İSTANBUL TEKNİK ÜNİVERSİTESİ ★ FEN BİLİMLERİ ENSTİTÜSÜ

ISO 9000+ BASED QUALITY SYSTEMS & GUIDE TO IMPLEMENT ISO 9002 IN THE DIVISION OF ENGINEERING SERVICES

YÜKSEK LİSANS TEZİ

Makine Mühendisi Levent IŞIK

Ana bilim Dalı : GEMİ MAKİNELERİ İŞLETME MÜHENDİSLİĞİ

Programı : GEMİ MAKİNELERİ İŞLETME MÜHENDİSLİĞİ

Tez Danışmanı: Doç. Dr. Oğuz Salim SÖĞÜT

Haziran 1998

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FOREWORD

In the increasingly global competitiveness of the marine engineering services business, quality control and quality assurance in construction is no longer optional.

Today, many repairs, overhauls, and even the whole job are performed off workshop. Therefore, to remain competitive at the turn of the century, creative. innovative ideas to meet quality standards must be explored. This is a crucial factor not only for business success, but also for mere survival.

In Engineering services, management is concerned with the standards of materials for design, material and construction functions. This mainly depends upon the material properties and workmanship. In 1987, the international organization for standardization (ISO) published a series of global quality system standards known as ISO 9000 which outline the requirements of a good basic quality management system.

They provide the structure and discipline to continually modify the procedures that will ensure the growth of a quality management program. Organizational, quality, cost, and marketing benefits can be realized through conformance and registration to these standards. In general, in today's global marketplace, every marine service industry must be prepared to be judged by recognized international standards.

This material is intended for persons concerned about the ISO 9000 standards and should help foster a wider interest in the use of quality systems in general.

The reader is invited to share any comments on the material presented in this document.

Levent IŞIK , Haziran 1998

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ABBREVIATIONS

A

AFAQ ASSOCIATION FRANCAISE POUR L'ASSURANCE DE LA QUALITE, FRENCH ACCREDITATION BODY AND QUALITY SYSTÈM REGISTRAR

ANSI AMERICAN NATIONAL STANDARDS INSTITUTE, U.S. MEMBER BODY TO ISO

ANSI/ASQC Q 90 SERIES U.S. EQUIVALENT OF THE ISO 9000 SERIES

AQAP-1 ALLIED QUALITY ASSURANCE PUBLICATION 1

ASQC AMERICAN SOCIETY FOR QUALITY CONTROL

B

BS 5750 BRITISH EQUIVALENT OF THE ISO 9000 SERIES

BSI BRITISH STANDARDS INSTITUTION

C

NIST NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

CASE CONFORMITY ASSESSMENT SYSTEM EVALUATION PROGRAM - NOW CALLED NVCASE

CD COMMITTEE DRAFT

CE MARK EUROPEAN COMMUNITY MARK

CEN EUROPEAN COMMITTEE FOR STANDARDIZATION

CENELEC EUROPEAN COMMITTEE FOR ELECTROTECHNICAL STANDARDIZATION

D

DESC DEFENSE ELECTRONICS SUPPLY CENTER, DOD

DFARS DOD FEDERAL ACQUISITION REGULATION SUPPLEMENT

DHHS U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIS DRAFT INTERNATIONAL STANDARD

DITI U.K.'S DEPARTMENT OF TRADE AND INDUSTRY

DOC U.S. DEPARTMENT OF COMMERCE

DOD DEPARTMENT OF DEFENSE

DOE U.S. DEPARTMENT OF ENERGY

DOT U.S. DEPARTMENT OF TRANSPORTATION

E

EAC EUROPEAN ACCREDITATION OF CERTIFICATION, A MEMORANDUM OF UNDERSTANDING SIGNED BY EUROPEAN NATIONAL ACCREDITATION BODIES AT UTRECHT ON MAY 22, 1991

EC EUROPEAN COMMUNITY

EDA ECONOMIC DEVELOPMENT ADMINISTRATION, DOC

EEA EUROPEAN ECONOMIC AREA (A TREATY DESIGNED TO ESTABLISH A NINETEEN (EC/EFTA) NATION FREE TRADE AREA)

EFTA EUROPEAN FREE TRADE ASSOCIATION (AUSTRIA, FINLAND, ICELAND, LIECHTENSTEIN, NORWAY, SWEDEN AND SWITZERLAND)

EN EUROPEAN NORM OR STANDARD

EN 29000 SERIES EUROPEAN EQUIVALENT OF THE ISO 9000 SERIES

ENV EUROPEAN PRE-STANDARDS

EOQ EUROPEAN ORGANIZATION FOR QUALITY

EOTA EUROPEAN ORGANIZATION FOR TECHNICAL APPROVALS

EOTC EUROPEAN ORGANIZATION FOR TESTING AND CERTIFICATION

EQNET EUROPEAN NETWORK FOR QUALITY SYSTEM ASSESSMENT AND CERTIFICATION, A BUSINESS AGREEMENT ESTABLISHED IN EARLY 1990 BY EIGHT QUALITY SYSTEM REGISTRATION BODIES

EQS EUROPEAN COMMITTEE FOR QUALITY SYSTEMS ASSESSMENT AND CERTIFICATION

ETA EUROPEAN TECHNICAL APPROVAL (APPROVAL BY AN EC AUTHORIZED BODY WHICH APPLIES TO CONSTRUCTION PRODUCTS FOR WHICH THERE ARE NO EXISTING OR PLANNED STANDARDS)

ETSI EUROPEAN TELECOMMUNICATIONS STANDARDS INSTITUTE

F & G

FAA FEDERAL AVIATION ADMINISTRATION, DOT

FAR FEDERAL ACQUISITION REGULATION

FDA FOOD AND DRUG ADMINISTRATION, DHHS

GMP GOOD MANUFACTURING PRACTICE GUIDELINES (FDA)

GSA GENERAL SERVICES ADMINISTRATION

H, I & J

HD HARMONIZED DOCUMENT

IEC INTERNATIONAL ELECTROTECHNICAL COMMISSION

IQA INSTITUTE FOR QUALITY ASSURANCE

ISO INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

ITQS RECOGNITION ARRANGEMENT FOR ASSESSMENT AND CERTIFICATION OF QUALITY SYSTEMS IN THE INFORMATION TECHNOLOGY SECTOR

JAS-ANZ AUSTRALIA/NEW ZEALAND ACCREDITATION BODY FOR QUALITY SYSTEM REGISTRARS

M & N

MOU MEMORANDUM OF UNDERSTANDING

MRA MUTUAL RECOGNITION AGREEMENT

MTC MANUFACTURING TECHNOLOGY CENTERS

NAC-QS COMITE NATIONAL POUR L'ACCREDITATION DES ORGANISMES DE CERTIFICATION, BELGIUM ORGANIZATION RESPONSIBLE FOR THE ACCREDITATION OF QUALITY SYSTEM REGISTRARS

NACCB U.K. NATIONAL ACCREDITATION COUNCIL FOR CERTIFICATION BODIES

NATO NORTH ATLANTIC TREATY ORGANIZATION

NIST NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

NCSCI NATIONAL CENTER FOR STANDARDS AND CERTIFICATION INFORMATION

NRC NUCLEAR REGULATORY COMMISSION

NVCASE NATIONAL VOLUNTARY CONFORMITY ASSESSMENT SYSTEM EVALUATION, FORMERLY THE CASE PROGRAM

NVLAP NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM, NIST

O, P & Q

QSR QUALITY SYSTEM REGISTRAR

R & S

RAB REGISTRAR ACCREDITATION BOARD, U.S. ACCREDITATION BODY FOR QUALITY SYSTEM REGISTRARS/CERTIFIER OF QUALITY SYSTEM AUDITORS

RVC RAAD VOOR DE CERTIFICATIE, DUTCH COUNCIL FOR CERTIFICATION

SC SUBCOMMITTEE

SCC STANDARDS COUNCIL OF CANADA, THE CANADIAN BODY RESPONSIBLE FOR THE ACCREDITATION OF QUALITY SYSTEM REGISTRARS

T

TAAC TRADE ADJUSTMENT ASSISTANCE CENTERS

TC TECHNICAL COMMITTEE

TC 176 THE ISO TECHNICAL COMMITTEE RESPONSIBLE FOR THE DEVELOPMENT OF THE ISO 9000 AND 10000 SERIES

TickIT U.K. QUALITY SYSTEM REGISTRATION SCHEME FOR SOFTWARE COMPANIES STANDARDS

W

WD WORKING DRAFT

ABSTRACT

This thesis, provides additional information on the ISO 9000 standards and related issues to readers unfamiliar with some of the new developments in this area. It attempts to answer additional questions on ISO 9000 standards related issues. It also identifies sources for further help in this area.

This project's aim is to establish a system that controls the critical activities affecting quality at Engineering Services and to assure the production and delivery of high quality goods and services.

The objective is to design and develop an outline for a quality system in Engineering Services, having the ISO 9000 standard as a framework.

At this point, the objective of the project can be satisfied to the fullest extent by writing a guide containing all the necessary information, including a conceptual quality system design to implement ISO 9002 based quality system in the division of Engineering Services, Marine Industrial Company. The conceptual quality system suggested in this guide can also be used as a structure through which to implement a Total Quality Management program.

Key Words: conformity assessment; EN 29000; EOTC; ISO Forum; ISO 9000; quality assurance; quality control; quality system; quality system registration

ÖZET

ISO 9000+ BAZLI KALİTE SİSTEMLERİ & MÜHENDİSLİK SERVİS BÖLÜMLERİNDE ISO 9002 YARATMA REHBERİ

Bu tez, ISO 9000 Standardlarında ek bilgiler sağladığı gibi, bu konuya uzak olan okuyuculara, konudaki yeni gelişmelerle ilgili dökümanları ve yayınları da sağlar.

ISO 9000 Standardları ile ilgili konularla ilgili ek sorularda yanıtlamaya gayret eder. Ayrıca bu alanda ileride yararlanılacak kaynakları da bilgi olarak sunar.

Bu tez ayrıca ISO 9000 Standartları ve kalite sistemleri tescili ile ilgilenen veya içinde olan herkes için hazırlanmıştır. Birleşik Devletler ticaretini etkileyebilecek Avrupa Birliğinde ISO 9000 ilgili konulara ayrı bir önem verilmiştir.

Bu projenin amacı, Mühendislik Servislerinde (Engineering Services) kaliteyi etkileyen kritik aktiviteleri kontrol edebilecek ve yüksek kaliteli mal ve servisin sağlanmasını ve üretilmesini güvence altına alacak bir sistem oluşturmaktır.

Hedef, ISO 9000 Standardlarını iskelet alarak, Mühendislik Servislerinde kalite sistemi için bir taslak dizayn etmek ve oluşturmaktır.

Bu noktada, projenin hedefi, ISO 9002 Tabanlı kalite sisteminin mühendislik servislerine uyarlaması ile oluşan kavramsal kalite sistemini de içeren tüm gerekli bilgileri, sağlayan tam içerikli bir rehber yazmakla sağlanabilir. Bu tezde bahsedilen kavramsal kalite sistemi aynı zamanda Toplam Kalite Yönetimi Programını oluşturmak için bir yapı olarak ta kullanılabilir.

Geçmiş yıllarda Toplam Kalite Yönetimi (TQM) tabanlı yönetim filozofisi Amerikan firmalarında her zaman dikkat çekmiştir. Amerikan Endüstri devleri - Motorola, Procter and Gamble ve Xerox başarının Toplam Kalite Yönetimi ile geldiğinin en büyük kanıtıdır. Buna benzer şekilde, ISO 9000 oanyı global market pazarında iş yapmak için gerekli bir pasaport gibi görülmektedir. Ayrıca başarılı bir Toplam Kalite Yönetimi Programının ISO 9000 tabanlı kalite sitemine benzer bir kalite sistemine sahip olduğu rahatlıkla görülebilir.

Kalite geliştirilmesi, Amerika Birleşik Devletleri ve uluslararası iş stratejileri için ve dünya çapında kalite sistemlerinin, ürünlerin ve servislerin bir standarta veya isteklere uygunluğunun güvencesini sağlamak açısından anahtar haline gelmiştir. Büyüyen uluslararası adaptasyon ihtiyacında hiç bir yer ISO 9000 Serilerinin kullanımının dışında kalamaz Avrupa birliğinin içinden ve dışından alıcıların ve kanun koyucuların ISO 9000 ihityaçlarına uyum için gösterdikeri büyüyen ihtiyaçları nedeniyle bu standartlara uyum ve çalışma uluslararası çalışan bütün firmalar için büyük bir önem kazanmıştır.

Bu kısım Mühendislik Serivisnde ISO 9000 esaslı bir kalite sistemini oturtmayı planlayan bir okuyucuya rehberlik etmesi açısından yazılmıştır.

Bölüm 1 okuyucuya ISO 9000 Serisinin neyle ilgili olduğunu veren genel bir bilgilendirmedir. ISO 9000'deki tanımlamalar, ISO 9000'in kısımları, ISO 9000'in uygulama alanları ve ISO 9000'deki dökümantasyonun önemi acıklanmıştır. Günluk örnek Rabbitt, John T., and Bergh, Peter A. tarafindan, 1994'de yazılan "The ISO 9000 book" 'dan alınmış, ve endüstriyel bir dev benzin istasyonunda veya bölgesel bir benzin istasyonu olsanız dahi, ISO 9000'in nasıl çarpıcı bir etki yaptığı ve işleri nasıl geliştirdiğini okuyucunun anlaması amacıyla verilmiştir .Bu bölüm ISO 9000 Standartlarının daha iyi anlaşılması ve iyice bilinmesi açısından diğer bölümlerden önce okunmalıdır.

Bölüm 2 ISO 9002 tabanlı kalite sisteminin oluşturulması için gerekli 18 konunun tanıtılmasının ve gözden geçirilmesini sağlar ve bununla ilgili soruları cevaplar. `What does it really mean for Engineering Services?' bölümünün formatı ve içeriğiArnold, Kenneth L.tarafindan yazılan, 1994 basımı "The managers guide to ISO 9000" kitabından alınmıştır.

Bu özel stil, okuyucunun, standardın her kuralının ihtiyaçlarını ve gereklerini kolay ve etkili bir yolla anlatarak daha hızlı ve etkili bir şekilde anlamasını sağlar. Aşağıda isimleri ve yazarları verilen kitaplar, Mühendislik Servisleri çalışma ortamına en uygun geliştirme ve uyum stratejilerini vermekte ve detayları sebebiyle hararetle tavsiye edilmektedir.

1. Arnold, Kenneth L. The Manager's Guide to ISO 9000. Newyork: Macmillan, 1994.

2. Kanholm Jack. ISO 9000 Quality System. AQA Co, Los Angeles, CA. 1994.

Bu bölüm okuyucuya Bir Mühendislik Servis firmasında ISO 9000standartlarının oluşturulması ve geliştirilmesi açısından bir bilgi sağlayacağı tahmin edilmektedir.

Bölüm 3 Mühendislik Servislerinde nasıl bir iş emri kullanılması gerektiğini ve bunların ISO 9000 ile ilgili bir çok kuralları sağlamak için nasıl düzenlenmesi gerektiğini ve nasıl değerli bir araç olduğunu gösterir.Bu bölümün içeriği Jack Kanholm tarafından , 1994 yılında yazılan "ISO 9000 Quality System" adlı kitaptan ve Bir Mühendislik Servisinin ihtiyaçlarına uyumu için yapılması gereken bir kaç modifikasyondan adapte edilmiştir.

Bölüm 4 Kalite sistem modeli olarak oluştururlmuştur. Bu model dökümantasyonun takip edilebilirlik güvencesini, uygun ve gerekli olan kolay kullanılabilir kalite sistem formlarını kullanarak, takip edilebilmesini sağlar. Bu kalite sistem modeli Mühendislik Servislerinin ISO 9002 uyum ve geliştirme projesine bir baz model olarak başlamak amacıyla sağlanmıştır.

Bölüm 5 ISO 9000 dökümantasyonunun detayına tartışıldığı bölümdür. Bir kalite sistem dökümantasyon yapısı, oluşturulabilecek en etkili ve verimli bir sistem olarak bulunmalı ve oluşturulmalıdır. Kalite Manualini, işletme prosedürlerini ve iş

emir ve detaylarını oluşturmak için verilen rehber ve kılavuz bu bölümde listelenmiştir.

Bölüm 6 standartın 1987 versiyonu ile bugünkü versiyonu arasındaki bazı değişikliklerin küçük bir özetini verir. Bu okuyucuları 1994 versiyonunda bazı önemli sayılabilecek değişikliklerin olduğuna dair bilgilendirmek içindir. Bununla 1987 veya 1984 versiyonlarının ana başlıklarının aynı kalmadığı veya geçersiz olduğu gibi bir mana çıkartılmamalı, sadece bunların bir önceki versiyonlara ek olarak çıkarıldığı gözönüne alınmalıdır.

Bölüm 7 ISO 9002 Standartının MÜGESAN Mühendislik ve Gemi Sanayii A.Ş.' ye uygulamasını belirtmektedir ve tezin uygulama adımıdır. Bu bölümde tezin diğer altı maddesinde oluşturulan ve anlatılan kalite standartı ve uygulama detayları gerçeğe dönüştürülmesi için yapılan çalışmadır. Böylece tez uygulanabilirliğini kanıtlayacak ve diğer firmalarını ISO Standartlarına hazırlamak isteyenlere bir yol göstermesi açısından faydalı olacağını gösterecektir.

Sonunda yazar şunları ekleyerek sözlerini sonuca erdirmek istemektedir.

Bizler zayıflığın ezildiği, yokedildiği ve güçlülerin üstte olduğu bir dünyada kritik bir zamanda yaşıyoruz. Dayanıklılık sadece büyüklükte veya seslilikte değil ama en az müşterileri elinde tutmakta, alıkoymakta değil; eğer birisi çevresini genişletemese dahi. Dev korkunç dinazorlar değişen zamana uyamadıkları / uymadıkları için yeryüzünden yokolsalar dahi, kaşındıran mutfak veba hamamböceği yaşamına devam etti ve karşı koyulmaz insan ırkına ve teknolojiyle alay edercesine yaşamaya devam ediyor; sadece değişime gösterdiği uyum nedeniyle; ve yaşamaya olan isteği nedeniyle. Kalite / servis gelişimi sonrasında devam ettiğimizde bizimde saldırgan olmamız gerekir.

