cultivates Customer Satisfaction, EDN, July, 1993.

Lamprecht, J.L., ISO 9000 - Preparing For Registration, ASQC Quality Press, Milwaukee, WI, 1992.

Mullin, R., ISO 9000: Contemplating the Benefits of Registering Design, Chemical Week, April, 1995.

Murakami, R., How to Implement ISO 9000, CMA Magazine, March, 1994.

Rabbitt, J.T. and Bergh, P.A., The ISO 9000 Book, Quality Resources, White Plains, NY, 1994.

Tingey, M.O., Comparison of Quality Management System Assessment Methodologies, IBM Glendale Programming Laboratory, Endicott, NY, 1994.

United States Department of Commerce, The Malcolm Baldrige National Quality Award, National Institute of Standards and Technology, 1995, p. 20.

Weightman, R.T., How to Select a Registrar: Benchmarks for the Screening Process, Quality Systems Update, January, 1992.

APPENDIX A-1: ACRONYM LISTING

ANSI	American National Standards Institute
AQAP	Allied Quality Assurance Publication
ASQC	American Society for Quality Control
BS	British Standard
COTS	Commercial off The Shelf
DoD	Department of Defense
EC	European Community
EN	European Normative
FMS	Foreign Military Sales
ILS	Integrated Logistics Support
LFS-M	Loral Federal Systems-Manassas
LRQA	Lloyd's Register Quality Assurance Ltd.
MBNQA	Malcolm Baldrige National Quality Award
NACCB	National Accreditation Council for Certification Bodies (United Kingdom)
NCP	Non-Conforming Product
NDI	Non-Developmental Item
NIST	National Institute of Standards and Technology
NQA	National Quality Assurance
OJT	On-the-Job Training
QMS	Quality Management System
RAB	Registrar Accreditation Board (United States)
RFP	Request For Proposal
RvC	Raad voor de Certificatie (Dutch Council for Certification)
SCC	Standards Council of Canada
SE	Systems Engineering
SPC	Statistical Process Control

APPENDIX A-2: DEFINITIONS

Action, Preventive: An action taken to eliminate the cause of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence.

Action, Corrective: An action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

Audit, Quality: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Audits, First Party: A quality system audit carried out by a company on its own quality system for the purpose of giving assurance to management that it is effectively achieving the planned quality objectives. These audits, also called internal audits, are carried out by the organization's own staff provided that the auditors are independent of the functions or systems being audited.

Audits, Second Party: The purpose of this audit is to provide assurance to the customer that the quality system of the suppliers is capable of providing goods or services to an agreed quality level. These second party audits can be carried out by functions within the customer's organization or by an outside agency.

Audits, Third Party: Audits carried out by independent agencies for the purpose of registering or certifying compliance with a national or international standard such as ANSI/ASQC Q9001-1994. Assessing compliance with these recognized standards provides assurance to existing and prospective customers for the product or service that required quality levels can be achieved and maintained.

Customer (Purchaser): The recipient of a product provided by the supplier.

Objective Evidence: Information which can be verified, based on facts and obtained through observation, measurement, test or other means.

Procedure: A specified way to perform an activity.

Product: The result of activities or processes.

Quality: The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs.

Quality Management: All activities of the overall management function that determine the Quality Policy, objectives and responsibilities and implement them by means such as quality planning, quality control, quality assurance and quality improvement, within the Quality System.

Quality Policy: The overall intentions and direction of an organization with regard to quality, as formally expressed by top management.

Quality Assurance: All the planned and systematic activities implemented within the Quality System, and demonstrated as necessary, to provide adequate confidence that an entity will fulfill requirements for quality.

Quality Control: The operational techniques and activities that are used to fulfill requirements for quality.

Quality System: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Quality Planning: The activities that establish the objectives and requirements for quality and for the application of quality system requirements.

Quality Plan: A document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, project or contract.

Quality Manual: A document stating the quality policy and describing the quality system of an organization.

Record: A document which furnishes objective evidence of activities performed or of results achieved.

Review, Management: A formal evaluation by top management of the status and adequacy of the quality system in relation to the quality policy and objectives.

Review, Contract: The systematic activities carried out by the supplier before signing the contract, to ensure that requirements for quality are adequately defined, free from ambiguity, documented and can be realized by the supplier.

Review, Design: A documented, comprehensive and systematic examination of a design to evaluate its capability to fulfill the requirements for quality, identify problems, if any, and propose the development of solutions.

Supplier (Contractor): The organization that provides a product to the customer.

Sub-Contractor: The organization that provides a product to the supplier.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Validation: Confirmation by examination and provision of objective evidence that the particular requirements for specific intended use are fulfilled.

Source of Definitions: Inchcape Testing Services, ISO-9000/Q9000 Training Courses, Revision 6, Release Date December, 1994.

APPENDIX A-3: INTERNAL QUALITY AUDIT CHECKLIST

4.1 Management Responsibility (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.1.1 Quality Policy				
4.1.1	1. Are company policies, objectives, and its commitment to quality documented?				
4.1.1	2. Are the policies understood, implemented and maintained at all levels of the organization?				
4.1.1	3. Is the stated policy relevant to internal organization goals and customer needs/expectations?				
	4.1.2 Organization				
4.1.2.1	1. Are the organizational structure, responsibilities, **interrelationships**, and authority of personnel documented (e.g. organization chart, job description, mission statements, etc.)?				
4.1.2.1	2. Does the quality organization report directly to upper management, and is sufficient responsibility and authority assigned to personnel to effectively resolve problems related to product, process, and service quality?				
4.1.2.2	3. Have trained personnel been assigned for management, performance of work, verification activities and internal quality audit? (see *Training, 4.18*).				