" Eğer kırılmayacaksa, yapıştırma" ve " ben 35 yıldır bu sektörde çalışıyorum, müşterimin ihtiyaçlarını ve beklentilerini herkesden daha iyi bilirim" gibi gereksiz tartışma ortamlarından kurtulalım. Her sinirimizi ve kasımızı kasalım ve kendimizi disiplinden, iyi yapılandırılmış, Kalite yönetim sisteminde sistematik olarak

desteklenen bir Toplam Kalite Yönetimi geliştirmek ve oluşturmak için yoğunlaştıralım. Bahsedilen Kalite Yönetim Sistemi için tariflerin formundaki nimet, ISO-9000 standartlarıdır.

Anahtar Kelimeler: Uygunluk Denetlemesi; EN 29000; EOTC; ISO Forum; ISO 9000; Kalite Güvencesi; Kalite Kontrol; Kalite sistem; Kalite sistem Onayı

INTRODUCTION

In recent years Total Quality Management (TQM) based management philosophy has drawn the attention of American business. The giants of U.S. Industry - Motorola, Procter and Gamble, and Xerox witness the success that can come by implementing TQM. Similarly, ISO 9000 registration is seen as the passport required to do business in the global market place. It is also seen that a successful TQM program will have a quality system that is similar to the ISO 9000 based quality system. Although ISO 9000 and TQM support each other, they do have different aims and objectives. When the different aims and focuses of ISO 9000 and TQM are understood, ISO 9000 as a path to TQM can be considered (Corrigan, 1994). In other words, ISO 9000 can be used as one of the tools in our TQM journey.

Quality improvement has now become a key U.S. domestic and international business strategy, and worldwide interest in quality systems as one method of assuring the consistent conformity of products or services to a defined set of standards or expectations has mushroomed. Nowhere is this more apparent than in the ever increasing international adoption and use of the ISO 9000 Standard Series. Growing demand by both buyers and regulators within and outside the European Community for conformity to ISO 9000 requirements has made these standards and their usage a matter of considerable importance and concern to U.S. companies

This thesis, meet the Questions and Answers on Quality, the ISO 9000 Standard Series, Quality System Registration, and Related Issues, attempts to answer additional questions on ISO 9000 standards related issues. It also identifies sources for further help in this area.

This thesis is intended for persons involved with or concerned about the ISO 9000 standards and quality system registration. Special attention is given to ISO 9000 related events within the European Community (EC) that might affect U.S. trade.

ABOUT THIS THESIS

This text is written to guide the reader who is planning to implement ISO 9000 based quality system in the Engineering Services.

Chapter 1 provides the reader with an overview on what the ISO 9000 series is all about. The definitions in ISO 9000, it's components, it's scope of application, and the role of documentation in ISO 9000 are discussed. An everyday example taken from "The ISO 9000 book", written by Rabbitt, John T., and Bergh, Peter A., 1994 is also given to enable the reader to understand that whether we are a big industrial giant or a local gas station, ISO 9000 will have a favourable impact on our business. This chapter should be read before reading other chapters to gain familiarity with the ISO 9000 standard.

Chapter 2 reviews each of the 18 elements in establishing a ISO 9002 based quality system and answers the question `What does it really mean for Engineering Services?' The format of this chapter had been adapted from the book "The managers guide to ISO 9000" written by Arnold, Kenneth L., 1994.

This unique style will help the reader understand the intent and requirement of each element of the standard in an easy and effective way. The following books were consulted in great detail to write down the implementation strategy that best fits the Engineering Services work environment.

1. Arnold, Kenneth L. The Manager's Guide to ISO 9000. Newyork: Macmillan, 1994.

2. Kanholm Jack. ISO 9000 Quality System. AQA Co, Los Angeles, CA. 1994.

It is sincerely felt that this chapter will provide the reader with an idea to implement the ISO 9002 standard in the Engineering Services.

Chapter 3 shows how the work order form currently in use in Engineering Services, can be used as an invaluable tool to satisfy many requirements of ISO 9000. The contents of this chapter have been adapted from the book "ISO 9000 Quality System", written by Jack Kanholm, 1994 with modification to suit Engineering Services needs.

Chapter 4 is the proposed quality system model. This model assures traceability through documentation, using easy to use quality system forms where applicable and necessary to provide traceability. This quality system model should provide Engineering Services a base model to start off the ISO 9002 implementation project.

However, it is a generic quality system concept and is meant to be built upon. The "ISO 9000 Questions and Answers + Quality System Manual" written and published by Gunther B. Gumpp, 1992 was referred throughout this chapter.

Chapter 5 discusses the documentation in ISO 9000 in detail. A quality system documentation structure that is found to be the most effective and efficient system is proposed. Guidelines for developing quality manuals, operating procedures and work instructions are listed down in this chapter.

Chapter 6 gives a summary of the significant changes to the 1987 version of the standard. This is to keep the reader informed on the significant changes that had taken place in 1994 version. This should not provide the reader with any concern regarding the validity of this guide as the basic intent of the standard (1987 or 1994 version) remains the same.

Finally the author of this text would like to conclude by saying the following. We live in a critical time in which the weaklings are being beaten, eliminated or taken over by the mighty ones. The strength is not in bigness or soundness but in at least retaining the customers instead of detaining them; even if one cannot expand the domain. Even the mighty dinosaurs have perished because they could not/did not adapt to the change, where as the irritating kitchen pest cockroach survived and is surviving against the onslaught of mankind and technology; just because of its adoption to change; and will to survive.

We need to be aggressive when we go out after service/quality improvement. Let us get rid of the blinding notions like `If it ain't broke, don't fix it' and `I have been in this business for 35 years, I know our customers' requirements/expectations better than anyone else.' Let's strain our every nerve and muscle, and commit ourselves to establish and implement a Total Quality Management supported by a disciplined, well structured, systemized quality management system. The boon in the form of guidelines for the aforesaid quality management system is ISO-9000 standards.

CHAPTER 1

ISO 9000 STANDARDS

This chapter provides the reader with an overview on what the ISO 9000 series is all about, its components and scope of application. The role of documentation in ISO 9000 is also briefly discussed.

1.1 WHAT IS ISO 9000 STANDARDS?

ISO 9000 is a universal quality system standard endorsed by European nations and many other countries. The standards were developed by the International Organization for Standardization (ISO), the international agency for standardization, headquartered in Geneva, Switzerland. The ISO is composed of national standards bodies from 91 countries. The U.S. is represented in the ISO by the American National Standards Institute (ANSI).

The ISO 9000 standards is neither a quality control standard nor a product oriented standard like the MIL-Q-9858A or the ASME Boiler Code. This standard is based on the philosophy that if the process used to produce the product was developed and maintained properly, the product would be consistent and the quality could be improved. It describes a quality management system which could prevent the production of nonconformities from design to servicing. If the system is adhered to, the supplier will always produce and deliver a predictable product or service. In other words, it makes sure that we actually do what we claim we do,all the time and that we have addressed some specific requirements as well.

The standard was first published in 1987. The 1994 revised version of these standards was issued in the spring of 1994 with the U.S. version being issued through the ANSI in late spring of 1994. The ISO 9000 standard is now known as ISO 9000-1. However this text is written in relation to the 1987 version of the ISO 9000 series standard. The major revisions have provided further clarification of the 1987 standard or added requirements exceeding those originally issued, but have not altered the intent or the basic requirements of the standard. A brief summary of the additional requirements of the 1994 version is identified and discussed in chapter 6.

1.2 EVOLUTION OF ISO 9000

The International Organization for Standardization (ISO) began working with European representatives in the quality field in 1979 to develop standards of quality for products traded across international borders. [1] The results of their work was approved in 1987 by ISO Technical Committee 176 as the ISO 9000 Quality Management and Quality Assurance Standards. The ISO organization is composed of member bodies from ninety-one countries. They provide a structure and mechanism for industries to come together to establish harmony and develop standards. The American National Standards Institute (ANSI) represents the United States in ISO. ISO 9000 series consist of five basic standards: ISO 9000, 9001, 9002, 9003, and 9004. They were designed to provide guidance on the selection of a suitable quality management system for operations of the company. [2] These were based largely on the British Standard BS 5750 and Defense Standard AQAP-1. [3] The main objective of ISO 9000 is to clarify the relationships between quality concepts and to provide guidelines for the use of international standards for quality management and assurance. Durand, Marquardt, Peach, & Pyle [4] stated that ISO 9000 have become the accepted basis of quality systems requirements for product conformity assessment in the global marketplace. The five standards have been adopted as national standards in more than 60 countries. It has been published in several languages. Each country has their own title and number system. In the U.S., the standards were adopted and jointly issued as the Q90 quality standards series by ANSI and the American Society for Quality Control (ASQC). The Q90 standards are the same as the ISO 9000 standards. Quality systems are certified by registrars (third-party) that are authorized

by national accreditation agencies. The three best known national accreditation agencies are: 1) the American Registrar Accreditation Board (RAB), 2) British National Accreditation of Certification Bodies (NACCB), and 3) the Dutch Council for Certification (RvC). [5]

1.3 WHY AND BY WHOM WERE THE ISO 9000 STANDARDS DEVELOPED ?

The International Organization for Standardization (ISO) is a worldwide federation founded in 1946 to promote the development of international standards and related activities (including conformity assessment) to facilitate the exchange of goods and services worldwide. ISO is composed of member bodies from over 90 countries, the U.S. member body being the American National Standards Institute (ANSI).

In 1979, ISO formed Technical Committee (TC) 176 on Quality Management and Quality Assurance to address the worldwide trend towards increasingly stringent customer demands with regard to quality combined with growing confusion in international trade resulting from differing national and subnational quality system requirements.

In 1987, based on the work of TC 176, ISO published the ISO 9000 Standard Series on quality management and assurance. These standards were based on considerable input from a number of countries, especially the United States (U.S.), Canada, and the United Kingdom (U.K.). In particular, the ISO 9000 standards were based in large part on the British Standards Institution's BS 5750 Series, Quality Systems.

1.4 HOW WAS BS 5750 DEVELOPED?

In 1959, the U.S. Department of Defense (DOD) established a Quality Management program with the designation of MIL-Q-9858. Four years later, it was revised to MIL-Q-9858A - its only revision to date. In 1968, the North Atlantic Treaty Organization (NATO) essentially adopted the provisions of MIL-Q- 9858A, Quality Program Requirements, in the form of Allied Quality Assurance Publication 1 (AQAP-l). In 1970, the U.K.'s Ministry of Defence adopted the provisions of AQAP-1 as its Management Program Defence Standard DEF/STAN 05-8. [6] In 1979,

the British Standards Institution (BSI) developed the first commercial quality management system standard, known as BS 5750. From these predecessors, ISO created the ISO 9000 Standard Series in 1987 - essentially adopting most of the elements of BS 5750. [7] That same year, the ISO 9000 standards were adopted in the United States as the ANSI/ASQC (American Society for Quality Control) Q90 Standard Series; and BS 5750 was revised to be identical to the ISO 9000 standards. NATO is currently revising its quality system standards to incorporate the ISO 9000 standards. [8]

1.5 WHAT IS THE U.S. ROLE IN ISO TC 176?

The United States has been an active participant in ISO TC 176 since 1987. The ASQC, through ANSI which serves as the U.S. member body in ISO, has been responsible for managing U.S. representation in TC 176. ASQC also has assumed responsibility for managing the adoption of the ISO 9000 and 10000 standards as American National Standards.

According to ISO procedures, all ISO standards, including those in the ISO 9000 Standard Series, must be reviewed and revised or reaffirmed at least once every five years. The initial ISO 9000 standards (ISO 9000, 9001, 9002, 9003, and 9004 without sub parts) published in 1987 were scheduled for review in 1992/1993, as was ISO Standard 8402 - Quality - Vocabulary, which contains relevant terminology and definitions. Minor modifications in the original ISO 9000 Series are expected in 1993/1994, with major revisions in 1997/1998. [9]

The United States, which adopted the original five ISO 9000 standards in 1987 as the ANSI/ASQC Q90 Series, is actively involved in their review. ASQC is coordinating the development of U.S. comments and positions on the 1992/1993 revisions.

1.6 DOES THE ANSI / ASQC Q90 STANDARD SERIES DIFFER FROM THE ISO 9000 STANDARD SERIES?

ISO 9000-9004 and ANSI/ASQC Q90-94 are technically equivalent. However, the ANSI/ASQC Q90 Series has been modified to incorporate customary

American language usage and spelling. Some supplementary guidance on sampling and other statistical methods and product liability and user safety has also been included in the appendices to ANSI/ASQC Q94. ASQC is planning to renumber the ANSI/ASQC Q90 Series as the ANSI/ASQC Q9000 series to clearly indicate their equivalency to the ISO 9000 Series

1.7 WHAT IS ISO TC 176 WORKING ON?

The following standards are under development in TC 176's subcommittees (SC) (5):

1.7.1 SC 1 - Terminology

- DRAFT INTERNATIONAL STANDARD (DIS) 8402-1 QUALITY SYSTEMS TERMINOLOGY

1.7.2 SC 2 - Quality Systems

- DRAFT INTERNATIONAL STANDARD (DIS) 9004-3, QUALITY MANAGEMENT AND QUALITY SYSTEM ELEMENTS - PART 3: GUIDELINES FOR PROCESSED MATERIALS (Will be published mid to late 1993.)

- DRAFT INTERNATIONAL STANDARD (DIS) 9000-2, QUALITY MANAGEMENT AND QUALITY SYSTEM STANDARDS - PART 2: GENERIC GUIDELINES FOR THE APPLICATION OF ISO 9001, ISO 9002, AND ISO 9003 (published mid to late 1993.)

- DRAFT INTERNATIONAL STANDARD (DIS) 9004-4, QUALITY MANAGEMENT AND QUALITY SYSTEM ELEMENTS - PART 4: GUIDELINES FOR QUALITY IMPROVEMENT (published mid to late 1993.)

- COMMITTEE DRAFTS (CD) 9000-1, 9002, 9003, AND 9004-1, REVISIONS TO ISO 9000, 9001, 9002, 9003, AND 9004 (Expected to be out for DIS ballot shortly.)

- COMMITTEE DRAFT (CD) 9004-6, QUALITY MANAGEMENT AND

QUALITY SYSTEM ELEMENTS - PART 6: GUIDELINES QUALITY PLANS

- WORKING DRAFT (WD) 9004-5, QUALITY MANAGEMENT AND QUALITY SYSTEM ELEMENTS - PART 5: GUIDE TO QUALITY ASSURANCE FOR PROJECT MANAGEMENT

- COMMITTEE DRAFT (CD) 9004-7, QUALITY MANAGEMENT AND QUALITY SYSTEM ELEMENTS - PART 7: GUIDELINES FOR CONFIGURATION MANAGEMENT

1.7.3 SC 3 - Quality Technologies

- WORKING DRAFT (WD) 10012-2: QUALITY ASSURANCE REQUIREMENTS FOR MEASURING EQUIPMENT - PART 2: MEASURING ASSURANCE

- COMMITTEE DRAFT (CD) 10013: GUIDELINES FOR DEVELOPING QUALITY MANUALS (Expected to be out for DIS ballot shortly.)

- WORKING DRAFT (WD) 10014: GUIDE TO THE ECONOMIC EFFECTS OF QUALITY

- WORKING DRAFT (WD) 10015: CONTINUING EDUCATION AND TRAINING GUIDELINES

1.8 DEFINITIONS IN ISO 9000

1.8.1 What Is Quality?

The answer is, there is no one single definition of quality. Quality is not just a product-based term or a service-based term or a manufacturing-based term. Quality is present in, or missing from, every aspect of a firm's operation. ISO 8402 (Quality Vocabulary) defines quality as `the totality of characteristics of an entity that bear on its ability to satisfy stated or implied needs.

In a contractual situation, `stated' needs are specified in the contract requirements.

In other situations, `implied' needs should be identified and defined by the company. Needs are usually translated into product features and characteristics with specified criteria [6]. Our three renowned `quality gurus': W. Edwards Deming, Joseph M. Juran, and Philip B. Crosby define quality as follows

`Quality is fitness for use.' J. M. Juran

`Quality means conformance to requirements.' P. B. Crosby

`Quality is dependable, customer satisfying product or service at a low cost.' W. E. Deming

These definitions clearly show that the days of limiting quality to the `soundness' of the product - its surface finish or durability, for example - are gone. Ultimately the customer decides whether the quality of a product or service is worthy of his/her hard-earned resources [22].

1.8.2 What Is A Quality Policy?

A company's quality policy is `the overall quality intentions and direction of an organization as regards quality, as formally expressed by top management.' (ISO 9000, Clause 3.1) The vision and mission statement position the company in the future and identify how that position is to be realized, where as quality policy will set the stage for a complete collection of activity specific company policies to be used in administrative procedures [18]. The public should get a high level of confidence about the company from reading the company's quality policy.

Sample quality policy statements [18] are given below. These statements exhibit what might be included in a quality policy.

A. The only acceptable level of defects is zero defects.

B. At no time will defective products knowingly be shipped.

C. Scrap-reduction techniques will be an integral part of every employee's job

description and work activity.

1.8.3 What Is Quality Management?

Quality management is `that aspect of the overall management function that determines and implements the quality policy.' (ISO 9000, Clause 3.2)

1.8.4 What Is A Quality System?

A quality system is designed to ensure the continued repeatability of a set of product and service characteristics that have been explicitly or implicitly agreed to by a customer and a supplier [15] The quality system's primary aim is to assure that all activities are planned, and done in pre-determined ways and that there are clearly defined channels for communication of information and instructions.

According to ISO 9000, a quality system is `the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.' (ISO 9000, Clause 3.3) The quality system of an organization is influenced by the objectives of the organization, by the product or service and the practices specific to the organization, and, therefore, the quality system varies from one organization to another.

Organizations which operate quality systems tend to exhibit the following attributes [16]

1. A philosophy of prevention rather than detection

2. Continuous review of critical process points, corrective actions, and outcomes

3. Consistent communication within the process, and among facility, suppliers, and customers

4. Thorough record keeping and efficient control of critical documents

5. Total quality awareness by all employees

6. High level of management confidence

In sum, the company with a well-designed and well-implemented quality system has a process which tends to be lean, sensitive to customers needs, highly reactive, efficient, and positioned at the leading edge of its market place. According to quality systems consultant Ian Durand `the basics of a quality system is to say what you do, do what you say, record what you did, check the results and act on the difference' [6].

1.8.5 What Is Quality Control?

ISO 9000 defines quality control as `the operational techniques and activities that are used to fulfill requirements for quality.'(ISO 9000, Clause 3.4) Raw material inspection, in-process inspection, and final product inspection fall under quality control activities.

1.8.6 What Is Quality Assurance?

Quality assurance (QA) includes `all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.'(ISO 9000, Clause 3.5)

1.9 THE ISO 9000 SERIES

In 1987, the ISO published a series of five standards which outline the requirements for a quality management system. ISO 9000 is not a single standard. It is actually a series of five separate, but interrelated, standards numbered from 9000 to 9004. ISO 9000 and 9004 provide general quality management guidelines. ISO 9001, ISO 9002, and ISO 9003 detail specific requirements for registration. Basically, the standards are of two types: guidance standards and conformance standards.

The first, ISO 9000 (ISO 9004-1) is a road map for the selection of three system models, ISO 9001, 9002, 9003. These models are quality management systems for different production environments. Companies generally are registered to one of these three standards. The ISO 9004 (ISO 9000-1), provides guidelines for quality system management. ISO 9000 and 9004 helps the firm to develop and achieve an internal

quality system that adapts to one of the three models. It provides a wide variety of conditions, and stresses internal improvements. At first, many of these standards were not clear. However, more standards were added to help companies to understand the intent and application of the standards such as: ISO/DIS 9000-2, ISO 9000-3, ISO 9004-2, ISO/DIS 9004-3, and ISO 9000 Compendium [3]. ISO 9000 provides guidelines for defining what a quality system should include to assure conformance to international standards. A brief description of each standard is presented below [3,6]:

ISO 9000: 1987 Quality Management and Quality Assurance Standards: A guidelines to help in the selection of the proper contractual standard (9001, 9002, 9003) for an organization. Today, this is called ISO 9000-1.

ISO/DIS 9000-2 Quality Management and Quality Assurance Standards-Part 2: Describes the purpose and application of ISO 9001, ISO 9002, and ISO 9003.

ISO 9000-3 1991 Quality Management and Quality Assurance Standards-Part 3: Describes application of ISO 9001 to the development, supply, and maintenance of software.

ISO 9001 1987 Model for Quality Assurance in Design/Development, Production, Installation and Servicing: Contractual standard contains twenty elements relating to quality standards. It applicable to companies that both design and manufacture products or produce computer software or design and offer services.

This model is for those companies that conform to specified requirements throughout the whole cycle from design to service. This is the most complete standard involving all the quality system elements. It includes 20 sections describing the various elements of a quality system.

ISO 9002 Model for Quality Assurance in Production and Installation and Servicing: The eighteen quality standard elements within this model applicable to companies that manufacture and services products. They do not have control of the design.

This model is for companies that perform all functions except the design/development of products and after sales service e.g., a job shop like Engineering Services, that

builds to prints supplied by a customer. It includes 18 sections describing the various elements of a quality system in production and installation. Here all one has to demonstrate is one's capabilities in production, and installation.

ISO 9003 1987 The contractual standard applicable to companies that assemble, test and final inspection of the products but, designed and manufactured elsewhere. The six comprehensive and ten less comprehensive quality standard elements contained within this document are designed to assure quality in testing and final product inspection.

This model is for those companies that addresses the requirements for detection and control of problems only during final inspection and testing. In this case, the product is supplied by an outside manufacturer. It is the least comprehensive standard and contains 12 sections.

ISO 9004 1987 Quality Management and Quality System Elements - Guidelines. Describes a quality management system more comprehensive than required by the contractual standards. Today, this is called ISO 9004-1.

ISO 9004-2 1991 Quality Management and Quality System Elements - Part 2: Guidelines for service industry.

ISO/DIS 9004-3 1991 Quality Management and Quality System Elements - Part 3: Guidelines for processed materials industry.

ISO 9000 Compendium-International Standards for Quality Management -Contain all of the above standards, plus quality auditing, manual and the vision 2000 document.

1.10 WHICH MODEL TO CHOOSE (9001, 9002, 9003) FOR ENGINEERING SERVICES (E.S.)?

From the previous paragraph it is quite clear that 9003 is a subset of 9002 which in turn is a subset of 9001. The most detailed model for quality assurance, 9001, consists of 20 elements. The 9002 standard consists of 18 elements wheres 9003 only has twelve. Since 9003 is the least used model, the decision as to whether 9001 or

9002 model should be made. In some cases, the decision can be made by answering the following question: Are we independently involved in design and development work?

If the answer is `No, the customer retains the decision making powers during design and development work ' then 9002 is very likely to suit our needs. Otherwise, the company should choose 9001. The decision as to which model to follow is not always straightforward. In these type of situations it is always wise to get help from an outside expert. In our case, since E.S. is not independent in its design and development work, the standard ISO 9002 is selected.

1.11 DOCUMENTATION

The ISO standards require that the company appropriately document the quality management system. A documented quality system sets out in a formal framework the basis of controlling critical activities that affect quality in an organization [22]. An appropriate documentation system is important to assure the production and delivery of high quality goods and services. Chapter 5 discusses the documentation in ISO 9000.

1.11.1 What ISO 9000 Demands In Documentation? A Scenario

Imagine that one day you arrive at work and discover that engineering company has ordered all personnel at Engineering Services (E.S.) to a new location except you. In a few hours an entirely new set of personnel will be coming to take over the operations. This new team includes the director, the supervisors, the machine operators, and the secretary. Unfortunately none of these people has ever seen Engineering Services before, but they do have sufficient work experience. In the few hours before they arrive, can you determine if there are enough Standard Operating Procedures (SOP's), work instructions, flow charts, and other forms of documentation to enable these people to understand what is required at their new jobs?. Take a moment and ponder what has just been asked, because it is critical in establishing a quality system.

These are the two questions primary asked by ISO 9000 [14]:

1. Have you documented your operations thoroughly enough so that a new person can read the documents and can understand what has to be done?

2. If your company is well-documented, then do the documents clearly state each person's role in assuring the quality of the goods and services your company produces?

In theory, if everybody in the plant were replaced with a new workforce, the documentation required by ISO 9000 would enable reasonably skilled people to produce exactly the same product as before.

1.12 Registration Process

To become registered, a company needs to do the following [16]:

1. Select an ISO 9000 quality system appropriate to its scope of operation (ISO 9001-2-3)

2. Document the quality system with a quality manual. plus supporting levels of documentation

3. Operate the quality system for a minimum of three and preferably six months

4. Contract with an accredited registration firm (`registrar')

5. Undergo and pass the prescribed pre-assessment and on-site surveillance stages

6. Pay the required fees

This is just a thumbnail sketch of the ISO 9000 registration process. The first three steps are the basic steps that can be used by any company desiring to develop a quality management system based on an ISO standard. As seen, documentation is central to the system and in fact, is an absolute pre-requisite to certification.

1.13 REASONS TO USE ISO 9000 STANDARD

Development of a quality system in accordance with ISO 9001 or 9002 typically occurs for one of the two reasons [13]:

The first reason is to obtain company certification. In this type of approach, being awarded the certificate becomes the entire focus of the certification program; quality and efficiency improvement becomes secondary.

The second reason to implement ISO 9001 or 9002 is to use the standard as a quality improvement tool for better business. Receiving the certification is secondary in this instance. This approach encourages development of a system to maintain product consistency and a mechanism to improve product quality. It is this approach that Engineering Services (E.S.) will follow at this point in time.

1.14 ISO 9000 AS A PATH TO TQM

ISO 9000 might not be the path to TQM but it could be a path to TQM. Any organization starting a TQM effort should assess the adequacy of its underlying quality system. Using an ISO 9000 standard for this assessment would provide an excellent measurement criteria [15].

An alternative is to integrate the ISO 9000 standard into TQM from the start. The quality system could be restructured into an ISO 9000 system during the initial stages. This integrated approach could accelerate the TQM process. If a company has no TQM initiative and has no reason to seek ISO 9000 registration, it should still consider doing an ISO 9000 assessment of its quality system and modifying it as appropriate [15]. The ISO 9000 standards can also be used as a foundation or a building block for meeting more stringent quality goals such as the criteria of the Malcolm Baldrige National Quality award in the U.S.

1.15 ISO 9000 - AN EVERYDAY EXAMPLE

Taken from: The ISO 9000 book, [19]

One example that demonstrates how ISO 9000 applies to an everyday situation is having the brakes of your car worked on at the local garage. You remember a local garage's advertisement for a special on brake repairs; in addition, you remember a neighbour speaking highly of the place.

As you approach the front counter of the shop your journey through ISO 9000 begins. The clerk listens to your experience with the brakes as well as about your car. He informs you that your car will require metallic brake pads that will cost extra. You agree to go ahead with the job and the clerk promises your car will be ready in one hour.

As you wait you mull over your main concerns: Will the car stop properly? Will the repair cost more than was stated? Will they complete the work in an hour? This is what ISO 9000 is all about - confidence that the task will be done as promised. The ISO 9000 standard encompasses many details that would easily be taken for granted.

You noticed an hour passed. You go to the front desk. The clerk says, `Your car is coming out right now and we saw that your driver's side windshield wiper was worn, so we replaced it free of charge, as our management believes your safety is paramount. Here are your keys and an itemized check sheet of all the tasks completed. This will also act as your warranty. Please note our toll-free number should you have any problems or wish to make an appointment for any of your other vehicles. Thank you for your patronage and please drive carefully.'

This is a simple tale about brakes being fixed and a very happy customer at the end. It illustrated an ISO 9000 compliant organization taking care of the customer in a way that meet customer's expectations. When you combine performance of the primary task to a normal expectation (ISO 9000 defined), and then go beyond that expectation, you end up with a very happy customer. That's what quality is all about - creating customer satisfaction.

CHAPTER 2

THE INTENT AND REQUIREMENTS OF THE ELEMENTS IN ISO 9002 FROM E.S. POINT OF VIEW

This chapter will go through all the 18 elements in establishing a ISO 9002 based quality system and will answer the question `What does it really mean for E.S.?' The format of this chapter had been taken from the book `The managers guide to ISO 9000' written by Arnold, Kenneth L., 1994 [13]. At this point of time, it is to be noted that the intent of ISO 9000 is to assure that any one new to the company will be able to read the procedures and thereafter understand their job responsibilities, especially those related to quality.

2.1 MANAGEMENT RESPONSIBILITY

The company management define the quality policy and the objectives of the quality system.

Our quality gurus Deming, Juran and many others pointed out that management was primarily responsible for 80% of an organization's problems. ISO 9000 also believes that the success of a quality system is directly related to the top management commitment and hence begins with a general requirement for management. If the upper management is unconcerned and gives the impression that the ISO standard is the middle management's (Director's) job to implement, the effort will usually fail. If this is the attitude of the upper management then a different standard should be identified to implement.

2.1.1 Quality Policy

Intent: The intent of this element is for a organization to develop a program that will provide leadership and direction by upper management while assigning authority and responsibility throughout the organization to establish a quality system.

Requirement: This standard requires top management to define and document its quality policy and objectives and to make sure that this policy is understood and implemented at all levels in the organization. The objectives define further and support the policies. An example is given below to detail the difference between policies and objectives [13].

Policy Statement: Crash and Burn Airlines is committed to provide a comfortable and clean smoke-free environment on every flight for all our passengers.

Objective: The objective of this policy is to eliminate customer complaints about exposure to second-hand smoke during the time the customer is on aircraft.

Implementation strategy: Top management should first make decisions to the direction of Engineering Services. These decisions are then placed in the policy statement. This document should give us an idea as where we want to go and not how we will get there. It is a good idea to post the policy in conspicuous locations throughout E.S., so that all personnel can familiarize themselves with it, and it can be seen by the visiting customers. During internal audits, the auditors should ask any employee what the quality policy is, how he or she understands it, and what he or she specifically does to implement it.

2.1.2 Organization

Intent: The intent of this element is for top management to demonstrate a systematic and logical approach to the quality system. It also intends to show that the management has given authority along with responsibility and is committed to proper funding for activities that will verify the system is working. For example,

verification activities might include internal audits, training personnel to carry out audits, servicing processes, inspection and testing requirements, etc.

Requirement: Management is required to define responsibility, authority, and interrelation of all personnel whose work affects quality. At E.S., since all employees work affect quality, their responsibility, authority, and interrelation with other personnel in the division should be defined.

The organizational chart should show the paths of authority very clearly and a list of responsibilities for key management personnel.

Whatever the size of the company-big, small, or medium-there must be a person, independent of production, who is in charge of assuring quality. Or else, a designated person from one group should be given the responsibility to inspect the others group's work. This ensures that `prisoners in charge of the prison' syndrome does not exist (i.e.) manufacturing functions for example, are not given the responsibility of inspecting their own work. This person should have the freedom and authority to stop the operation if required and report it appropriately. Those responsible for identifying nonconforming products must have a direct and independent line of communication with this person. This should be clearly demonstrated in the organizational chart.

Next the standard requires top management to designate a management representative (MR). The reason for this is, both the registrars who are accredited to issue ISO 9000 certificates and the customers who want to purchase from an ISO 9000 certified company want to know that there is a person responsible for implementing and enforcing quality requirements. Still another reason is to make sure that there is someone in the top management involved with the quality system, and that he/she can report its performance to the other executive mangers. The MR must possess sufficient rank and authority within the company to ensure that the requirements specific to the particular standard (9001, 9002, 9003) are implemented and maintained. In our case, the manager of E.S. can be designated as the MR.

The MR, together with other members of management, should also actively

participate in the quality system by conducting regular documented verification and review activities. The verification activities must be carried out only by persons who do not have direct responsibility for the work being performed. These audit personnel known as `Internal Auditors' must be adequately trained to verify that entire operation conforms to all the elements specified in the respective standard. These audits need to be carried on a regular basis to ensure compliance.

Implementation strategy: Management should decide how the quality program will be structured and who will be responsible for its maintenance. Each of the areas identified in the requirements section should be addressed. Answer questions like [13],

1. Who is going to be given the responsibility for directing the quality program?

2. What authority will the responsible person have to assure the program is implemented?

3. What are the interrelationships of the people responsible for implementation of the program?

Responsibility, authority, and interrelation of all personnel can be documented in their job descriptions. Existing job descriptions can be modified to meet this need. Work instructions is a another option. Usually, most companies provide an organizational chart, with designated individuals having specific responsibilities for quality control or quality assurance.

Next, responsible management levels should identify the process and product verification requirements. This is commonly accomplished and documented in the operating procedures and associated flow charts. Once these activities are identified, it is management's responsibility to fund the proper performance of each activity.

The next step is to decide if the personnel are adequately trained to perform the verification activities. This step will require identifying the skills and knowledge needed to perform the function. These skills and knowledge requirements are usually listed in job descriptions. The next step is to evaluate the staff to determine if the

skills and knowledge are available: the results need to be documented in a personal file for each person. The last step is the development of training programs to bridge the gap if any.

The most important requirement is that the person involved in verification of the product or processes should be independent of the people directly responsible for the product or process being verified. One method that has been proven effective calls for the operator to check his or her work, after which the shop supervisor signs off on a check sheet showing that the work was evaluated. Then the person who is independent of production, and who is in charge of assuring quality audits the results to ensure conformance.

The area of internal auditing also falls under this requirement. The internal audit team should have no responsibility over the elements being audited. In the case of E.S., a cross functional audit team seems to be appropriate. Auditors from outside the company can also be used to meet this requirement. For a small division like E.S. where an independent quality control department cannot be justified, it is advisable to designate the director and vest him with the responsibility and authority to deal with all quality matters.

2.1.3 Management Review

Intent: The intent of this element is to make the program a constantly evolving program. This element is included to encourage the executive management involvement in the quality system.

The main reason for this requirement is to avoid the writing of 500-page `quality control manuals' and shelves of procedure books that is put on shelf for years to collect dust.

Requirement: The management should meet at least once in 6 months or once in a year to assess the results of internal audits. Corrective actions if any, should carefully address the root causes and propose effective solutions. Apart from internal audit reports, production should supply data indicating how the quality system affects

productivity. Based on these inputs, management should conclude if the quality system is suitable or should it be improved. These documented reviews must consider at a minimum [16]:

1. Results of the internal audits

2. Management effectiveness

3. Resolution of customer complaints

4. Solutions to quality problems

5. Implementation of past solutions

6. Handling of nonconforming product

7. Results of statistical tools

8. Impact of quality methods on actual results

Implementation strategy: First a procedure should be developed to identify a method by which the entire system will be reviewed by the top management on an ongoing basis. The management can review the system and its effectiveness in an annual meeting or in four meetings that are held quarterly. As long as the suitability and effectiveness is reviewed and direction given for the next program, the review is accepted. For E.S., a single person can prepare a report addressing each area of management review and submit it to the director.

2.2 Quality System

The company establish, implement, and maintain a quality system in accordance with the requirements of the ISO standards (9001, 9002, or 9003). The document include manuals, procedures, work instructions, etc.

Intent: The basic intent of this element is to ensure that the quality system is defined, documented, and maintained in a way that results in customer satisfaction. The quality system should be directed by top management and cover all aspects of the

company.

Requirement: This element requires the company to prepare and maintain a `documented quality system' that meet the requirements of the standard. This element calls for preparation of `Standard Operating Procedures (SOPs) and work instructions' in accordance with the requirements of the standard. Finally this element demands the effective implementation of these procedures and instructions.

The amount of detail in documented work procedures will be left up to the discretion of the company based on the skills and training of the affected work force (see section 2.8.1 for more details on work instructions). Each company should, however, develop and document the program that best fits its operation.