4.1 Management Responsibility (2 of 2)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.1.2.3	4. Has a management representative with executive responsibility, been appointed for ensuring the following: a. implementing and maintaining the Quality Management System b. reporting on the performance of the quality system to management?				
	4.1.3 Management Review				
4.1.3	1. Does upper management periodically review and approve all aspects of the quality system to ensure its continuing suitability and effectiveness?				
4.1.3	2. Are the following items covered during the reviews? a. Internal Quality Audit results (see *Internal Quality Audits, 4.17*) b. Corrective and Preventive Actions (see *Corrective and Preventive Action, 4.14*) c. Customer complaints (see *Corrective and Preventive Action, 4.14*) d Any other items ensuring that the Quality Policy objectives are being met.				
4.1.3	3. Are records maintained of management reviews? (see *Control of Quality Records, 4.16*)				

Comment:

4.2 Quality System (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	No	Yes	N/A	Objective Evidence and/or Comments
	4.2.1 General				
4.2.1	1. Has a Quality Manual been developed defining the Quality system? Is it under document control? (see *Document and Data Control, 4.5)*				
	4.2.2 Quality–System Procedures				
4.2.2	1. Are written procedures prepared in accordance with ANSI/ASQC Q9001–1994 and the Quality Policy?				
4.2.2	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
4.2.2	3. Has the supplier effectively implemented the quality system and its documented procedures?				
4.2.2	4. Does the degree of documentation consider the methods used, skills needed and training levels of personnel conducting activities in accordance with this International Standard?				
4.2.2	5. Are Work Instructions referenced in higher level governing Procedures?				
	4.2.3 Quality Planning				
4.2.3	1. Has a Quality Plan been developed and documented defining how the requirements of quality will be met?				

4.2 Quality System (2 of 2)

ISO References	Requirements	No	Yes	N/A	Objective Evidence and/or Comments
4.2.3	2. Does quality planning consider the following items, as appropriate, in meeting specified requirements? a. the preparation of the quality plan; b. the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources, and skills needed to achieve the required quality; c. ensuring the compatibility of the design, production process, installation, servicing, inspection and test procedures, and applicable documentation; d. the updating, as necessary, of quality control, inspection, and testing techniques, including development of new instrumentation; e. the identification of any measurement requirements involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed; f. the identification of suitable verification at appropriate stages in the realization of product (during development of product); g. the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element (taste, smell, feel, color); h. the identification and preparation of quality records.				

Comment:

4.3 Contract Review (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.3.1 General				
4.3.1	1. Are procedures established and maintained for contract review and for the **coordination** of these activities?				
4.3.1	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
4.3.1	3. Are communication and interface channels with the customer's organization established?				
	4.3.2 Review				
4.3.2	1. Are contracts or orders reviewed prior to submission or acceptance by the supplier?				
4.3.2	2. Have the following items been reviewed prior to acceptance? a. Are the contractual requirements adequately defined and documented by the customer. b. Procedures are in place to address the handling of verbal orders, where applicable. c. Differences between the contract/ order requirements and those in tender have been resolved. d. Contract has been reviewed to ensure that the supplier has the capability to meet contractual requirements (e.g. right materials, skills, tooling, resources, etc.).				

4.3 Contract Review (2 of 2)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.3.3 Amendment to Contract				
4.3.3	1. Does the documentation define what constitutes contract amendment and how amendment information is correctly transferred to concerned functions within the organization?				
	4.3.4 Records				
4.3.4	1. Are records of contract reviews maintained? (see *Control of Quality Records 4.16*).				

Comment:

4.4 Design Control (1 of 3)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.4.1 General				
4.4.1	1. Have documented procedures to control and verify the design of the product been established and maintained?				
4.4.1	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
	4.4.2 Design and Development Planning				
4.4.2	1. Are plans drawn up to identify the responsibility of each design and development activity?				
4.4.2	2. Are personnel involved in design verification qualified and provided with the necessary resources?				
4.4.2	3. Are these plans reviewed and updated as the design evolves?				
	4.4.3 Organizational and Technical Interfaces				
4.4.3	1. How are the organizational and technical interfaces between different groups identified?				
4.4.3	2. Do procedures exist for the documentation, transmittal and review of intergroup data exchanges?				

4.4 Design Control (2 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.4.4 Design Input				
4.4.4	1. Are design–input requirements relating to the product identified, documented, and reviewed by the supplier for adequacy?				
4.4.4	2. Are incomplete, ambiguous, or conflicting requirements resolved with those responsible for imposing the requirements?				
4.4.4	3. Has design input taken into consideration the results of any contract review activities?				
	4.4.5 Design Output				
4.4.5	1. Has design output been documented and can it be verified against design input requirements? (each input must have an output)				
4.4.5	2. Have the design output documents been reviewed prior to release?				
4.4.5	3. Is documentation available that assures that the final design: a. meets input requirements; b. identifies acceptance criteria; c. identifies crucial safety and functional characteristics?				
	4.4.6 Design Review				
4.4.6	1. Have design reviews taken place at each defined stage of design?				
4.4.6	2. Did representatives from all affected functions participate?				
4.4.6	3. Are the reviews documented? (see Control of Quality Records, 4.16)				

4.4 Design Control (3 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.4.7 Design Verification				
4.4.7	1. Are design verifications performed, at appropriate stages, to ensure that the design–stage output meets the design–stage input requirements?				
4.4.7	2. Has the design been verified through design reviews, qualification tests, alternative calculations or comparison to similar proven designs?				
4.4.7	3. Are design verification records maintained? See *Control of Quality Records* (4.16).				
	4.4.8 Design Validation				
4.4.8	1. Has design validation been performed to ensure that the product conforms to defined user needs and/or requirements?				
	4.4.9 Design Changes				
4.4.9	1. Have all design changes and modifications been identified, documented, reviewed, and approved by authorized personnel prior to their implementation?				

Comment:

4.5 Document and Data Control (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.5.1 General				
4.5.1	1. Have documented procedures been established and maintained to control all documents and data, including applicable external documents, in hard copy or electronic media?				
4.5.1	2. Are the procedures under Document Control?				
	4.5.2 Document and Data Approval and Issue				
4.5.2	1. Are documents and data reviewed and approved by authorized personnel prior to issue?				
4.5.2	2. Is a master list or equivalent document–control procedure in place which identifies the current revision status of documents in use in order to preclude the use of invalid and/or obsolete documents?				
4.5.2	3. Is the master list available at all locations where operations are performed?				
4.5.2	4. Are invalid and/or obsolete documents promptly removed from all points of issue or use?				
4.5.2	5. Are obsolete documents retained for legal and/or knowledge–preservation purposes suitably identified?				

4.5 Document and Data Control (2 of 2)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.5.3 Document and Data Changes					
4.5.3	1. Unless specifically designated otherwise, are changes to documents and data reviewed and approved by the same functions/organizations that performed the original review and approval?				
4.5.3	2. Do designated functions/organizations have access to pertinent background information upon which to base their review and approval?				
4.5.3	3. If practical, is the nature of the change identified in the document or appropriate attachments?				

Comment:

4.6 Purchasing (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.6.1 General				
4.6.1	1. Have documented procedures been established and maintained for the purchase of products and services required to ensure they meet specified requirements?				
4.6.1	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
	4.6.2 Evaluation of Subcontractors				
4.6.2	1. Do documented procedures define how subcontractors are evaluated and selected on their ability to meet subcontract requirements, including the quality system and any specific quality assurance requirements?				
4.6.2	2. Is the type and extent of control exercised by the supplier over subcontractors defined?				
4.6.2	3. Does the definition show dependency upon a. type of product; b. impact of subcontracted product on the quality of final product; c. and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractor?				
4.6.2	4. Are quality records of acceptable subcontractors established and maintained? (see *Control of Quality Records, 4.16*).				

4.6 Purchasing (2 of 2)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.6.3 Purchasing Data					
4.6.3	1. Do purchasing documents contain information specifying requirements for product ordered?				
4.6.3	2. Are these documents reviewed and approved for adequacy of specified requirements prior to release?				
4.6.4 Verification of Purchased Product					
4.6.4.1	1. Is source verification performed to ensure that procured products and services conform to specified requirements?				
4.6.4.1	2. Are source verification records and procedures maintained?				
4.6.4.1	3. Have verification arrangements and product release methods been defined in documented procedures and purchasing documents for verification activities conducted at subcontractor locations?				
4.6.4.2	4. Do contracts exist that specify customer verification of subcontracted product?				
4.6.4.2	5. In those cases where contractually required, do procurement documents flow down the right of customer verification to the subcontractor(s)?				

Comment:

4.7 Control of Customer–Supplied Product

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.7	1. Have documented procedures been established and maintained for the verification, storage and maintenance of customer supplied material for incorporation into the supplies and/or for related activities (e.g. test equipment, etc.)?				
4.7.1	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
4.7	3. Has a record and feedback mechanism been established for any damaged, lost or unsuitable–for–use parts and/or material? (see *Control of Quality Records, 4.16*).				

Comment:

4.8 Product Identification and Traceability

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.8	1. Have documented procedures been established and maintained for product identification from receipt and during all stages of production, delivery and installation (including customer supplied product)?				
4.8	2. Have documented procedures for traceability been established and maintained, when traceability is a specified requirement, for unique identification of individual product or batches?				
4.8	3. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
4.8	4. Has the identification been recorded? (see *Control of Quality Records, 4.16*).				

Comment:

4.9 Process Control

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.9	1. Have production, installation, and servicing processes which directly affect quality been identified and planned?				
4.9	2. Are processes carried out under controlled conditions? Do they include the following: a. documented procedures defining the manner of process, where the **absence** of such procedures **could adversely** affect quality; b. use of suitable equipment and work environment; c. compliance with standards/codes, quality plans, and/or documented procedures; d. monitoring and control of suitable process parameters and product characteristics; e. approval of processes and equipment, as appropriate; f. criteria for workmanship; g. suitable maintenance of equipment to ensure continuing process capability?				
4.9	3. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
4.9	4. Have qualification requirements for process operation, equipment and personnel been specified? (see *Training, 4.18*).				
4.9	5. Are records maintained for qualified processes, equipment, and personnel, as appropriate? (see *Control of Quality Records, 4.16*).				