Implementation strategy: The implementation strategy for the documentation of the quality system is for the upper management to decide what makes best business sense for the company's needs. ISO 9000 allows for the unique approaches to be taken provided they meet the intent of the standard and are proven effective. For a small division like E.S., the division's quality manual itself can include both it's policies and procedures. Irrespective of the approach taken, all documentation must be practical, useful and orderly; manuals, procedures, and operational instructions should be written in a way that assures optimal understanding by all personnel using them.

2.3 CONTRACT REVIEW

The company establish and maintain procedures for contract review to assure that: 1) contract requirements are adequately described and documented, 2) differences in contract interpretation are resolved, 3) the company has the ability and capacity to fulfill the obligations of the contract.

As per ISO 9000, contract is any agreed sale of a product or service. If the company sells a product, the act of selling constitutes a contract. This contract must therefore be reviewed [13].

Intent: The basic intent of this element is to establish a system to verify that the customer's requirements are adequately and clearly defined, and that the company

can deliver what is required.

Requirement: The requirements of contract review are relatively specific. They are as follows:

1. The customer requirements must be clearly defined, documented and understood.

2. Any discrepancies between the contract and the tender must be resolved.

3. The company must be able to meet the requirements of the contract.

4. The records of such contract reviews should be maintained.

In the case of E.S., it is the customer who defines the aspects of the product ordered. The important part of dealing with these type of customers is making sure what they want. Logically speaking, the customers should know best what they want, and they usually do most of the time. But sometimes they do not accurately or completely define their requirements. In these situations the contract review system must determine if the stated requirements are sufficiently clear and complete so that there can be no doubt what the customer wants.

Once a common understanding is reached, the next requirement is to establish a mechanism that will identify and address differences between the tender and the contract. For complex projects, the requirements will continually be redefined as the contract is executed. Each of these changes should be evaluated to ensure that both parties have a common understanding of the new requirements.

The last requirement is to schedule an evaluation to determine if the company has the necessary means, resources and time to manufacture the requested product. This requirement is good business practice. The company should not contract for services that it cannot deliver. Finally the record of the review and the order must be maintained.

Implementation strategy: The first step in implementation is to identify all the ways a contract is executed. Implementation will vary significantly from one company to another, depending on whether the products are standard catalog items or

custom designs. Custom design might include `standard changes' to an existing and proven design, and those that require a completely new engineering design. E.S. deal with custom designs and hence the strategy for implementing custom design contract review system will be discussed.

The major concern is the system for receiving incoming orders. The path of the incoming orders must be controlled. Once the orders are received at the respective locations they should be processed, logged or recorded to prevent their misplacement or loss. The second concern is the verification that the customer's requirements are adequately and clearly defined, and that the company can deliver what is required. Personnel assigned to order verification must have the knowledge to assess if these requirements can be accommodated (technical feasibility, and capability) and to estimate the time it will take to manufacture or customize the ordered products.

Contract review is more vulnerable to noncompliance. For standard catalog products, it is easy to establish a contract review procedure whereas for custom design products, it is fairly complex because the process is not always the same for each contract. Factors include the size of the contract, the manner in which the customer states the requirements, and whether it is an old or new customer. To accommodate this wide spectrum of possibilities, the contract review procedure should focus on what is applicable in every case. As long as the scope of the contract review is complete, there should be no problem.

Following this, a record must be established evidencing that the verification was in fact carried out with a satisfactory result. The simplest contract review record is a sign-off or a stamp placed directly on the reviewed order, or on the form in to which the order information was transferred.

In computerized systems, the personnel entering orders may be required to type in their initials or identify themselves to evidence a successful order review. The manner of establishing order review record must be described in a procedure. The storage location and retention period for these records must also be identified. The steps that need to be taken to process a change order must also be described in a

procedure. The purpose and scope of the change order review is the same as for the initial order review.

Taking verbal orders (telephone order or a walk-in order) is a special case and the personnel taking these orders should be provided with specially designed forms which ensure that the customer will be asked for all necessary information. These forms must be adapted to accept special requirements. Finally ISO 9000 requires that all these verbal orders be confirmed either verbally or written. The effectiveness of the contract review system can be verified by checking the history of product returns, back orders, partial shipments and by comparing the requested and accepted delivery dates with the actual completion dates [5].

2.4 DOCUMENT CONTROL

The company have a system to review and approve documents prior to issue; make these documents available where needed; control and record revisions to these documents; and remove outdated documents from circulation.

All documents that are pertinent to the ISO 9000 standard must be under some type of formal documentation control, with procedures defining their creation, review, upgrade, authorization, and removal upon obsolescence. This is one of the greatest weak point in many companies. The time and effort involved in this task is seen as a `waste' by many people which in reality is not true. This disciplined approach will help in preventing many serious problems. Before we discuss the elements in this requirement, let us define the difference between a document and a record. A document can be defined as an instruction or plan containing information on how a company functions, how specific tasks are to be carried out, and how to build specific products or provide services. A record, by contrast, is a written statement of data and facts pertaining to a specific event, person, process, product, and so forth [5]. For example, a form used in inspection is a document. Once the form is filled out, it becomes a record, a written statement of facts pertaining to a specific event.

2.4.1 Document Approval And Issue

Intent: The intent of this element is 1) for everyone to have the latest revisions of all documents, approved by authorized personnel, at their point of use and 2) for obsolete documents to be removed promptly.

Requirement: The requirements include the following:

1. To establish and maintain procedures to control all documents and data that relate to the requirements of this international standard ISO 9002. 2. Pertinent documents should be made available at their point of use. 3. Obsolete documents need to be promptly removed from all points of use.

Implementation strategy: The first step is to develop a procedure that defines and classifies all the documents that need to be controlled. These controlled documents can usually be divided into two types [13]: those that are retained and are not changed (for example, test reports, purchase orders, etc.,), and those that change and should have a revision level (for example, blue prints, inspection instructions, policies, procedures, etc.,).

Then procedures for the document control system should be written down that would specifically identify the method used to maintain the documents and records. These documents and records should be readily retrievable and protected. A master listing of all documents and their appropriate revision status would be a good idea. This listing will ensure that only current revision documents are being used and that all obsolete documents are removed. A practical way to remove any doubt is to stamp the obsolete documents with a large red stamp. A person should be authorized to approve all the documents and this person should be capable of assessing the adequacy of the document. It is very important that a document is not revised, removed, or copied in the company without the permission of this authorized person. The wide and unrestricted availability of copy machines makes it easy for a person to make an unauthorized copy of a document. This should be taken care off.

Ideally speaking a separate secured room exclusively for storage of master documents is the best solution. But for very small companies like E.S., even a single cabinet or rack designated for storage of masters is accepted as long as it is

separated and identified. The trouble starts when one drawer contains masters, the next some `personal stuff', the third some more masters, and the fourth some unfinished drawings, a poster, and drafting paper. Every drawer. rack, shelf or cabinet containing the master documents needs to be labeled, identifying its contents.

2.4.2 Document Changes / Modifications

Intent: The basic intent of this element is to address as how changes should take place on controlled documents. In most companies, two procedures will have to be developed to take care of the changes in controlled documents. One procedure should address changes in engineering documents such as drawings. bills of materials, and specifications. The second procedure should address changes to documents such as Standard Operating Procedures (SOPs) and manuals. E.S. should be more concerned about the procedures addressing changes in SOPs and quality policies rather than changes in engineering documents.

Requirement: This element requires the following:

1. Changes to the document shall be reviewed and authorized by the same functions that approved the original review, unless specifically designated otherwise. The designated organizations should have access to the needed information and background for an appropriate decision to be made.

2. Where practicable, an overview of the change to the document should be included with the new release.

3. A document control procedure should be established to identify the current revision levels of documents.

4. Documents shall be reissued after a practical number of changes have been made.

Implementation strategy: Personnel in the company should be encouraged to critically review the procedures that affect their work and be instructed how to request changes. At the time of initial implementation of the quality system, the

procedures are far from perfect. If within the first couple of months there are no requests to change these procedures, then it means that nobody cares about the new quality system. Changed or corrected documents must be reviewed and approved by the same authority that issued the original documents, unless designated otherwise. As mentioned in the requirement the designated organizations should have access to the needed information and background for an appropriate decision to be made. In situations where this is not practical or feasible, the procedure for document changes should allow for provisional authorization. This should be promptly reported to the party that initially issued the document with a request to confirm the authorization for change.

In the second requirement the words `where practicable' should not be interpreted as `where convenient'. It is expected that changes are identified whenever the absence of identification could cause anyone to miss a change. Identifying changes will allow readers to identify quickly what has changed and understand how the change will affect them. An example method would be to highlight the change or mark on the margins.

The revision levels of procedures and policies should be identified by maintaining a master list of this documentation. This list should show the document number, the title, and the current revision level. In addition to the current revisions, each of the earlier revisions should be kept for future reference. Finally, the document should be reissued after a practical number (to be decided by E.S.) of changes have been made.

2.5 PURCHASING

The company will ensure that purchased components meet specified requirements. This include documentation clearly specifying requirements and testing, and assessing the quality of subcontractors to meet the requirements. In most companies, purchases are made using formal contracts, explicit purchase orders, and certified vendors. However, some companies do all their purchasing with a handshake. In general, the purchasing requirement simply asks these companies to formalize and document their purchasing activities. In the case of E.S., since it does not have full control over the

purchasing activities, it can at least formalize and document the activities that it has control over. Changes to the university controlled activities should be recommended to the appropriate authorities and followed up by E.S.

The ISO 9004 explanation of this requirement requires the company to develop a close working relationship and feedback system with each vendor. In this way, a program of continual quality improvements can be maintained and quality disputes avoided and settled quickly. The underlying intent of this requirement is that good quality in the final product is possible only if you begin purchasing parts of good quality.

2.5.1 General

Intent: The intent of this element is to make sure that the product being purchased conforms to specified requirements. This element sets the tone for the remaining three elements in this requirement.

Requirement: This element requires the company to ensure that the purchased product conforms to specified requirements.

2.5.2 Assessment Of Sub-Contractors.

The term sub-contractor is used to indicate the company's supplier/vendor. This element is designed to get rid of the old-boy network approach that is being followed by most of the small and big companies. E.S. is no exception in this case.

Intent: The intent of this element is for the company to have prior knowledge that the vendor selected has the ability to deliver the needed product or service as per the specified requirements and desired time window. Without any doubt, all office, janitorial, safety and other supplies that have no relation to the final product quality can be excluded from the requirements of the standard. Whereas, all materials, components and subassemblies intended for incorporation into the final product offering, including spare parts, manuals, and packaging, must be subjected to all requirements of the standard.

Requirement: This element requires the company to select their sub-contractors based on:

1. the ability of the sub-contractor to meet stated requirements 2. the type of product being ordered 3. the past performance of the sub-contractor

In addition, the company is required to maintain records of acceptable sub-contractors, and to ensure quality system controls are effective. There is a strong hint in this element that the sub-contractors should also mimic the intent of ISO 9000. Small job shops with four or five people should have some type of guideline for conducting business and need not necessarily be certified by ISO 9000.

Implementation strategy: It is only good common sense to make a judgement about the sub-contractor's ability to deliver the product. ISO 9004 lists five guide lines, in making this judgement. They are as follows:

1. An on-site assessment of the supplier's quality system

2. An evaluation of samples of product

3. The supplier's history with similar supplies

4. Test results of similar supplies

5. Published experience of other users

If one or more of these methods are employed to evaluate the sub-contractor, the goods or services received have a higher probability of meeting the agreed-upon quality level than if the product was ordered blind. Some of the evaluation tools might include the sub-contractors filling out a quality questionnaire, sending in their quality manuals and testing and inspection procedures, providing data pertaining to their process equipment, presenting samples of similar products, and so forth. When the subcontract is for design or consulting, professional resumes of key personnel may be also relevant.

Auditing the sub-contractor's quality system is, of course, the most effective

way to evaluate their quality capabilities. But auditing is costly for both parties and should be employed only when the situation merits it. The most common method would be to evaluate the sub-contractor based on his past performance. Using this method, the sub-contractor can be `grandfathered' in, provided the past performance is within the acceptance criteria. The acceptance criteria can take in to account the rejection rates, on time deliveries, cost, etc. The sub-contractor can also be evaluated based on its industry reputation and other users experience. For noncritical standard products, if there is no history of serious quality problems, evaluation, qualification, and monitoring of suppliers does not need to be very elaborate. Again it is up to the company to decide which of the products are critical and which are non critical.

However, it is a must to maintain records of all these evaluation as well as the acceptability of materials received. A sub-contractor quality record file established for each sub-contractor, containing the initial evaluation record and records evidencing the quality of products ordered is a good idea. And finally, an approved vendor list should be distributed to all personnel involved in issuing requisitions and purchase orders. In small companies like E.S., the sub-contractors quality record file may be consulted directly to verify their approval status. If an approved vendor list exists, it should be controlled as per the document control requirement (4.4) of the standard. The last requirement of this section (quality system control) can be satisfied by monitoring the supplier's quality performance and requesting corrective actions if the performance is not satisfactory. The contents of the sub-contractors quality record file must demonstrate that corrective actions are indeed requested and followed up. Sub-contractor's who repeatedly fail to deliver satisfactory products and/or do not deliver on time despite earlier complaints and requests for corrective actions are disqualified and removed from the approved supplier list. This or a similar system must be documented in a procedure.

2.5.3 Purchasing Data

Intent: The intent of this element is for the company to ensure that the sub-contractor has a through understanding of what is being ordered.

Requirement: The standard requires the company to provide adequate information in the purchasing documentation to enable the sub-contractor to understand exactly what is being ordered. This information is divided in to three areas:

1. The product should be precisely identified-including type, class, and grade-when applicable.

2. Identification of referenced drawings, specifications, specific process instructions (if any), special markings, inspection instructions, and any other information relevant to the acceptance of the material is required.

3. Identify the type of quality system requirements (if required) under which the product will be constructed. Typically a specific program like API Q1, MIL-STD-9858, or ISO 9002 should be referenced in the contract or on the purchase order. The purchasing documents should always require compliance with ISO 9000 when addressed to an ISO 9000 certified sub-contractor or to those claiming that they have implemented ISO 9000.

The last requirement mandates review and approval of purchasing documents by an authorized person prior to release.

Implementation strategy: The method to implement this element is to develop a documented purchase order system. All products and/or services should be ordered using this system. Each product or service ordered should be evaluated to determine what documentation is necessary so that the sub-contractor will have an exact understanding as what is being ordered and how it is to be delivered. The required information should be included in writing on the purchase order. The requirements should be specific and address the following, 1. physical description, 2. Required specification, and 3. required quality system, as applicable. Process instructions, special markings, inspection instructions, and any other information relevant to the acceptance of the material might also be included. The purchase order should finally be accurate and must be reviewed and signed by authorized personnel. The issue here is not approval of financial commitment, however, but the verification of specified

requirements.

2.5.4 Verification Of Purchased Products

This section deals with product verification at the sub-contractors site and it may or may not be relevant for E.S. The use of the term `purchaser' in this element refers to the company's customers.

Intent: The intent of this element is to ensure that, if specified in contract, both the company and it's customer have the right to verify that the product received conforms to the requirements of the purchase order.

Requirement: The requirements of this element are as follows:

1. The purchaser (company's customer) shall have the right to verify, either at the source of manufacture or upon receipt, that the product meets the requirements of the contract.

2. Verification by the purchaser does not prevent the purchaser from rejecting the product at a later date if it does not meet the requirements of the contract.

3. Verification of the product by the purchaser does not absolve the sub-contractor (company's vendor) from the responsibility of producing product that meets the contract requirements.

4. When the purchaser carries out verification at the sub-contractor's site, it doesn't relieve the company from the responsibility of delivering acceptable product. In other words, this should not be used as evidence to show that a company has adequately assessed the control of quality in the sub-contractors operations.

Implementation strategy: Implementation of this requirement requires addressing two aspects of this element [13]. The first is to create a boilerplate statement of the rights and responsibilities of the customer and sub-contractor on a purchase order. This would include 1) right of access 2) right of verification at source or verification in-house, and (3) right to reject at subsequent operations. The purchase order should state that these activities do not absolve the sub-contractor from it's responsibility

to provide acceptable product or service. This statement should be applied as a practice to all purchase orders and/or contracts.

The second aspect is the verification of the product samples to control the processes used to produce the product at sub-contractors site. The successful past performance of the sub-contractor will not guarantee future acceptable performance. Several approaches can be taken to ensure future acceptable performance. The first method is to perform an audit of the sub-contractors system. This audit should make sure that there is documentation in place to produce parts. Secondly, a contract can be written between the sub-contractor and the company that outlines the method to be used when producing the part.

2.6 PURCHASER SUPPLIED PRODUCT

The company have procedures to verify, store and protect components supplied by the customer for the incorporation into the product or service purchased. This requirement is merely an extension of the previous requirement (4.5). The use of the term `purchaser' in this requirement refers to the company's customers. The ISO standard defines purchaser supplied product as `product that is supplied by the customer to be included in that customer's final product'. In companies that manufacture custom made products or services (e.g., job shops), customers may want to have their own parts, equipment, or furnishings incorporated in to the final product. This is a common situation for E.S.

Intent: The intent of this element is for a company to define procedures as to how purchaser-supplied-product should be handled when it is received, as well as how it will address lost, damaged, or nonconforming product.

Requirement: This section requires that the company should establish and maintain procedures including record keeping for the following:

1. To verify the acceptability of customer supplied product. 2. To store the product in such a way as to prevent damage during the time it is being stored. 3. To define the maintenance of the product during the time it is being held, so that the product

will not deteriorate. This may not be applicable for E.S. 4. To record and report to the customer if the product is lost, damaged, or found to be unsuitable while in the charge of the company.

Implementation strategy: For this requirement to be implemented effectively, a company should inspect the product as it is delivered to ensure that it is suitable for use and then put them in a holding area for protection [13]. This product must be identified positively so that a similar product held in the company's inventory is not accidentally included in to the product.

Next, everyone involved in the project should be informed as where these parts are located and how they will be combined with the rest of the parts. Also, a reporting system should be established to report any lost, damaged, or nonconforming parts. A record of this situation is a must. Finally the company should make sure that the customer-supplied-product is included in the customer's final product. In summary, if customer products are received an appropriate procedure should either state that customer products are subjected to exactly the same requirements as purchased products are, or describe how verification, storage, and maintenance of customer supplied products are to be carried out.