Comment:

4.10 Inspection and Testing (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.10.1 General				
4.10.1	1. Have documented procedures been established and maintained for inspection and testing to verify that specified requirements for the product are met?				
4.10.1	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
4.10.1	3. Does the quality plan or documented procedures for inspection and testing define the records to be established? (see *Control of Quality Records, 4.16*)				
	4.10.2 Receiving Inspection and Testing				
4.10.2.1	1. Is product held until the required inspection and tests are completed, except when positive recall procedures are in effect?				
4.10.2.1	2. Is verification of the specified requirements in accordance with the quality plan and/or documented procedures?				
4.10.2.2	3. Is consideration given to the amount of control exercised by the subcontractor when determining the amount and nature of receiving inspection?				
4.10.2.3	4. If incoming product is released for urgent production purposes prior to verification, are procedures in place to positively identify and record information in order to permit immediate recall and replacement in the event of nonconformity to specified requirements? (see *Control of Quality Records*, 4.16)				

4.10 Inspection and Testing (2 of 2)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.10.3 In–Process Inspection and Testing					
4.10.3	1. Is the product inspected and tested as required by the quality plan and/or documented procedures?				
4.10.3	2. Is product held until the required inspection and tests are completed, except when positive recall procedures (see 4.10.2.3) are in effect?				
4.10.4 Final Inspection and Testing					
4.10.4	1. Are written procedures in use to control final inspection and test operations and do they conform to the specified requirements?				
4.10.4	2. Is there evidence that the product conforms to the specified requirements?				
4.10.4	3. Is there evidence that the requirements of the Quality Plan and/or documented procedures have been met prior to allowing release for shipment?				
4.10.4	4. Has all required data been recorded and stamped or otherwise authorized?				
4.10.5 Inspection and Test Records					
4.10.5	1. Do inspection records clearly show that a product has passed or failed inspections and/or tests according to defined acceptance criteria?				
4.10.5	2. Do inspection and test records identify the inspection authority for the release of product? See *Control of Quality Records* (4.16).				

Comment:

4.11 Control of Inspection, Measuring, and Test Equipment (1 of 3)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.11.1 General				
4.11.1	1. Are documented procedures established and maintained for the control, calibration, and maintenance of inspection, measuring, and test equipment (including test software) to demonstrate the conformance of product to specified requirements?				
4.11.1	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				
4.11.1	3. Are inspection, measuring, and test equipment used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability?				
4.11.1	4. Are test hardware and software verified prior to use and rechecked at prescribed intervals?				
4.11.1	5. Are hardware and software verification records maintained? See *Control of Quality Records* (4.16).				
4.11.1	6. Is measurement equipment technical data available to the customer or customer's representative when required contractually?				

4.11 Control of Inspection, Measuring, and Test Equipment (2 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.11.2 Control Procedure				
4.11.2	1. Are written procedures in use to describe and control all aspects of the calibration system, including: a. measurements to be made; b. accuracy required; c. type of inspection, measuring, and test equipment to be used?				
4.11.2	2. Are inspection, measuring and test equipment, and measurement standards calibrated with standards of required accuracy, which are traceable to national standards?				
4.11.2	3. Are written procedures used for performing in–house calibrations, and do these procedures include: a. equipment type; b. identification; c. location of use; d. frequency of checks; e. check method; f. acceptance criteria; g. action to be taken when results are unsatisfactory?				
4.11.2	4. Is inspection, measuring and test equipment marked to indicate: a. item identification or serial number? b. date last calibrated, by whom, and date next due; or for items too small for application of a label, an identifying code to indicate calibration status?				
4.11.2	5. Are calibration records maintained? (see *Control of Quality Records, 4.16*).				

4.11 Control of Inspection, Measuring, and Test Equipment (3 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.11.2	6. Are written procedures in place for assessing the validity of previous inspection and test results when equipment is found to be out of calibration and for disposition of products which have already been tested using that equipment?				
4.11.2	7. Are the required environmental conditions maintained during calibration, storage and use of inspection, measuring and test equipment, and measurement standards?				
4.11.2	8. Are protective handling procedures used for transportation and storage of inspection, measuring and test equipment, and measurement standards for in–house and outside calibration services?				
4.11.2	9. Are inspection, measuring, and test facilities, including both test hardware and software, safeguarded from adjustments which would invalidate the calibration setting?				

Comment:

4.12 Inspection and Test Status

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.12	1. Is inspection and test status of all products identified in accordance with the quality plan and/or documented procedures? Note: identification includes if either conforming or nonconforming to requirements.				
4.12	2. Is the identification of inspection and test status maintained throughout production and installation for incoming, in–process and finished goods and services to ensure that only conforming goods and services are released for use?				
4.12	3. Are inspection stamps, markings, tags, labels, or other suitable means used for identifying the inspections and tests performed and conformance to requirements? (see *Product Identification and Traceability, 4.8*)				

Comment:

4.13 Control of Nonconforming Product (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.13.1 General				
4.13.1	1. Are documented procedures in place for handling of nonconforming product and preventing it from unintended use?				
4.13.1	2. Are the procedures under document control? (see *Document and Data Control, 4.5*)				
4.13.1	3. Do the procedures cover the following controls: a. **identification** of nonconforming product (tags, markings, stickers, stamping, location, etc.); b. **documentation** indicating required to indicate product is nonconforming; c. **controls** necessary for the proper evaluation of nonconforming product (controls include review of repetitive problems and processes out of tolerance); d. **segregation** of nonconforming product with conforming (can be areas sectioned off, containers, holding rooms, etc.) e. **disposition** of the nonconforming product (including rework, repair, scrap, MRB activity, corrective action board, etc.) f. **notification** of nonconforming situations to areas affected? (e.g. Class A, reports, Cost of Quality)?				
4.13.1	4. Does nonconforming material reference or accompany the applicable rejection document?				

4.13 Control of Nonconforming Product (2 of 2)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.13.2 Review and Disposition of Nonconforming Product				
4.13.2	1. Do personnel performing nonconforming product reviews have sufficient authority for their task (e.g. review and disposition of product)? Where is this **defined**?				
4.13.2	2. Are nonconformances investigated and analyzed to determine causes of the nonconformity?				
4.13.2	3. Are nonconformances reviewed and dispositioned in one of the following: a. reworked to meet specified requirements; b. accepted with or without repair by concession; c. downgraded for alternative applications (e.g. engineering use, lab use only, etc.); d. rejected or scrapped?				
4.13.2	4. When accepted by material review boards, is material provided with identification as to its acceptance and authorizing documentation?				
4.13.2	5. If required by contract, is the repair or proposed use of product not conforming to requirements reported to the customer or customer's representative? (see 4.13.2(b))				
4.13.2	6. Are records of nonconformances and material review activity provided with detail of deficiencies, dispositions and corrective actions? (see *Control of Quality Records, 4.16*)				
4.13.2	7. Are reworked, repaired or modified nonconforming items reinspected and retested in accordance with the quality plan and/or documented procedures?				

Comment:

4.14 Corrective and Preventive Action (1 of 3)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.14.1 General				
4.14.1	1. Are there documented procedures in place for implementing corrective **AND** preventive action?				
4.14.1	2. Are the procedures under document control? (see *Document and Data Control, 4.5*)				
4.14.1	3. Does the documentation describe the criteria for taking preventive and corrective action based upon the magnitude of problems and/or potential risk? Note: can use SPC and pareto techniques to rank magnitude of problems.				
4.14.1	4. Have documentation changes resulting from corrective and preventive action been recorded?				

4.14 Corrective and Preventive Action (2 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.14.2 Corrective Action				
4.14.2	1. Do the procedures for corrective action include the following: a. effective handling and tracking of **customer complaints** and report of product nonconformities; b. investigating the cause of nonconformities and recording the results of the investigation (see *Control of Quality Records, 4.16*); c. determining corrective action needed to eliminate the cause; d. applying controls to ensure that corrective action is taken and that it is effective, thus preventing recurrence of the problem (including timely turn around and response by deficient areas)?				
4.14.2	2. Are corrective actions initiated when analysis of inspection data and/or nonconformance records reveal repetitive discrepancies or unsatisfactory trends?				
4.14.2	3. Is implementation of corrective action verified through follow–up checks?				
4.14.2	4. Are customer complaints handled by personnel in accordance with documented procedures?				
4.14.2	5. Is customer satisfaction confirmed upon action taken as a result of a customer complaint?				

4.14 Corrective and Preventive Action (3 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.14.3 Preventive Action				
4.14.3	1. Do the procedures for preventive action address the following: a. All inputs used to detect, analyze and eliminate (prevent) potential causes of nonconformities; b. methods and steps to be used in addressing problems requiring preventive action; c. initiating and controlling preventive action to ensure that it is effective; d. **confirmation** that information relevant to preventive action is reviewed during management reviews (see *Management Review, 4.1.3*)?				

Comment:

4.15 Handling, Storage, Packaging, Preservation and Delivery (1 of 3)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.15.1 General				
4.15.1	1. Are there documented procedures in place to address handling, storage, packaging, preservation, and delivery of product? Note: preservation includes shelf life, sealing, moisture/corrosion, and first–in–first–out (FIFO).				
4.15.1	2. Are the procedures under document control? (see *Document and Data Control, 4.5*)				
	4.15.2 Handling				
4.15.2	1. Are methods in place to prevent damage or deterioration of items during handling?				
	4.15.3 Storage				
4.15.3	1. Are storage areas and stock room properly designated and in use?				
4.15.3	2. Are the areas in use adequate to prevent damage or deterioration of product (including temperature and humidity)?				
4.15.3	3. Are material in stock identified to indicate contents, chemical and physical characteristics and other essential information?				
4.15.3	4. Are "age controlled" items identified as such and are there procedures in place to ensure their use (e.g., First–In–First–Out stock rotation) or recall prior to the expiration date?				
4.15.3	5. Is the condition of stock assessed at defined intervals to detect deterioration?				

4.15 Handling, Storage, Packaging, Preservation and Delivery (2 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.15.3	6. Is access to stock rooms and material storage areas restricted to authorized personnel?				
4.15.3	7. Is the issuance and receipt of material by stock rooms and material storage areas controlled by use of appropriate defined methods (e.g. requisitions and authorizations)?				
4.15.3	8. Is "good housekeeping" maintained in stock areas?				
	4.15.4 Packaging				
4.15.4	1. Are written instructions in use for controlling: a. packaging (during manufacture through delivery); b. packing (including special handling and protection); c. marking of packages and packing; d. shipping, including items to be shipped in each package?				
4.15.4	2. Are written instructions, checklists or other means used to verify item configuration and inclusion of documentation (such as customer's purchase order and inspection acceptance) to be shipped in each package?				
	4.15.5 Preservation				
4.15.5	1. Are methods defined, documented, and implemented for preservation and segregation of product?				