2.7 PRODUCT IDENTIFICATION AND TRACEABILITY

The company have procedures as required for the identification of product at all stages of production, delivery and application.

This section in the ISO 9002 standards starts of with the word `where appropriate'. This indicates that there may be cases where product identification is not required. `Identification and traceability' refers to system of marking/labeling and record keeping that enable companies to determine the origin and/or destination of raw materials, parts, components or final output. This significance of this requirement is to identify product during all stages of production, delivery and installation. This requirements significance is relative to the type of product being manufactured and it may sound strange for E.S. For example, it can be especially important if the output

is of a type that may be subject to recall in the future.

This section refers to three general types of identification and traceability systems which a company may use .[16]

1. Means of tracking input (supplied product or services) from source all the way through the process is input traceability. This input traceability may be integral to the company's sub-contractor management system. 2. Means of identifying specific operations upon output is operations traceability. Operations may apply to equipment or personnel. This operational traceability may be part of procedures to monitor employee effectiveness, equipment maintenance or other critical process-oriented characteristics. 3. Means of identifying the ultimate destination of the output is output traceability. This destination traceability may be a key to ensuring long term customer satisfaction.

Intent: The intent of the element `product identification' is for a company to develop a method to identify parts readily and consistently during all stages production, delivery and installation. The intent of the second element `traceability' is to verify receipt of actual desired product or service by the customer and to track the product from a group or lot of common products to the final end user

Requirement: The standard requires the following:

1. Procedure for identifying the product by using applicable drawings, specifications, or other documents. 2. System should extend through all stages of production, delivery and installation. 3. Individual product(s), batches, etc. should have unique identification. 4. The whole identification and traceability system should be documented in procedures, and records shall be maintained to support the documentation.

Implementation strategy: Assignment of a part number is the most common way to identify materials and components when the later are supplied by sub-contractors. A cost-effective way would be to place identification labels on storage bins. Standard stock items, such as bolts, screws or O- rings can be identified by their trade

names or physical configurations. Identification is not required when the recognition of the product is obvious. Remember, the concept of product identification is to ensure that any product is readily and consistently identifiable.

For E.S. the products or batches of products moving through production processes can be identified by their work orders or job numbers. If products are accompanied by a work order, the individual products do not need to be marked or labeled. If the work orders are kept in a central location, the work order number should be labeled on the products or on the containers holding them. When needed the work orders can then be retrieved to provide the full technical information. Identification of finished products is rarely an implementation problem. The product identification system must be fully documented. Procedures and work instructions should explain who is responsible for assigning part numbers, how they are generated and controlled, etc. When coded numbers are used, the meaning of every group of numbers or letters in the code should be explained.

Traceability systems must be established only where it is a specified requirement by the customer's contract or government regulation. If a company decides on its own that it is a good business practice to maintain traceability on given products, then additional analysis should be performed to define the scope and detail for the program. Typical questions that need to be asked during this analysis will include the following [13]:

1. Why are we doing it?

2. What products should be included in the traceability program?

3. Should the traceability be input, operation, or destination traceability (see previous page for definitions)?

4. What are the critical factors to be traced?

5. What are the specific documents that need to be retained, in what detail and for how long?

For E.S. input, operation, and destination traceability seems logical and need to be considered. However, the need for product identification and traceability, and the type of quality system to implement can only be determined by the responsible management levels. But the company's quality system should provide for regular consideration of identification and traceability systems.

It is to be noted that many traceability programs fail because of lack of planning, lack of discipline, or lack of consistency [13].

2.8 PROCESS CONTROL

The company control of production processes as required. This include documentation of work instructions, monitoring (gauging) of processes, approval of processes and equipment, and establishing criteria for workmanship.

A process is defined as any series of steps leading to an output, which means paper work, design, manufacturing, installation, service, and training are all processes. In the following paragraphs, focus is on those activities that have a bearing upon quality. At E.S. process control may refer to such activities as cutting material, folding, welding, riveting, grinding, etc. These are the main processes that must be effectively planned and controlled to satisfy this section. This will make sure that a consistent product of high quality is produced on an ongoing basis.

2.8.1 General

Intent: The intent of this standard is for a company to set up a program to identify what it takes to make a product, to identify the sequences & equipment used in production, and to assure that these processes are controlled input to output.

Requirement: The requirement of this standard consists of the following

1. All processes used to produce the product and, where applicable, the installation of the product, and that which directly affects quality should be identified.

2. The company should plan the processes and, where applicable, the installation used

in production

3. The processes should carried out under controlled conditions.

Identification, planning and control are the three key terms in this section. The outcome of these activities if properly carried out, will be processes that are predictable, are repeatable, and work at or close to their maximum capability. Controlled conditions include the following:

1. Document work instructions which relate to production and installation. The standard states that documented work instructions are needed `where the absence of such instructions would adversely affect quality'. Training / experience may negate the need for work instructions. 2. Process and product characteristics should be monitored during production or installation. 3. Approve the process and equipment as appropriate. 4. Determine criteria of workmanship, where appropriate.

Implementation strategy: The identification and planning for process control usually starts with a process flowchart or production plan. The production plan is a sequential listing of all operations and processes required to manufacture a product or a subassembly. [5] These production plans are a result of technological know-how and experience. Establishing a production plan requires referencing and analyzing drawings, specifications and standards. For every operation or process applicable drawings, specifications, work procedures or workmanship standards should be referenced or attached to the work order. The production plan can be combined with a quality plan which can be accomplished by inserting the required inspection or testing operations between the production processes. `Quality plan' means a program for receiving, in-process, and final inspection and testing relevant to a particular product. Where applicable, specific inspection and testing procedures and acceptance criteria should be referenced for every quality operation. This is an area where continuous improvement plays a big role. At E.S. the production plan, can be documented in a work order and can be used as a listing of all operations and processes required to manufacture a product or a subassembly. With the implementation of this activity the identification and planning portion of this

element will be met.

Job shop (E.S.), usually produces small numbers of product and does not have a highly repetitive process. The operator often works on the product from start to finish with limited work instructions. These shops make a small quantity of high-dollar products. Control in this situation depends heavily on the ability of the operators to know how to perform an activity. If an activity is successfully accomplished several times on a product, then control of that process comes in the form of a trained operator following good workmanship practices. [5]

In this type of job shop environment, there is not enough product to obtain statistical data about the processes easily: however, it can be done to some extent. The process itself must be monitored and the step-by-step sequence of events monitored and recorded. Inspection of the product must take place at certain stages of production by the concerned personnel. The documentation that would be used to demonstrate process control in this type of environment includes the following [5]:

1. Manufacturing, inspection and test plans (production and quality plans) 2. Detailed work instructions (See the following paragraph for a discussion on work instructions) 3. Inspection reports 4. Process variable charts 5. In-process and final inspection and test reports 6. Written procedures 7. Detailed workmanship standards

As per ISO detailed work instructions are required where the absence of such instructions would adversely affect quality.

1. Who decides if lack of instructions could affect quality? 2. What should be the criteria for making this judgement?

The answer to these questions are E.S. should make this judgement for itself. The following questions can guide E.S. in making this judgement. [5] 1. Is the operation sufficiently simple so that an unskilled person, or a person only generally skilled in the art, could be quickly qualified by a simple demonstration and instruction?

2. Do operator qualification requirements for this position comprise the skills necessary to operate this machine or carry out this operation? Are these

qualification requirements documented and are there records demonstrating that our operators are qualified?

3. Do we provide class room training and/or on-the-job training for this operation? Is this training documented and recorded?

4. Are there manufacturer's manual that completely explain how to operate this machine or computer program? Are these manuals available to the operators? If yes is the answer for any one or all of the above questions, then work instructions are not needed for that particular operation or machine. In short, each operator should know what to do, how to do, when it is done correctly and what to do if something goes wrong. But, work instructions are expected for the operation of most complicated machines, especially those with adjustable performance parameters.

Work instructions are very important for companies dealing with a large and a fluid work force, where even the most basic and simple operations will not be obvious to everyone. E.S. does not have this problem and hence should be careful to economize on work instructions. However, work instructions should be reviewed and approved prior to issue, and a master list identifying their current revision and placement (a log, for example). Finally, these instructions and data sheets should be taped to walls or machines and need not even be taken down. Occasionally every work instructions should be reviewed to determine if additional instructions are needed.

2.8.2 Special Processes

As per the ISO standards these are processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use. Here the words inspection and testing mean, non-destructive inspection and testing. Example of special processes are: joining materials by welding, soldering, splicing, and gluing: casting of metals: coating with metals, epoxies and paints: heat, radiation, and chemical treatment of materials; an many others.

Intent: The intent of this element is to identify special processes. clearly define

their process parameters, operate it with highly trained personnel using qualified equipment, and to continuously monitor them with supporting records.

Requirement: The requirements of this element include the following:

1. Continuous monitoring and/or compliance with documented procedures is required.

2. The process shall be qualified.

3. The process shall comply with the requirements of the element 4.8.1.

4. Appropriate records

will be maintained for qualified processes, equipment, and personnel.

Implementation strategy: The first step in implementing the special processes requirements is to assign the production department to identify and draft a list of these processes. Next each special processes should be reviewed to determine how it is currently controlled and if controls are sufficient to satisfy the ISO 9000 standards. Most of these processes have an industry standard and/or specification that provides guidance to process qualification and verification.

An example adapted from the book 'The managers guide to ISO 9000' written by Arnold, Kenneth L., 1994 is given for better understanding. For welding process to be effectively verified and controlled, generally a weld procedure specification (WPS) is developed for a given type and thickness of material. The critical variables (taken from AWS structural code or ASME pressure vessel code) are listed on the WPS. The WPS is then followed and a test weld is made on the appropriate material. If the test passes, the results are placed on a form called a procedure qualification record (PQR). This PQR indicates that an acceptable weld is possible if the settings used for the test are duplicated by a competent welder. The next step is to test a welder to the WPS. If the WPS is followed and the welder is competent, then the results should be acceptable.

The process is qualified and verified to produce a good weld, and the operator becomes qualified for that WPS. If the test is failed, it can safely be assumed the

operator was at fault. This is a common method by which special processes and operators are qualified.

The choice of special process control in E.S. will depend on the process itself. If it is a manual or a semi-manual process requiring special skills, the emphasis will be on operator qualification. If it is an automatic process performed by a complex machine, the equipment qualification (capability, setting and calibration) will be the key. Process qualification, i.e. destructive testing of specimens is applicable when there are specified performance characteristics resulting from the process; for example, strength of a joint, strength of a coating, and so forth.

The special process controls and instructions, if any, need to be documented, and every special process control element and its performance must be recorded. Operators qualification can be evidenced by education, training records, and experience. Equipment qualifications is evidenced by the performance data specified in manufacturers manuals, a capability test report, or calibration certificates, when applicable. Process qualification will most often be recorded in a report analyzing the destructive testing results of a specimen.

2.9 INSPECTION AND TESTING

The company have procedures to: assure the quality of incoming material, identify discrepant material used under emergency conditions, to inspect product as required by the quality plan or other procedures.

This section deals with the testing of the materials at receiving, during production and after production. The ISO 9002 allows for inspection to be used as one of the several methods to verify product. The most difficult part of conforming to this requirement is the discipline of actually holding materials and parts until inspection and recording of the results.

2.9.1 Receiving Inspection And Testing

Intent: The intent of this element is for a company to ensure that incoming products are not used unless they have been inspected. A recall system should be in

place whenever the product is released before testing is complete.

Requirement: This element requires a company to verify that product conforms to specifications before it is processed. The second requirement of this element relates to product released for use or processing before the results of the verification process are known. If this activity occurs, a method of positive recall must be in place. This activity is not applicable for E.S. and hence is not taken in to consideration. A note at the bottom of this section implies that if a sub-contractor's processes are controlled and documented, receiving inspection of the product may not be needed.

Implementation strategy: Some of the receiving inspection responsibilities are as follows [13]:

1. Parts-count verification

2. Material identification

3. Mechanical dimensions within tolerance

4. Physical properties (hardness, heat treatment)

5. Paint (color, thickness, coverage)

6. Identification (lot number or serial number)

7. Fit (assembly compatibility)

8. Correct threads

9. Drawing revision

10. Marking products with part numbers or other identification and affixing a PASSED label, tag, or stamp.

Visual testing of steel products is meaningless. In this case steel testing certificates might replace receiving inspection. These procedures need to be documented and should instruct what to look for, what the acceptance criteria is, and how many

items in a batch to inspect. The best format for inspection procedures are check lists or forms listing all inspection steps. Receiving must also have and use nonconforming material report forms and ON HOLD, PASSED, and REJECTED tags, labels, or stickers. The receiving inspection record can be established by stamping or signing of a copy of the purchase order.

Receiving inspection need not always be carried out at the point of receiving. The material can be verified on the production shop floor just prior to being used in production, but it is not acceptable if process operators inspect the materials or components issued to them for processing. Usually it is best for the shop supervisor to verify/inspect the material as soon as it is received, rather than postponing it. Source inspection represents the eyes and ears of a company in its sub-contractors shop and should also be viewed as a method of performing receiving inspection. But, this may not be suitable for E.S. at this point of time.

2.9.2 In-Process Inspection And Testing

Intent: The intent of this element is to ensure quality during fabrication or assembly. At E.S., it is to ensure that the work performed is in accordance with the correct drawing and/or procedure, and that it is accomplished by qualified individuals.

Requirement: This section states four requirements for the product as it is being built:

1. Products will be inspected, tested, and identified in accordance with the quality plan.

2. Process monitoring and control methods will be used to verify product acceptability.

3. Products will be held until the specified inspections and tests have been completed.

4. All nonconforming products will be identified.

Implementation strategy: Some of the in-process inspection responsibilities are as

follows [13]:

1. Ensure all inspections are performed as requested by the customer. 2. Ensure that correct drawings are used in the shop and obsolete drawings are removed from the shop. 3. Determine that correct methods are followed and that current procedures, are available at each work station. 4. Verify that individuals performing special processes are qualified. 5. Verify that the equipment and gauges are qualified. 6. Verify that the individual craftsmen sign their work, when required.

All inspections must result in clear identification of the inspected products with their inspection status by stamping, marking or signing off the accompanying work order. Products awaiting inspection or the next processing stage must be held in areas (hold areas) designated for this purpose.

Two views exist about who should have the responsibility for in-process inspection .[13] The first proposes an individual (inspector) other than the process operator. Under the second approach, the operators are provided with the responsibility to build, inspect, and accept the product. In some cases, a lead operator, or a shop foreman, makes the inspection. The attitude under this philosophy is that if the operator can be trusted to produce the part, he or she should be trusted to accept it. This way the operator becomes responsible for the total quality.

E.S. will adopt the second approach only for in-process inspection. Once the decision is made as to who will direct the effort, a test plan should be developed identifying the inspections to be performed. The intent is that appropriate areas are addressed effectively to show that there has been some plan established for in-process quality.

2.9.3 Final Inspection And Testing

Intent: The intent of this element is to ensure that each manufacturing step has been completed properly and that the correct drawings and procedures are followed by qualified individuals.

Requirement: This element includes the following:

1. Assure that all the specified inspections and tests have been performed 2. Verify that all final tests and inspections specified in the quality plan were conducted and properly documented. `Quality plan' means a program for receiving. in-process, and final inspection and testing relevant to a particular product. 3. Ensure that product is not delivered until all the required tests and inspections have been satisfactorily completed, documented, and authorized.

Implementation strategy: The first step is to assign responsibility for final inspection. The responsibilities of the final inspector are as follows [13]:

1. Review signed process sheets (work order sheets containing the process plan) 2. Verify materials used 3. Inspect the final coating, finish and critical quality characteristics of the product. 4. Evaluate the completeness of documentation provided to the customer.

As far as E.S. is concerned, final inspection activities can be assigned to the production supervisor with audits performed by a another person independent of production. This allows a second set of eyes to view the product objectively and without bias. Final inspection should include a review of plan-and-process sheets to assure the company that all steps were correctly performed. One focus is to perform 100% inspection. The second focus is to inspect sample parts to make a value judgement on the entire lot based on the sample. Since the lot size is extremely small in E.S. 100% verification of the final product can be performed. Whatever the focus, final inspection should be conducted in accordance with the quality plan for the product or by following a final inspection procedure Finally, it should be made clear that the final product is not delivered until all the required tests and inspections have been satisfactorily completed, documented, and authorized.

2.9.4 Inspection And Test Records

Intent: The intent of this element is for the company to provide documented evidence that all tests were conducted and results compared against acceptance criteria.

Requirement: The element requires that the company maintain documentation to prove that the product passed the inspection and test.

Implementation strategy: E.S. should define for itself the method used to retain the inspection test records when a product is finally accepted and/or tested. E.S. can hold the completed work order along with the process plan and quality plan in a test report file (portfolio) for a specific period of time. This file would include such information as the test acceptance criteria, test results, and documentation provided with the parts that make up the final assembly. The inspection and test should have defined acceptance criteria

2.10 INSPECTION, MEASURING, AND TEST EQUIPMENT

The company maintain and calibrate measuring and testing equipment to nationally established standards, and maintain records of calibration.

This is the most detailed and specific section in the whole standard. The role of this section is critical in the verification of engineering specifications, monitoring the process, and the final inspection of the product. In most companies arguments are made for not having calibrated test equipment (for example, `It's close enough,' or `These measurements are not that critical'), but most of these reasons are not true. This can be traced to a lack of understanding of a calibration program and/or a lack of discipline within an organization.

Intent: The intent of this element is to direct a company to list, track, and calibrate every piece of equipment used for measuring, inspecting, or testing the products produced. In other words, this element requires the company to exercise control over the means used to perform measurements and analyses. Control must be sufficient to ensure confidence in decisions made on the basis of measurements

Requirement: The requirements of this section are very specific. The company must control, calibrate, and maintain inspection, measuring and test equipment, regardless of ownership. It is the user's responsibility to ensure that equipment is calibrated. The inspection, measuring and test equipment could range from a tape

measure for inspecting the length of an I-beam to a device that measures the change in electrical potential in micro volts. It also includes such items as jigs, fixtures, templates, patterns, or test software. These should be verified at appropriate intervals determined by the company.