4.15 Handling, Storage, Packaging, Preservation and Delivery (3 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.15.6 Delivery				
4.15.6	1. Are written procedures in use to safeguard the quality and traceability of items after final inspection and test through delivery and installation?				
4.15.6	2. Do shipping records indicate delivery lot identification and relation to inspection lot, shipping date, destination and identity of shipping inspection personnel?				

Comment:

4.16 Control of Quality Records (1 of 3)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.16	1. Are documented procedures in place and cover the following for control of quality records: a. identification of the records to be retained; b. collection of these records; c. indexing and filing of these records; d. who has access; e. how they are filed; f. where they are filed (location and method); g. maintenance of records; h. disposition of records?				
4.16	2. Are the procedures under document control? (see *Document and Data Control, 4.5*).				

4.16 Control of Quality Records (2 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.16	3. Are the records maintained demonstrate conformance to specified requirements and effectiveness of the quality system? See the following sections: a. *Management Review, 4.1.3* b. *Contract Review, 4.3* c. *Design Review, 4.4.6* d. *Design Verification, 4.4.7* e. *Evaluation of Subcontractors, 4.6.2* f. *Control of Customer–Supplied Product, 4.7* g. *Product Identification and Traceability, 4.8* h. *Process Control, 4.9* i. *Inspection and Testing, 4.10.1* j. *Receiving Inspection and Testing, 4.10.2* k. *Inspection and Test Records, 4.10.5* l. *Control of Inspection, Measuring and Test Equipment, 4.11.1* m. *Calibration, 4.11.2(e)* n. *Review and Disposition of Nonconforming Product, 4.13.2* o. *Corrective Action, 4.14.2(b)* p. *Internal Quality Audits, 4.17* q. *Training, 4.18* **Note:** Pertinent quality records from subcontractors may make up this data.				

4.16 Control of Quality Records (3 of 3)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.16	4. Are the quality records legible? **Note:** records may be in the form of any type of media, such as hardcopy or softcopy.				
4.16	5. Are the quality records stored and retained in a facility that allows easy access and prevents damage, deterioration, and loss?				
4.16	6. Are retention times of quality records established and **recorded**?				
4.16	7. Are the quality records properly disposed upon the defined expiration date(s)?				
4.16	8. If contractually required, are quality records available for evaluation by the customer or customer representative?				

Comment:

4.17 Internal Quality Audit (1 of 2)

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.17	1. Are documented procedures in place for performing internal quality audits?				
4.12	2. Are the procedures under document control? (see *Document and Data Control, 4.5*)				
4.17	3. Do the procedures address the following elements: a. audit planning; b. audit execution; c. verification of quality activities and related results comply with planned arrangements; d. determination of the effectiveness of the defined quality system (e.g. audit activity covers all 20 elements of ISO 9001)?				
4.17	4. Are audits scheduled on the basis of status and importance of the activity under audit? Note: Audits with continuing problems should be more frequent than others with little to no problem. Audit frequency may also depend on life cycle phase the program is currently at.				
4.17	5. Are audits carried out by personnel independent of those managing the area(s) under audit?				

4.17 Internal Quality Audit (2 of 2)

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.17	6. Are auditors adequately trained to perform audits? (see *Resources, 4.1.2.2* and *Training, 4.18*).				
4.17	7. Are the results of audits recorded and distributed to affected organizations and management? (see *Control of Quality Records, 4.16*)				
4.17	8. Does the reporting of audit findings cover: a. description of nonconformances and possible causes; b. suggested corrective actions; c. time period when a response is required?				
4.17	9. Has timely corrective action been taken by management? (see *Corrective Action 4.14.2*).				
4.17	10. Has follow–up activities been taken and documented by the auditors to verify and determine the effectiveness of the corrective action? (see *Control of Quality Records, 4.16*).				
4.17	11. Are audit results reviewed during management reviews? (see *Management Review, 4.1.3*).				

Comment:

4.18 Training

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.18	1. Have procedures been established and maintained for identifying training needs?				
4.18	2. Do the procedures provide for training of all personnel affecting quality? See the following sections: a. *Quality Policy, 4.1.1* b. *Resources, 4.1.2.2* c. *Design and Development Planning, 4.4.2* d. *Process Control, 4.9* e. *Inspection and Testing, 4.10* f. *Control of Inspection, Measuring, and Test Equipment, 4.11* g. *Internal Quality Audits, 4.17.*				
4.18	3. Are the procedures under document control? (see *Document and Data Control, 4.5*)				
4.18	4. Are personnel assigned to specific tasks qualified on the basis of one or more of the following: a. appropriate education b. training (OJT, informal, etc.) c. experience?				
4.18	5. Are qualification and training records maintained for personnel? (see *Quality Records, 4.16*)				

Comment:

4.19 Servicing

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
4.19	1. When specified in the contract, are procedures established and maintained to perform, verify, and report servicing? **Note:** Servicing occurs after product delivery.				
4.19	2. If required, are the procedures under document control? (see *Document and Data Control, 4.5*)				

Comment:

4.20 Statistical Techniques

Program ID: _____ Audit Date: _____
Auditor: _____
Participants: _____

ISO References	Requirements	Yes	No	N/A	Objective Evidence and/or Comments
	4.20 Identification of Need				
4.20	1. Has the need for statistical techniques to establish, control and verify process capability and product characteristics been defined? (e.g. sampling, SPC, pareto, CpK, etc.) **Note:** If statistical techniques are not implemented, and defects are being encountered, then Quality System is not meeting *Process Control, 4.9 (d) & (g).*				
	4.20.1 Procedures				
4.20.1	1. Are there documented procedures for implementing and controlling the application of statistical techniques as identified?				
4.20.1	2. Are the procedures under Document Control? (see *Document and Data Control, 4.5*).				