The standard identifies ten specific guidelines that must be met for the calibration program to be accepted. They are as follows [13]:

1. The company shall determine the accuracy needed for a measurement and select equipment that will have at least that accuracy.

2. Identify, adjust, and calibrate all inspection, measuring, and test equipment that can affect quality. This should occur at designated intervals of time. The calibration will be against a national standard. If no national standard is used, a decision must be made as to how the calibration will be conducted. This decision should be documented as the basis for future calibration.

3. The company should develop a documented procedure covering the calibration of all inspection and test equipment. This procedure should include the following as a minimum.

a. The equipment type.

b. Identification or serial number

c. Where the equipment is located

d. How often the equipment is checked for calibration

e. The method used to check calibration

f. Definition of the acceptance criteria for each piece of equipment

g. Actions to be taken when a gauge cannot meet the acceptance criteria

4. Decide if the inspection, measuring, and test equipment have the proper

accuracy for the measurements that are to be taken with the equipment.

5. The equipment must be identified to show the calibrations status.

6. Maintain the calibration records.

7. If a equipment is found to be out of calibration, a system should be in place that will require the assessment and documentation of the validity of measurements taken since the last time the gauge was calibrated.

8. Assure that equipment is calibrated, checked, and used in a suitable environment.

9. The equipment will be properly handled, preserved, and stored in such a way as to maintain the accuracy and its fitness for use. 10.Protect the equipment (and soft ware if applicable) from adjustments that would destroy the accuracy of the equipment.

Implementation strategy: The traditional gauge calibration program is one of the more effective methods to meet the intent and requirements of the standard. But sending the inspection, measuring, and test equipment to a calibration lab and asking them to calibrate it without providing specific information will not meet the requirements of the standard. [13] The calibration lab must be asked to calibrate to a specific standard or procedure and to a specified acceptance criteria. Without specific instruction, the calibration lab might calibrate a gauge to +0.001 inch rather than the required +0.00001 inch calibration.

Industry standards require equipment to have an accuracy that is four to ten times the required specification accuracy of the measurement to be taken. In other words, if a part is to be measured to +0.003 inches, the measurement instrument should be accurate from +0.0007 to +0.0003 inches. Hence, the person inspecting the job should know the calibrated accuracy of the instrumentation and select the proper tool for the job. [13]

All controlled measuring equipment must be marked with calibration stickers and the calibration must be evidenced with a certificate. As a minimum, the calibration

certificate should precisely identify the piece of equipment, the standard that was used in calibration and it's traceability number to the corresponding national standard, and the calibration date. In some cases, no national standard exist. In these instances the company should decide what standard will be appropriate to check the equipment against. Certificates for comparative reference hardware, such as blocks, rings, gauges, or jigs, should provide the actual dimensions measured. Measuring equipments that are not calibrated and inspected must be labelled with a warning that it is NOT CALIBRATED and a procedure must instruct that such equipment may not be used for inspections and testing. Uncontrolled equipment must be stored separately. Equipment that is damaged must also be labeled and separated or, even better, quarantine in a locked cabinet. The backbone of any calibration control system is a list of all controlled measuring and test equipment. Every piece of equipment on the list is identified by it's type and serial number, its usual location. the prescribed calibration periodicity, the last calibration date, and the next due date for calibration. The list is usually maintained in a spread sheet on a computer. The next element of a calibration system is work instructions for calibrating various types of measuring equipment. However, work instructions are only required when special skills, beyond those that can be learned from a simple demonstration are required. These three items-equipment list, calibration certificates & stickers, and work instructions-are the pillars of the calibrations system. [13] Next, if a piece of equipment is found to be out of calibration, the company must follow a procedure to determine the cause of the problem and take remedial action. The company must also re-evaluate previous work affected by the device for conformance to requirements. If this assessment shows a probability of a problem, then the reports are researched, and the specific parts that were checked with that equipment since its last successful calibration are recalled. Also, necessary precautions need to be taken to ensure that the equipment is calibrated, checked, and used in a suitable environment. The equipment should also be properly handled, preserved, and stored in such a way as to maintain the accuracy and its fitness for use. Finally, permit only authorized personnel to make adjustments to the equipment or software.

A common problem in meeting this requirement is the situation in which the

operators own their own measurement equipment, e.g., the skilled tool and die maker with his own set of micrometers. The skilled tradesman takes excellent care of his tools and it is a good illustration of the intent of this requirement. However, the company should track their measurement gauges either by buying the right measurement gauge for the job and making it available, or by offering free calibration and adjustment services for the employee owned equipment. This situation in which the operators their own instrument is prevalent in E.S. The difficult aspect in implementing the requirements of this element is identifying exactly which pieces of equipment should be included in this program and which pieces, if any, can be excluded. One proven definition, however is to include only those pieces of equipment that are used to accept, calibrate, or verify the calibration of product. Instruments used to verify rough cut dimensions prior to further operations could be excluded from the calibration program. But these instruments should be pasted with a sticker that says, 'Not to be used for acceptance, calibration, or to verify calibration.' The situation in E.S. is that, a instrument which is used to verify rough cut dimensions in one project might be used to verify final specifications in a another project.

Hence, it is advisable to include all pieces of inspection, measuring, and test equipment in the calibration program. The decision is left to the appropriate levels of the management.

2.11 INSPECTION AND TEST STATUS

The company assign personnel responsible for the release of conforming product. There will also be a procedure for the identification of the current inspection or test status of the product.

This section is an extension of the other test and inspection requirements, particularly element 4.9. and 4.10.

Intent: The intent of this element is for a company to develop a method of identifying the status of a part with respect to inspections and tests. In other

words, the intention is to assure that the next person to use the materials can successfully identify unacceptable from acceptable materials.

Requirement: The requirement for this section is very short and straight forward. The company must establish and maintain a method to identify the inspection and test status of product, as necessary. These requirements as follows:

1. Throughout the process, status of output should be identifiable through the required inspection and tests.

2. The identification of inspection results or the status of the product (conforming or nonconforming) should be evident.

3. Persons having authority and responsibility to release conforming product should be defined.

Implementation strategy: The requirement for maintaining the inspection status identification throughout all stages of production and storage makes sense and is relatively easy to implement in E.S. If the work order accompanying the product contains the quality plan (i.e. calls out inspection and testing operations), and has the provision for the inspection sign-offs, the inspection status is self-evident. Sign-off indicates a passed inspection and an empty place means on hold, awaiting inspection. A failed inspection can be identified by other means, such as a red tag or label and segregation. The use of red or green stickers is a common practice that would conform to this requirement. The nonconforming products should be physically separated from the rest. Physical locations can also be used to identify the acceptance status of the product. The difficult part for E.S. is to require a sign off at each stage of production.

2.12 CONTROL OF NON CONFORMING PRODUCT

The company establish and maintain procedures for the control of product which does not conform to requirements, and prevent the inadvertent use of this material.

The issue here is identification and control of nonconforming product so that it will

not flow down the production line and finally reach the customer. Once the nonconforming products are identified and controlled, the next step is how to prevent the nonconformance from recurring. And this is the next requirement (4.13) of ISO 9002. Therefore, 4.12 and 4.13 can be read as a single topic.

2.12.1 Nonconformity Review And Disposition

Intent: The intent of this element is for a company to set up a program to prevent the rejected product from reaching the customer.

Requirement: The requirements are as follows:

1. Nonconforming products should be identified.
2. The nature of nonconformance and the product affected need to be documented and evaluated.
3. The nonconforming products should be segregated (where practical) to prevent them from unintended use.
4. Disposition (accept, rework, regrade or scrap) of the nonconforming product should be determined.
5. Notification of the departments, suppliers and customers affected by this nonconformance should be made.
6. Responsibility for review and disposition of the nonconforming product should be defined.
7. If the product is repaired or reworked the product should be inspected in accordance with documented procedures.

Implementation strategy: The first step, after finding a nonconforming product, is identification of the product as nonconforming. The easiest way to identify nonconforming products is marking, tagging, or labeling the products or their containers with clearly visible HOLD, NONCONFORMITY, or REJECTED labels.

The background or the letters of these should be red and not green. These labels should firmly attached to the products. After the part is identified as nonconforming, it should be segregated. This need to be done only if it is practical.

For example large and heavy objects that cannot be moved, can be exempted from this requirement for segregation. This will help in identifying the nonconforming product with other products even if the label identifying its nonconforming status is removed. In addition to segregating the nonconforming products, purchased materials and components should also be held in a designated area. Similarly, finished products should be held in a designated area away from products that are in process.

Next step is the documentation of the identified nonconformity in the Nonconformance report log, and evaluation & disposition of the nonconforming product. A nonconformity report should be generated and distributed to all interested parties (vendors, operators, etc.,). The documentation should identify the activities that have occurred from the time a part is identified as nonconforming until the disposition is carried out. Suppose in a situation if it is determined that the product does not fully meet the specifications, but still considered acceptable from the customer's perspective, then a full report of the material's condition must be recorded and retained.

Every single nonconformity has its causes and if this is not documented, the causes may never be identified and corrected. One of the major objective of a quality system is continuous improvement, and this is not achievable if the level of rejects and their associated causes are not known. Since E.S. is dealing with a small series of a relatively complex products, every single occurrence of nonconformce need to reported.

2.13 CORRECTIVE ACTION

The company establish procedures to investigate the causes of non-conforming product, analyze any trends, initiate preventative actions, and follow up on

corrective actions to verify effectiveness.

Every company including E.S. routinely takes action to fix mistakes and correct the causes of problems. `Corrective action' is the standard's term for these activities. The standard spells out the typical elements of a corrective action system, covering nonconformances before as well as after the fact. Corrective actions stem from two types of investigation approaches. [13] One is to identify the root cause of a defective product or nonconformance and then correct it to prevent future occurrence (reactive approach). The other one is to identify potential problem areas and to correct them even before nonconforming product is produced (proactive approach).

Intent: The intent of this element is for the company to develop a program that will identify nonconforming product and investigate the root causes.

Requirement: The requirement are as follows:

1. Investigate causes of nonconforming product and take corrective action to eliminate those causes.

2. Analyze processes, records, customer complaints, etc. to detect main causes of nonconforming product.

3. Implement corrective actions to eliminate those causes in order to prevent nonconforming product.

4. Apply measures to assure implementation and effectiveness of corrective actions.

5. Implement the procedural changes necessitated by corrective action.

Implementation strategy: The first step of corrective action is to identify problems that may require corrective action. The typical approach to do this is to identify nonconformances that have something in common. The investigation should try to detect defects that are caused by the same elements (for example, process, machine, operator, etc.). If a trend is seen, the next step is to identify the root cause.

This identification phase should involve the appropriate personnel in E.S. The identification can take the form of reactively evaluating the causes of nonconforming product, or it can evolve to a proactive analysis. However, people with sufficient background in that area in E.S. should be encouraged to suggest initiation of corrective actions. Initiation of a corrective action can be caused by

1. Identification of a major product nonconformity 2. Accumulation of minor nonconformities of a similar character 3. Recurring problem with a process or operation 4. Noncompliance raised during an audit 5. Field performance problems 6. Customer complaints 7. Nonconforming delivery times, etc.

In the proactive approach to this element, many activities and processes need to be analyzed. This analysis identifies areas where improvement of specific activities will reduce the possibility of producing defective product. Operators in E.S. can be empowered to identify quality problems and develop solutions. To aid the operators in doing this task, they should be given training in problem solving and process improvement tools.

The suggestions for corrective actions must be evaluated and approved by the management before they are issued as formal corrective action requests (CARs). CARs should be issued to the concerned party responsible for proposing the solution and implementing it. The authority requesting corrective action and the party implementing it should be identified. These CARs can also be supplied to E.S. vendors if corrective action is requested from their side.

2.14 HANDLING, SSTORAGE PACKAGING AND DELIVERY

The company establish procedures for the storage, handling, packaging, and delivery of the product. This section requires that the quality system extend well beyond the process itself. The areas covered in this section are associated with protecting the condition of the material from the time it is received from a supplier through the storage, processing, packaging, and delivery stages.

These activities can take place in multiple locations with in a single division. For example, the movement of parts between production stages can be considered `handling.' The temporary awaiting period for further processing could be `storage.' Placing protective wrap on some critical components could be considered packaging.

Packaging & delivery are only relevant when shipping is included in the contract. Since E.S. is not involved in packaging and delivery, these elements will not discussed in this guide. Even though products do not require any special handling and storage (preservation) techniques at E.S., these requirements should be given due consideration.

2.14.1 General

Intent: The intent of this element is for a company to develop a program as to how the product need to be handled and stored and to develop procedures that will provide for protection of the product at all stages of storage and production.

If a part is improperly stored or handled, it could invalidate the results of any final inspection that has been completed, or if a part is damaged while in storage, before delivery to the customer, the result is the same as if the design was inadequate or the parts improperly manufactured. And also poor handling will render the most meticulous and costly inspection in futility. Hence, the company should recognize that good product cannot be manufactured from improper, damaged, or defective parts.

2.14.2 Handling:

Requirement: The company must provide means and develop methods to prevent the damaging of parts while handling them.

2.14.3 Storage:

Requirement: The specific requirements for this element are as follows:

1. The company should provide secure storage areas to prevent the products from

deterioration and damage.

2. The company must have an appropriate method for authorizing receipt and dispatch of product to and from storage areas.

3. The condition of stock must be assessed at appropriate intervals

Implementation strategy: At first, E.S. should evaluate the methods it has established to handle and store products. The evaluation should start with listing the types of goods that are being stored in the company and matching them with the list of existing storage areas. This evaluation will immediately show what types of goods are `homeless'. They are usually materials purchased long ago for products that have since been discontinued; excess material left over from production; broken machine and equipment; discarded product that may some day find a customer; and so forth. This exercise will enable E.S. to check if the storage capacity is sufficient, and will also make it aware of what it really needs and uses. Typically the work will consist of reassigning areas, rearranging items, and discarding scrap and junk. It can be a big job for E.S.

It should also determine if operators have the proper training and equipment to handle the product in such a way as to prevent damage. Next, storage areas should be examined to guarantee that the condition of the product is properly maintained. The product should also be evaluated to determine if special handling and storage conditions are necessary for integrity to be maintained. Special conditions will include items ranging from the marking and packaging of products such as elastomers to the protection of steel parts from the moisture. In some locations, the humidity will be extremely high resulting in mildew or fungus. So atmospheric conditions must be identified, evaluated, and properly addressed. In addition, material identification in stores becomes a critical issue. Marking to identify the material is important to guarantee that the proper material is used in production. This becomes especially important when material cannot be visually identified as with different grades of steel or different types of chemicals.

Storage of materials, components, finished products, supplies, tools, etc., outside the

designated areas is noncompliance. It is understood that E.S. cannot afford to assign a separate designated area for five different categories of goods. It will, however, be expected that different kinds of items are at least assigned to different aisles, racks, or shelves. Regardless of space constraints, items such as defective goods and scrap may not be stored with new stock. All these activities must have fully documented and maintained procedures.

2.14.4 Packaging NOT APPLICABLE for E.S. at this point in time. ----------

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2.14.5 Delivery NOT APPLICABLE for E.S. at this point in time. ----------

2.15 QUALITY RECORDS

The company identify, collect, and store quality records. These records will be maintained to demonstrate effective operation of the quality system. They will be identifiable to the product involved, and stored in a manner to prevent deterioration, and made available to meet contractual obligations.

Record keeping is a vital element Without records, the company's quality system cannot be properly assessed, by itself, customers or third parties.

Quality records, as defined by this standard, serves three very important purposes. [13] First they verify that the required activities for the certified program are maintained and followed.

The second purpose is to verify the condition of the product at a given point in time. For example, test records or inspection reports can verify that proper processing occurred and that the product was either acceptable or nonconforming. The third purpose for quality records is to provide a history of a part, process, or program. For example, without the history of the process, there would be no data to review, and the process would have to run as before until enough data could be generated to analyze. Hence, this section's primary focus is on quality record keeping, maintenance, retention, storage, and availability.

Intent: The intent of this element is for a company to identify and control the documentation generated to demonstrate the effective operation of the quality system and the product that results.

Requirement: The seven requirements of this section are listed below:

1. To control quality records the company must establish a procedure to identify, collect, index, file, store, maintain, and dispose of quality records. 2. The records maintained should demonstrate the achievement of required quality for the product and the effectiveness of the quality system. 3. Records should be legible and identifiable to the product involved. 4. Records should easily accessible and readily retrievable by those who need them. 5. Quality records should be protected from deterioration while stored. 6. Retention periods should be determined by the company and documented. 7. If mentioned in contract, records should be made available to the customer for evaluation.

Implementation strategy: Records that verify product compliance to requirements must be retained. Records must also demonstrate the verified effectiveness of the quality system through internal audits, corrective actions, senior management reviews, assessment of suppliers, calibration, training, customer contracts, product nonconformances, inspection and testing, and product identification. These records should be defined & filed for easy access, and maintained for a reasonable period of time.

2.16 INTERNAL QUALITY AUDITS

The company plan and conduct a systematic internal quality audits. Corrective action and follow-up will take place for any discrepancies noted, according to procedures.

Internal quality audits are formal management audits in which the auditor is independent from the function being audited. Quality audit can be defined as an inspection of the company's adherence to the established program. It is similar to the act of verifying whether the final product conforms to the established specification. The objective of this activity is to find out if the quality system is implemented and

effective. These audits should be designed to answer three basic questions about the company being audited [13]:

1. Does the company have a quality system? A quality system is usually evidenced by the quality manual, operating procedures, work instructions, and record keeping. 2. Is the quality system being followed? A review of activities is conducted to determine if there is on going compliance with the procedures. 3. Is the system effective? Are the results of following the procedures consistent, positive, and meeting the intent of the standard? This question can only be answered by internal auditors and not by third-party audits or outside audits.

The third party audit puts more emphasis on compliance with the standard and implementation, while internal audit is best suited to verify effectiveness. However, the purpose of this section is to give management assurance that the established procedures are being followed and are effective.