Comment:

APPENDIX A-4: GAP ANALYSIS SPREADSHEET

ANSI/ASQC Q9001 - 1994 Element			Rating	Weight	Score
4.1	**MANAGEMENT RESPONSIBILITY**				
	4.1.1	Quality Policy		0.30	
	4.1.2	Organization			
		4.1.2.1 Responsibility and authority		0.10	
		4.1.2.2 Resources		0.05	
		4.1.2.3 Management representative		0.15	
	4.1.3	Management review		0.40	
		Total Score for Element 4.1			
4.2	**QUALITY SYSTEM**				
	4.2.1	General		0.30	
	4.2.2	Quality-system procedures		0.40	
	4.2.3	Quality planning		0.30	
		Total Score for Element 4.2			
4.3	**CONTRACT REVIEW**				
	4.3.1	General		0.35	
	4.3.2	Review		0.25	
	4.3.3	Amendment to contract		0.25	
	4.3.4	Records		0.15	
		Total Score for Element 4.3			
4.4	**DESIGN CONTROL**				
	4.4.1	General		0.20	
	4.4.2	Design and development planning		0.10	
	4.4.3	Organizational and technical interfaces		0.10	
	4.4.4	Design input		0.10	
	4.4.5	Design output		0.10	
	4.4.6	Design review		0.10	
	4.4.7	Design verification		0.10	
	4.4.8	Design validation		0.10	
	4.4.9	Design changes		0.10	
		Total Score for Element 4.4			
4.5	**DOCUMENT AND DATA CONTROL**				
	4.5.1	General		0.40	
	4.5.2	Document and data approval and issue		0.30	
	4.5.3	Document and data changes		0.30	
		Total Score for Element 4.5			
4.6	**PURCHASING**				
	4.6.1	General		0.40	
	4.6.2	Evaluation of subcontractors		0.20	
	4.6.3	Purchasing data		0.20	
	4.6.4	Verification of purchased product			
		4.6.4.1 Supp. verification at subcontractor's premises		0.10	
		4.6.4.2 Customer verification of subcontracted prod.		0.10	
		Total Score for Element 4.6			

	ANSI/ASQC Q9001 - 1994 Element	Rating	Weight	Score
4.7	CONTROL OF CUSTOMER-SUPPLIED PRODUCT		1.00	
	Total Score for Element 4.7			
4.8	PRODUCT IDENTIFICATION AND TRACEABILITY		1.00	
	Total Score for Element 4.8			
4.9	PROCESS CONTROL		1.00	
	Total Score for Element 4.9			
4.10	INSPECTION AND TESTING			
	4.10.1 General		0.35	
	4.10.2 Receiving inspection and testing			
	4.10.2.1 Incoming product		0.05	
	4.10.2.2 Amount and nature of receiving inspection		0.05	
	4.10.2.3 Urgent production release		0.05	
	4.10.3 In-process inspection and testing		0.15	
	4.10.4 Final inspection and testing		0.15	
	4.10.5 Inspection and test records		0.20	
	Total Score for Element 4.10			
4.11	CONTROL OF INSPECTION, MEASURING, & TEST EQUIPMENT			
	4.11.1 General		0.50	
	4.11.2 Control procedure		0.50	
	Total Score for Element 4.11			
4.12	INSPECTION AND TEST STATUS		1.00	
	Total Score for Element 4.12			
4.13	CONTROL OF NONCONFORMING PRODUCT			
	4.13.1 General		0.55	
	4.13.2 Review and disposition of nonconforming product		0.45	
	Total Score for Element 4.13			
4.14	CORRECTIVE AND PREVENTIVE ACTION			
	4.14.1 General		0.40	
	4.14.2 Corrective Action		0.30	
	4.14.3 Preventive Action		0.30	
	Total Score for Element 4.14			
4.15	HANDLING, STORAGE, PACKAGING, PRES., & DELIVERY			
	4.15.1 General		0.25	
	4.15.2 Handling		0.15	
	4.15.3 Storage		0.15	
	4.15.4 Packaging		0.15	
	4.15.5 Preservation		0.15	
	4.15.6 Delivery		0.15	
	Total Score for Element 4.15			
4.16	CONTROL OF QUALITY RECORDS		1.00	
	Total Score for Element 4.16			

	ANSI/ASQC Q9001 - 1994 Element	Rating	Weight	Score
4.17	INTERNAL QUALITY AUDITS		1.00	
	Total Score for Element 4.17			
4.18	TRAINING		1.00	
	Total Score for Element 4.18			
4.19	SERVICING		1.00	
	Total Score for Element 4.19			
4.20	STATISTICAL TECHNIQUES			
	4.20.1 Identification of need		0.40	
	4.20.2 Procedures		0.60	
	Total Score for Element 4.20			

Key to Compliance Ratings

0 - No attempt has been made to comply with the stated requirements of the standard. 0% of the final effort has been completed. (e.g. No records of acceptable subcontractors exist, and plans have not been put in place to create such a database).

1 - Planning stages to meet the requirements of the standard, however the system has not yet been implemented. 1% to 25% of the final effort completed. (e.g. Plans are in place to develop the database, however it has not yet been implemented).

2 - Implementation of a compliant solution to meet the requirements of the standard has commenced. 26% to 50% of the final effort completed. (e.g. The database has been developed, users trained, and format has been specified).

3 - System has been implemented, yet many areas of non-compliance across the company remain. 51% to 75% of the final effort completed. (e.g. The database is now in use, but only by a few programs across the site).

4 - Much progress has been made towards compliance to the requirements of the standard, minor work remains. 76% to 99% of the final effort completed. (e.g. The database is in full use, but a handful of programs still need to comply with the requirement).

5 - Element meets the requirements of the standard and is fully compliant. 100% of the final effort completed. (e.g. The database is in full use, and each program audited can produce objective evidence proving 100% usage of the subcontractor database).

KEVIN S. MASSIE

8008 Folkstone Road
Manassas, VA 22111
Voice: (703) 369-1652

QUALIFICATIONS:

- DoD Security Clearance: Secret
- Major Proposal Preparation and Evaluation
- Program Management and Subcontract Program Management for Large/Complex Programs
- Cost Engineering and Competitive Analysis
- Human Resource Management
- Business Process Re-Engineering and Total Quality Management
- Certified ISO 9000 Assessor (Intertek Technical Services)
- Trained and Experienced Malcolm Baldrige National Quality Award Assessor
- Experienced user with the following: Microsoft's Word, Excel, PowerPoint, Project, Works, Windows; Lotus' 1-2-3, AmiPro, Freelance Graphics; Harvard Graphics; and Interleaf Document Processor. Able to quickly learn any additional software as required.
- Experienced with Desktop, LAN, and Host environments.

PROFESSIONAL EXPERIENCE:

Loral Federal Systems-Manassas

Program Manager/Consultant, ISO 9000 **10/94 - 10/95**
Responsible for attaining ISO 9001 registration for the Manassas Division consisting of approximately 1600 employees. Personally led a site wide ISO Working Group consisting of representatives from all key functional disciplines. Developed site implementation strategies while serving as an ISO consultant to other Loral Divisions throughout the United States.

New Business Proposal Development **02/94 - 10/94**
Experienced in proposal preparation and evaluation. Management Proposal Manager for several significant (>$100M) winning proposals. Also served as management proposal consultant for several main thrust and challenge programs.

IBM Federal Systems Company

Deputy Proposal Manager, P-3C AIP **03/93 - 02/94**
Responsibilities included volume lead for four management sections, development of proposal and program schedules, estimating bid & proposal cost bogies, compliance matrices, win theme generation and implementation, and assisted with the Executive Summary. Mgmt. volume rated as "outstanding" and received the highest score of all bidders.

Manager, Proposal Development & Competitive Analysis **06/91 - 03/93**
Managed 14 people in Business Acquisition department supporting existing contracts and new business proposals. Responsibilities included managing cost volume, management volume, and competitive analysis efforts across multiple programs and business areas. Responsible for the initiation and successful implementation of the competitive analysis mission supporting the site of Manassas.

Manager, Cost Engineering **06/90 - 06/91**
Responsibilities included ensuring accurate should cost estimates, development of negotiation positions for major subcontractors, and production support through mitigation of cost exposures. Experienced in cost and schedule management of large scale programs worth approximately $2 billion. Handled difficult personnel performance issues while maintaining high employee morale.

Cost Engineer - New Business Proposals **10/89 - 06/90**
Responsible for estimating hardware costs for several new business proposals, while setting cost targets and analyzing cost and schedule variances on existing programs worth approximately $900 million. Performed evaluations, fact-finds and negotiated with major subcontractors.

Subcontract Program Management **10/86 - 10/89**
Lead production and development coordinator responsible for various large scale programs. Managed deliveries from major subcontractors and vendors, while scheduling and planning all Navy submarine sonar system deliveries. Every system was delivered on time and within budget. Personally responsible for savings to Navy programs in excess of $5 million.

Production Programs Coordinator **02/83 - 10/86**
Coordinator working system, unit, kit, and spare deliveries to the Navy customer. Developed an automated requirements tracking system which resulted in increased efficiency and an annual savings of approximately $100k. Met all planned and unplanned customer requirements, including emergency part failures at Naval shipyards throughout the United States.

EDUCATION:

- **M.S. - Systems Engineering, Virginia Polytechnic Institute and State University**
  - Graduated in December of 1995

- **B.S. - Industrial Engineering, West Virginia University**
  - Graduated in December of 1982
  - Alpha Pi Mu Industrial Engineering Honorary

- **Professional Education**
  - Performance Management (Earned Value) Seminar, Loral
  - Program Management School, Loral
  - Systems Engineering Principles and Practices, Loral
  - Proposal Management, Leadership and Writing Courses, IBM
  - Malcolm Baldrige Assessment Training, IBM Corp. and IBM FSC Division Level
  - New Manager School, IBM Corp. HQ, Armonk, NY
  - Process Analysis Technique, Defect Prevention Process, and Stat. Process Control, IBM

AWARDS:

- Outstanding Achievement Award (1993) - Proposal Manager, Malcolm Baldrige Assessment
- IBM FSC Marketing Symposium in Boca Raton, Fla., (1993) - Cost Engineering Management
- Informal Award (1989) - AN/BQQ-5E Development Program
- IBM FSD Marketing Symposium in Orlando, Fla. (1987) - Leadership on Production Programs
- Informal Award (1985) - Outstanding Contributions as Program Coordinator