Intent: The intent of this element is for the company to take a proactive approach when assessing the quality program. This activity helps management determine if the implemented system is effective in achieving stated quality objectives. The overall intention is to promote continuous improvement of the system. Internal audits should help prevent the program from becoming stagnant and ineffective.

Requirement: The requirements to this section are as follows:

1. The company must develop a program in which internal audits are planned, scheduled and documented.

2. Internal audits and corrective action should be carried out in accordance with documented procedures.

3. Audit findings should be documented and brought to the attention of the responsible personnel in the area audited.

4. Management personnel responsible for the area being audited shall take timely corrective action on any nonconformances found during the audit.

Implementation strategy: Internal quality audits are a self-analysis (a benchmark tool) tool; they permit a company to determine where it is in relation to where it wants to be. This section is used to verify the requirements of other sections in the standard. Implementation strategies for this section will be focussed in three areas: internal audit plan, conducting internal audits, and internal audit reports. [5]

INTERNAL AUDIT PLAN: Internal quality audits require planning and scheduling. To complete an audit cycle, every element of the quality system must be audited at least once in all areas where it is implemented. To minimize the disruption, it is best to take one area at a time and audit all the applicable elements of the quality system in this area. But to get a good picture of how the system performs, it is better to do just the opposite: take one element at a time and audit it in all areas where it is implemented. The final audit plan should be a compromise between these two approaches. The maximum acceptable audit cycle time is one year. Newly implemented systems should be audited more frequently and also the frequency of audits should be increased for those activities that are either especially important or have a history of quality problems. It is best to schedule the audit as regularly as possible. If the audits are always conducted every second Monday, for example, the auditing will quickly become a routine event, one of E.S.'s usual activities.

CONDUCTING INTERNAL AUDITS: Internal audits can be conducted by just one person, even in large companies. One person audit team, however, should be avoided unless the auditor is experienced and has lot of authority. A team, even a two person-team, carries more weight. As discussed in the section Management Responsibility (4.1), personnel involved in verification activities (internal auditors) such as audits must be properly trained. This audit team should also have no responsibility over the elements being audited. In the case of E.S. a cross functional audit team would be appropriate or the appointed MR can be given the responsibility to audit the quality system policies and procedures annually. To insure consistency in audits a formal training program should be set up. Proper auditor training can be gotten from courses offered by universities and consultants. Self-study and self-acquired experiences are also sufficient. No matter how the training is acquired, it must be documented and recorded. A quality system evaluation form can be used as a checklist for

internal audits. By simply answering the questions and analyzing the responses, E.S. can determine how far it complies with ISO 9002 standards.

INTERNAL AUDIT REPORT: Audit report should focus on noncompliances and should not request implementation of specific solutions. The format of long descriptive observations does not work either because, even though it presents the problems with all their complexities, it leads to a dead end. The description of the noncompliance should precisely identify the object, location, context of the noncomplying condition, and objectively state the nature of the noncompliance, using concise and factual language. The final audit report does not need to be very elaborate. It should consist of all the individual noncompliance reports established during the audit. The report can also include a summary and conclusions of the audit. At the end of the auditing cycle the individual audit reports should be bound together into one report for presentation at the management review meeting.

2.17 TRAINING

The company will implement procedures for the identification of training needs, and provide appropriate training. A well-trained work force is critical to the successful performance of a company. For example, E.S. operators are forced to work from poor or incomplete designs many times. In such cases, a well trained work force can compensate for this condition, by making controlled modifications while the product is being produced.

In another situation, if a process is malfunctioning, a trained operator can adjust the process to allow for production of good product. In contrast, a good design produced by capable process can produce scrap if the processes are controlled by an untrained operator. Hence it becomes necessary to bridge the gap between the knowledge and skill required for the job and that possessed by the operator by giving proper training.

Intent: The intent of this element is for a company to develop a program that provides a systematic approach to training. The standard does not in itself specify

training of any kind.

Requirement: The requirements are as follows;

1. Company should have a mechanism to identify training needs of people whose work affects quality.

2. Company should provide training where need exists.

3. Persons performing work affecting quality shall meet established qualification standards based on education, training and/or experience.

4. Company must maintain training records.

Implementation strategy: E.S. should first evaluate each job position to determine the skills and knowledge needed to perform the job. One of the more popular methods used to identify required knowledge and skills is a job description. [13] In a job description the educational, training and experience requirements for the position are usually listed. The results of this job evaluation produce a checklist of necessary skills and knowledge. The items in the list should be specific and measurable. When the required knowledge and skills are specifically identified, it becomes much easier to evaluate employees skills and develop a plan to provide specific training to the work force.

The second area is evaluation of the skills and knowledge possessed by each individual operator. This should be done by comparing the operators knowledge, training, and education to the list of necessary skills and knowledge. If deficiencies are identified, the company should develop a plan to provide sufficient training.

An easier way to do this is to fill out a form for each employee in E.S. This form can then be used for comparison. This form can also be used as a training record for each individual employee by updating it periodically. This can be given as a certificate to the employee when he/she leaves the job.

In general, training should be provided to all levels of people. Training should be provided to technical personnel, supervisors, and operators to teach or

improve the knowledge and skills required to perform their tasks. For example, personnel carrying out inspections, are expected to be trained in the use of measuring and testing equipment, in inspection and testing techniques, and in application of statistical techniques. Operators of special processes should be trained in carrying out and/or monitoring these processes. All personnel in the organization are expected to be trained in the objectives, use, and maintenance of the quality system. The operational procedures dealing with training should list the training categories and the policies guiding identification of training needs in each category.

The scope of the training should be specified. An entry in an employee file stating that the employee was trained in computers does not have any meaning unless the scope of the training is specified. The training can take any form deemed by the company to be appropriate and effective. It can be classroom lecturing, on-the-job discussions in small groups, or distribution of written material for self reading. All these training programs (even self-study) should be documented and recorded. Self study is appropriate when learning how to operate new computer software. The best method for organizing the training records is based on maintaining an individual training record file for each person working in the company. All documents evidencing the employee qualifications can be kept in their personal file with a section identified as training.

The standard acknowledges that many employees may meet the qualifications for their positions by virtue of experience. However, the standard clearly regards training as a valuable tool. People whose work affects quality, as well as new hires and transferees, are logical candidates for training. Thus, the planning and evaluation of a systematic training program actually can help E.S. towards grater efficiency and effectiveness.

2.18 Statistical Techniques

The company will establish procedures to identify appropriate statistical techniques or accessing machine and process capability when required.

This the second section in the ISO 9002 standards which starts of with the word

`where appropriate'. It begins by stating that `where appropriate,' the supplier (E.S.) shall identify `adequate statistical techniques for verifying the acceptability of process capability and product characteristics.' No reference is ever made to statistical process control (SPC) or other techniques. Invariably SPC is the most common and popular technique of using statistics in production. But, if a company makes no mention of specific statistical techniques in its procedures or policies and justifies this decision, then this element need not be applied. Intent: The intent of this element is for the company to set up a program that will control and verify the process capability and product characteristics. In other words, to determine if processes could be improved or properly controlled by the use of statistical techniques. These techniques would include SPC, process capability studies, design of experiments. statistical sampling and so forth.

Requirement: This section requires the company to establish and maintain documented procedures for identifying adequate statistical techniques to verify the acceptability of process capability, and product characteristics

Implementation strategy: The focus of this requirement should be on process improvement and control, rather than generating paperwork for show. Statistical quality control (SQC) is a tool that can vastly improve the process producing a product. If properly understood and implemented, SQC can drastically improve productivity.

CHAPTER 3

WORK ORDERS - AN EXCELLENT INSTRUMENT

Work order refers to a document which initiates manufacture of a product, or a batch or series of products and is the most widely used term in most industries. E.S. has used a work order form to initiate a work since its inception and this document can serve as an invaluable tool for E.S. to satisfy many requirements of ISO 9000. In the following paragraphs it will be discussed how the work order in E.S. can be used to identify the product; plan production; define and document the quality plan; become an inspection record; serve as a configuration and traceability record; and track the use of time and resources.

Implementation of ISO 9000 may become more difficult when work orders are not used. There is no such problem in E.S. But, it is not being used for all the functions that could benefit the implementation of ISO 9000. Hence, the existing work order system in E.S. needs to be modified to accommodate the requirements in the ISO 9000 standard. Although the primary function of the work order is to initiate and monitor production, the potential functionality listed and described below is much broader in scope. This additional functionality can help satisfy various quality requirements of the ISO 9000 standards. E.S. should judge for itself which functions from the following list to adopt in their work orders. Refer to the corresponding sections (4.x) in chapter two for additional details on a particular function.

3.1 PRODUCTION PLAN

The production plan referenced in ISO 9002 section 4.8, can be documented in a work order and is a sequential listing of all operations and processes required to manufacture a product or a subassembly. For every operation or process the applicable drawings, specifications, work procedures or workmanship standards should be referenced or attached to the work order.

3.2 QUALITY PLAN

Quality plans are referenced in ISO 9002 section 4.2 and are mentioned in a couple of other sections. `Quality plan' means a detailed program for receiving, in-process, and final inspection and testing relevant to a particular product. This quality plan can be documented in a work order, to include inspection and testing requirements. Each quality operation, such as in-process inspection, is inserted after the applicable production operation or process, the result of which must be verified. In this case, the last operation on the work order would be the final inspection. If the scope, method, or acceptance criteria for a given inspection is not obvious, a reference to a relevant drawing or inspection procedure should be included.

3.3 PRODUCT IDENTIFICATION

Section 4.7 in ISO 9002 requires that products be identified during all stages of production. If the work order accompanies the product very closely and the name, type, etc., are stated on the work order, then the work order can be considered to also identify the product, and there by compliance with the section 4.7 is achieved. But, the condition is that the work order should always accompany the product.

3.4 TRACEABILITY

If traceability (section 4.7) is required, the serial number is identified on the work order before it is possible to label the product. For every operation and process, operators can enter on the work order their initials, process machines used, serial or batch number of parts and raw materials, and any other records that may assure

traceability. After the product is completed, the work order constitutes the record of traceability.

3.5 INSPECTION RECORD

A sign-off or inspection stamp in the field adjacent to where an inspection operation is called out constitutes a valid record of inspection. If the inspection results need to be recorded and/or the inspection equipment needs to be identified. this can also be recorded in the work order or on a separate report that is then referenced to assure traceability. This function in the work order will fully comply with ISO 9002 section 4.9.4, Inspection and test records.

3.6 INSPECTION AND TEST STATUS

Section 4.11 in ISO 9002 requires that inspection and test status of product be identified through out production. If the work order accompanies the product, contains the quality plan (i.e. calls out inspection), and has the provision for the inspection sign-offs, the inspection status is self-evident.

Sign-off indicates a passed inspection and an empty space means on hold, awaiting inspection. A failed inspection can be identified by other means, such as a red tag or label and segregation.

3.7 DOCUMENT THE WORK ORDER FUNCTIONS

If the work order is used for any of these functions, there should be a procedure explaining how the function is implemented in this way. It is best to have one dedicated procedure that deals with all aspects of the work order, but the same can be achieved by explaining in separate specialized procedures dealing with each and every elements. When there is a dedicated work order procedure it is sufficient to reference it in the other specialized procedures.

At the time the work order is produced it is a document containing important instructions on how to manufacture and inspect a product. But after completion of the product, it becomes a record. It contains traceability data and inspection

sign-offs. Thus the work order must comply with both ISO 9002 section 4.4, Document control, and section 4.15 Quality records. As a controlled document, the work order should be reviewed and approved before issue. Every work order should be signed off to evidence approval before issue and a procedure should name the personnel authorized to carry out the review and approval.

CHAPTER 4

QUALITY SYSTEM MODEL

As mentioned in chapter 1, the quality system's primary aim is to assure that all activities are planned, and done in pre-determined ways and that there are clearly defined channels for communication of information and instructions. According to ISO 9000, a quality system is `the organisational structure, responsibilities, procedures, processes and resources for implementing quality management.' (ISO 9000, Clause 3.3) However, the quality system of most organisations involved in manufacturing a product or providing a service related to manufacturing is influenced by the objectives of the organisation, and the particular product or service itself and, therefore, the quality system varies from one organisation to another.

The quality system model discussed below is based on ISO 9002 guidelines. In order for it to provide adequate confidence in a product or service with regard to given quality requirements, this model assures traceability through documentation, using quality system forms where applicable and necessary to provide traceability. This quality system model should provide E.S. a base model to start off the ISO 9002 implementation project. However, it is a generic quality system concept and is meant to be built upon. The current activities that are beneficial and not included in the model described should be given due consideration.

4.1 DEFINE AND DOCUMENT THE QUALITY POLICY AND OBJECTIVES

Top management should first make decisions to the direction of E.S. and then place these decisions in the policy statement. The policy should then be posted in

conspicuous locations throughout E.S., so that all personnel can familiarize themselves with it, and can be seen by the visiting customers. Management should also make sure that this quality policy is understood and implemented at all levels in E.S. See section 4.1.1, chapter 2 for more details on quality policy and objectives.

4.2 DEFINE RESPONSIBILITY AND DESIGNATE AUTHORIZED PERSONNEL

All employee's responsibility, authority, and interrelation with other personnel in the division should be defined. The organisational chart should show the paths of authority very clearly and a list of responsibilities for key management personnel, especially those related to quality. One person, who is independent of production should be designated to assure quality. Or else, a designated person from one group should be given the responsibility to inspect the others group's work. The top management should also designate a management representative who is responsible for implementing and enforcing quality requirements. Names of assigned personnel should be recorded into the respective boxes in the organisation chart and should be made known to all personnel interfacing with designated and authorized personnels. See section 2.1.2 chapter 2 for more details on organisational structure.

4.3 ASSING A WORK ORDER NUMBER

After being given a contract (work order), review the Service request form containing the work order carefully (see paragraph 5 for contract review) and assign a work order number to the received work order. A work order number file card can be used to keep track of numerically issued work order numbers. The issued work order number should be entered in all parts order form used with in E.S. purchase order form used to purchase parts from outside vendors pertaining to this one work order. All incoming invoices and other documents relevant to this work order should be marked with the corresponding work order number. If possible, it should be clearly stated in the purchase order form that the work order number must appear in all packages, slips, invoices and correspondence. This makes it possible to easily identify incurred cost against respective work order.

4.4 OPEN UP A WORK ORDER FILE FOLDER FOR RECORD KEEPING

Once a work order number has been assigned against a received work order and after all pertinent data has been recorded on the work order number file card, a work order file folder should be opened up. The most important data such as: assigned work order number, date of work order received, name of customer, etc., should be typed upon index table. This work order file folder will mainly serve to retain records which have been generated by received work order.

Once the work order has been completed and billed, work order file folder should contain all documentation issued and generated in the course of completing the work order, thereby assuring traceability through documentation. A master record containing all the numbers (Work order number, P.O. number, E.C.O. number, etc.) generated during the course of the project should also be maintained.

4.5 REVIEW THE WORK ORDER

As a rule, all work orders should be submitted in the director's office. Upon receipt of the work order (contract) it should be verified and reviewed (in conjunction with the supervisor and the customer) for accuracy and compliance according to section 2.3 in chapter 2. After work order has been reviewed and found acceptable, apply work order review stamp onto work order and fill in the respective boxes. To assure further traceability a logbook may be initiated at time of review, indicating any pertinent data with regard to work order review.

4.6 CONTROL DRAWINGS, DOCUMENTATIONS AND CHANGES

Upon receipt of the work order all applicable blueprints, drawings, documents and related specifications should be forwarded to the designated documentation control personnel. In the case of E.S., either the supervisor or a separate Quality Control person should be given this responsibility. This person will now check, evaluate and review all applicable data including legibility of documents and drawings. While doing this if the person finds an error and/or an improved method or an economical method of complying with all work order requirements while still being able to

maintain or improve the quality of the product, then he/she should communicate these findings to the respective customer for further evaluation, either through an Engineering Change Proposal or an informal letter.

Before any drawing and/or specification is released to manufacturing, a Blueprint/Specification & work order review stamp should be applied to these documents by this person, indicating compliance with above review and official release to manufacturing. Whenever change orders to a blueprint, drawing or specification are received, all outstanding blueprint, drawing or specifications which are affected by the change order should be recalled and changes incorporated or new documents issued. These engineering changes must be recorded under an Engineering Change Order form and any drawings affected by this E.C.O. must have an E.C.O. stamp. All blueprints, drawings, change orders and related specifications should be controlled, implemented, and maintained by the concerned documentation control person. After the work order has been completed, the blueprints should be filed in the respective work order file folder and kept for a desired retention period. Obsolete drawings, & documents if any, should be stamped VOID (see paragraph 10) and kept in a separate file cabinet for reference purposes only.

4.7 OPEN UP A MANUFACTURING OPERATION SHEET AND APPLICABLE INSPECTION REPORT SHEET

Open up a Manufacturing operation sheet and a respective Inspection report sheet, by filling in boxes under the sheet headings. These sheets should then be submitted along with the work order form to the Quality Control (QC) person for planning quality requirements. As mentioned in chapter 2 (section 2.1.2), for a small division like E.S. where an independent quality control person cannot be justified, it is advisable to designate the director and vest him with the responsibility and authority to deal with all quality matters. The work order should now be reviewed by the QC person for quality requirements (in conjunction with supervisors/customers) and incorporated into the Manufacturing operation sheet and Inspection report sheets. In the case of E.S., depending on the size of the work order, the QC person can delegate the whole responsibility for quality to his deputy or to the shop supervisor. After

the above review and planning has been performed, the respective columns should be signed off by the concerned QC person.

Now the work order along with the Manufacturing operation sheet and Inspection report sheet should be forwarded to the shop supervisor for production planning. The operation sequence (production plan) need to planned (in conjunction with the technicians) and entered into the Manufacturing operation sheet by the shop supervisor. This operation sequence will show all planned manufacturing operations followed by respective QC operations necessary to assure an acceptable quality product, complying with the applicable blueprints, specifications and work order requirements. As a rule each manufacturing operation should be followed by inspection control operation. This inspection control operation can be done by either one of the following personnel: the technician, the supervisor, the QC person's deputy, or the QC person himself. This decision as who should inspect what quality characteristics should be taken by the QC person. Special quality requirements such as verification by CMM or optical comparator should be reviewed and addressed during quality planning, and entered as an appropriate operation in the Manufacturing operation sheet.

Apart from that, receiving inspection, first article inspection, in-process inspection, and final inspection & testing should also be incorporated into Manufacturing operation sheet. The Manufacturing operation sheet should now be signed off by the person responsible for planning manufacturing operations in the space provided.

Upon completion of the planning for manufacturing and quality, Manufacturing operation sheet should be forwarded to the QC person for verification and approval. Neither the Manufacturing operation sheet can be released for production nor any changes made in the Manufacturing operation sheet without prior approval of the QC person.

4.8 DESIGNATE QUALITY CONTROL AREAS

As a minimum apply quality control area signs to designated control points such as:

a. Inspection area/room - Authorized personnel only

b. Bond room - Authorized personnel only (This area usually stores and keeps separate rejected items waiting for disposition. Also the Rejection Log Book is kept in this area.)

c. Certified material storage area - Removal by authorized personnel only

d. Non-certified material storage area

e. Receiving inspection area - Authorized personnel only

f. Stock room - Authorized personnel only.

E.S. management should decide on the authorized users or better placed control on who has access to space. This will avoid visitors/students walking into the shop floor and picking up what ever they want from wherever they see without anyone's permission.

4.9 CONDUCT RECEIVING, FIRST ARTICLE, IN-PROCESS AND FINAL INSPECTION

Inspection operations and testing procedures should be reviewed and approved before issued to production for actual manufacturing. Only after the final inspection is performed should the finished and/or final product, material or operation be presented to customer for acceptance. If applicable, a policy for an employee to have their vision tested, particularly if they perform inspection, should be maintained. Refer section 2.9 in chapter 2 for more information on inspection and testing.

4.9.1 Receiving Inspection

All shipments received should be inspected and/or tested for conformance and compliance to blue print, drawing and specification requirements. Actual

measurement values should be recorded on Inspection report sheet for traceability, if applicable. Otherwise accept/reject criteria should be used and recorded in Receiving inspection log. Upon completion of receiving inspection, the items should be identified with an Acceptance tag if all criteria are met, or a Rejection tag if deficiencies are found. Nonconforming parts after disposition by the appropriate authority should be returned to the supplier with a Corrective action request form. All material received should be properly handled and stored to prevent damage. Records of all receiving inspections and tests performed should be maintained and filed in designated work order folder for traceability.

4.9.2 First Article Inspection

Upon completion of a manufacturing set-up, the first item produced should be submitted to the concerned QC person for first article inspection and recorded in Inspection report sheet for traceability. The QC person should inspect this first item to verify all blueprint/drawing configurations for the specific manufacturing operation and shall, if item complies, initiate acceptance by signing the Inspection report sheet. If the first article does not meet the specifications, the concerned person should tag the rejected item with a Rejection tag. The person should notify the operator and/or whoever is in charge of manufacturing and first article set-up, with a request to submit after respective change of set-up, a new item for first article inspection. Rejected part should be segregated and placed in the bond room for evaluation and disposition. First article Inspection report sheet should be filed in the respective work order file folder for record and traceability. Instructions should be given to the operators that no items should go to the production unless first article inspection finds item accepted by inspection and complies. The approval for manufacturing should be initiated by signing of the Inspection report sheet.

4.9.3 In Process Inspection

In process inspection should be pre-planned during quality planning (see paragraph 7) to be compatible with manufacturing operations. In case of lot size more than one, at periodic intervals during the production run, inspection should verify that the

articles produced continue to meet drawing specification. All applicable inspection findings should be recorded on the Inspection report sheet and filed in the work order file folder for traceability. If certain characteristics are found to be discrepant, all parts produced since the last inspection should be screened for those characteristics. All parts found to be discrepant should be segregated from the remainder of the lot and identified with a `Reject tag'. Specified tolerances should be considered to be `absolute' and measurements should not be `rounded off' to meet requirements. Good house keeping and clean and orderly manufacturing and inspection areas should be maintained and inspected.

4.9.4 Final Inspection

Upon completion of all manufacturing and processing operations conforming to Manufacturing operation sheet all items should be forwarded to the QC person or the person designated by the QC person for final inspection. The items should be final inspected against all blueprint/drawing configurations. The Inspection report sheet should be filled out and filed in respective work order file folders. All items found to be discrepant should be identified with a `Reject tag' and placed in the bond room.

If rejected parts are allowed for modification or rework by the QC person or the customer, then this should be recorded in the Manufacturing operation sheet, for traceability. All accepted final items should tagged with an `Acceptance tag' and then stored in the appropriate area for dispatch. At this time the QC person should pull the work order folder and check and verify that all related and required documents (receiving, first article, in process, & final inspection report sheet, etc.) are on file and conform with the work order requirements.

4.10 INDICATE INSPECTION STATUS

All items should retain an indication of their inspection status at all times. This can be accomplished through the use of either Manufacturing operation sheet, and/or `Accepted' and `Rejected' tags. All items either in lot or as a single entity should be accompanied by either a Manufacturing operation sheet and/or identification tags.

An Inspection report sheet, should also accompany the items, if applicable.

The following stamp configuration can be used on documents such as blue prints, SOP's, work instructions, etc. to denote that they are no longer in use but are stored for future reference.

These documents should have a desired retention period

|Void Stamp| - Denotes non usability of any item that need to stored for future reference. Used only by authorized persons.

4.11 CALIBRATE GAUGES AND INSPECTION EQUIPMENT

As discussed in chapter 2 section 2.10, E.S. should implement and maintain a calibration system for measurement and test equipment to support and fulfill all contractual requirements. All company owned and in house inspection, measuring and test equipment should be individually serialized with a serial number and recorded on Instrument record and calibration card with the following additional information: name of tool and instrument, frequency of calibration, procedure for calibration, the date calibrated, inspected and date due for next calibration, name of inspector performing calibration, and the certificate document number showing deviation from standard values. All customer furnished or employee owned tools, instrument, gauges and test equipment, should be subjected to the same control as company owned tools.

4.11.1 Measurement Reference Standards

Measurement reference standards (gauge blocks, surface plates, etc.) used for calibrating measuring and test equipment in house should be calibrated at regular intervals by approved outside commercial metrology labs. It should be made certain that the calibration performed by those approved facilities is certified and documented as being traceable to the National Institute of Standards. Certifications and related documents should be kept on record and made available for inspection and verification. Calibration intervals should be established based upon stability, purpose and usage of these measurement reference standards. Serial number of any measurement-reference standards should be recorded on respective instrument

record and calibration card, when used for actual calibration, to assure traceability.

4.11.2 Measurement Transfer Standards

Measurement transfer standards (micrometers, dial calipers, dial indicators, optical comparator, hardness tester, etc.) used to measure, gauge, test, and inspect products for compliance to blueprints, specifications and contractual requirements should be calibrated in house against standard written calibration procedures, if feasible, or sent outside to be calibrated by approved metrology lab-contractors. Sub-contractors lab facilities should be inspected and made sure that their calibrations are traceable to the National Institute of Standards. If applicable, necessary calibration adjustments should sealed after calibration.

Record serial numbers of all measurement reference standards and measurement transfer standards onto Instrument record and calibration card. The calibration interval may be shortened or lengthened only when documented evidence exists that this may be done without violating the continuing accuracy of the tool or instrument. After calibration of each tool or instrument, a calibration certificate label should be affixed to the tool/instrument or if appropriate to the tool container, which will indicate the date of current calibration, the date when calibration is due, and identify the source who performed the current calibration. If calibration is performed by outside approved calibration lab, keep calibration certificates up to date and readily available. Use forms that remind the upcoming recall calibration dates. This form can be posted in a conspicuous place in the inspection department to serve as a reminder of upcoming in house calibration due dates. Un-calibrated, damaged and misused measuring, inspection and test equipment should be segregated, identified and put into bond room to prevent accidental use. If excessive wear or defects in equipment prevent proper calibration, equipment should be removed and scrapped. If out of tolerance measuring and test equipments are inadvertently used for inspection on actual manufactured products, those products should be 100% reinspected with calibrated and acceptable measuring and test equipment. If parts have already been given to the customer and are inadvertently inspected and/or tested by out of tolerance measuring and/or test equipment, such customer should be

notified immediately and a 100% reinspection of the described product should be initiated, if at all possible.

4.12 CONTROL NON-CONFORMING MATERIAL AND TAKE CORRECTIVE ACTION

A documented system of corrective action and nonconforming material should be maintained, and kept on file for traceability. This system should be designed for detection, segregation, and identification and/or marking of discrepant material. It should also determine the cause of nonconformance, initiate corrective action and serve to prevent future reoccurrence. All nonconforming material or products should be identified with a Rejection tag, segregated and stored in bond room area until reviewed and decision made on disposition. Material and products which are rejected either in house or by customer should be recorded into the Nonconformance report log book. After detection of a discrepancy or nonconforming material and a corrective action has been initiated, repair or rework should only take place at customer's disposition. Refer to sections 2.12 and 2.13 in chapter 2 for more details.

4.13 AUDIT QUALITY SYSTEM OF OUTSIDE SUPPLIERS

Section 2.5.2 in chapter 2 discusses in detail about the assessment of sub-contractors (suppliers / vendors). External audits shall be performed only where criticality of product or past quality performance of supplier or specific requirements in contract dictate an audit. A questionnaire designed to survey the quality system of outside suppliers can be mailed, to gather initial information on supplier's quality system. Follow up with visit to each supplier should be performed if situation demands it. A log of accepted sub-contractors, based upon an adequate quality system should be maintained.

4.14 AUDIT IN-HOUSE QUALITY SYSTEM

See section 2.16 in chapter 2 for a detailed discussion on internal quality audits. When the quality system has been completely implemented, authorized internal audit team should conduct a quality system audit to assure compliance to quality

system manual procedures. Noncompliances should be recorded on to a Internal audit noncompliance notice and forwarded to the upper management for review and evaluation. Audit intervals should be loosened or tightened depending on previous audit results.

4.15 DOCUMENT PURCHASING FROM OUTSIDE SUPPLIERS

This should be done in written form, using the Engineering Service Company's purchase order form. A copy of the in house parts order form and the Engineering Service Company's purchase order form should be forwarded to the concerned person who receives the parts. Once outside supplier delivers the ordered items, receiving inspection should be performed by the person receiving them. The person should inspect items against copy of purchase order. Findings of receiving inspection should be recorded on Receiving inspection log. After acceptance of received items, copy of parts order and the purchase order form should be signed by the person inspecting it, indicating acceptance of received items. Copy of signed parts order and purchase order form should be forwarded to the person responsible for accounting to match incoming invoice, showing assigned purchase order number and work order number. Invoice should then be processed and paid accordingly. If items had been rejected, it should be noted on the parts order, and nonconforming material procedures according to section 2.12 in chapter 2 should be initiated.

4.16 MAINTAIN RECORDS

4.16.1 Work Order Records

All documents relating to each work order such as: the work order, inspection and rejection record, copy of Manufacturing operation sheet, applicable correspondence, etc., should be filed and maintained in designated work order file folders. Once the work order has been completed and billed, work order file folder should contain all documentation issued and generated in the course of completing work order, thereby assuring traceability through documentation.

4.16.2 Other Records

Records maintained to substantiate the quality system shall include, but not be limited to, the following:

a. Certifications and test reports for all materials and processing, if applicable.

b. Completed `Manufacturing operation sheet'.

c. Copies of all purchase orders.

d. Copies of all inspection and test reports.

e. Tooling inspection records

f. All inspection and test related documents.

g. Inspection and test equipment calibration records.

h. Personnel certification, if applicable.

i. Records of any other documents pertaining to quality system.

j. All internal and external audit reports.

k. Reports of management review, etc.

4.17 TRAIN AND CERTIFY PERSONNEL

When work order assignments, special processes, inspection and testing requires special skills and knowledge in production and quality-control, then designated personnel should be trained and certified. Appropriate education, training and experience are a prerequisite for applicable assigned tasks. The training and certification should include all personnel performing activities pertaining to quality. Training should also be provided, when applicable, to inspection and manufacturing and production personnel to familiarize them with procedures and instructions given in the quality system manual and respective forms. Qualification and training records should be maintained for designated personnel, and be available upon request

for review. See section 2.17 in Chapter 2 for additional information.

CHAPTER 5

DOCUMENTATION FOR ISO 9000

In chapter 2, the 18 elements of the ISO 9002 quality system were discussed and in chapter 4 a quality system design was proposed. Once the quality system has been designed (defined and developed) by E.S., the next step is to document the quality system. This chapter discusses methods for documenting the quality system.

A documented quality system sets out in a formal framework the basis of controlling critical activities that affect quality in an organisation. It should reflect the way a company operates. A well-documented and effective quality system communicates the following to everyone in the organisation. [22]

1. The objectives of the system

2. The policies of the organisation

3. Employee's responsibilities within the organisation

4. The operational procedures (work instructions)

In answering the question what to document, it is required to identify the scope of the quality system and to determine which company functions and areas of activity are critical. Critical areas require a systematic approach with documented procedures. In summary, the documented quality system, when completed, should

help customers and auditors understand how E.S. quality management system addresses the elements of the respective ISO standard.

5.1 UNDERSTANDING THE QUALITY SYSTEM DOCUMENTATION STRUCTURE

Although ISO 9000 standard does not recommend any specific structure, a three tier documentation system supported by records (fourth tier) is found to be the most effective and efficient system. [26]

5.1.1 Tier 1: Quality Manual

The quality manual (tier one) is the highest level of quality system documentation. As a document it should be brief and concise, not exceeding 20 - 25 pages. It should discuss how E.S. will comply with each element of the standard and should state the policy and objectives of E.S. for each of the pertinent sections of ISO 9002. The format is left to the individual organisation. But it is necessary that the manual address each section of the ISO 9000 model to which the organisation adheres. The purpose of quality manual is to communicate the quality policy and the objectives of the company to each and every individual in the company and to assure the reader of the quality manual that the company has addressed all of the relevant ISO requirements. The management's first step in implementing a conforming ISO 9000 quality system is to document the quality system with a quality manual.

The ISO 9000 Quality Pyramid

Quality Manual ----->Tier 1

Policy objectives

organisation

authority

Standard Operating

Procedures ------->Tier 2

Departmental who, what, when, and where

Work Instructions -------> Tier 3

How to' machine/equipment/manual

task-oriented instructions

Records ----------> Tier 4

Reviews, audits, inspection/tests, calibrations, non-conformities, corrective actions.

5.1.2 Tier 2: Quality System Procedures

The next step is to generate operating procedures that describe how the quality system functions. In other words, procedures relating to each element in the standard are written down. The intention is to explain how the quality policy described in the quality manual will be executed by actual activities and responsibilities. A well written procedure will instruct the reader who should perform the procedure, what to do, where to do it, and when it should be done. [14]

The procedure must explain what is to be done when, where, why and by whom. Once the tier 1 and tier 2 are written down they need to be implemented by issuing specific work instructions. These work instructions form the third tier. Small companies include tier 2 documentation within the quality manual and call it the `operations manual'. Some companies develop separate tier 2 documentation. E.S. might adopt anyone of these two strategies. However, the ISO 9000 auditors will read both the tier 1 and tier 2 documents before they visit any site. They approve the quality manual by assuring that it meets the requirements of the standard and that it references the correct tier 2 documents. They then use the tier 2 documents to form their audit checklist. The prior reading is only to assure written conformance.

The audit will confirm that what is written is what is actually practiced.

5.1.3 Tier 3: Work Instructions

As mentioned above, this level documentation concerns work instructions. The detailed requirements of any particular task, such as the operating instructions for a piece of equipment may need to be defined to ensure consistent working methods and to achieve required quality standards. [22] How much and what to write seem to be the two major road blocks in writing tier three documentation. These levels of documentation are highly specific to individual worker and tasks. Care should be taken to limit documentation to the extent pertinent to the application (ISO 9004: 1987, 5.3.1). The instructions on the hand drier in the rest room and the folding directions printed on the sides of a mail box or other storage boxes are examples of an efficient, effective and easy to use work instruction. See section 2.8 in chapter 2 for a discussion on work instructions.

5.1.4 Tier 4: Records

Records are written statement of facts pertaining to a specific event - an inspection that took place at a specific date, time and location. [23] Records include files, completed forms, drawings and specifications, etc. These records are evidences of the quality system and evolve from the processes. Section 2.15, chapter 2 details on record keeping.

5.2 THE QUALITY MANUAL (TIER 1 DOCUMENTATION)

As mentioned above a quality manual should describe what you do and should not exceed 20 - 25 pages. But when the quality manual itself includes procedures and work instructions, it could be longer. A common pitfall is to include too much detailed information. Examples of information that should not be included in the quality manual are technical specifications, names of individuals, etc. The format suggested by Lamprecht, 1992 in his book `ISO 9000' is suggested for E.S. Following the title page and table of contents, one of the first pages should be the revision list page. The Distribution list page can follow the Revision list page. It's format can also vary. The manual format should include the name of the company on the top of each page as well as have the `document control box' at the bottom or

top of each page. A typical quality manual format, consists of three sections [17] and they are 1. Scope, 2. Policy, and 3. Responsibilities. The Scope states the purpose of the section. The Policy section describes in generic terms, the actual company policy regarding the ISO clause (4.1, 4.2, etc.,). The Responsibility section explains who is responsible for the policy stated. See the following page for an example quality manual format. The manual need not be structured in the same order as the standard, but the manual must be cross referenced to each of the 20 sections.

Some of the important questions to answer while starting the quality manual documentation are as follows.

1. who will write the quality manual?

2. How will the revisions be handled and by whom?

3. How will the task of coordinating all the paragraphs be addressed?

4.. Who is responsible for removing obsolete quality manuals from circulation?

5. Who will review the manual for accuracy prior to final release?

6. How will the document be controlled?

5.3 QUALITY SYSTEM PROCEDURES (TIER 2 DOCUMENTATION)

The most difficult hurdle to overcome in writing the company's procedure is to get people involved and motivated to finish their procedures. They might feel that they already have much to do and may not fully appreciate the value of increased documentation. It is a challenge to get people involved in writing the procedures.

Tier 2 documentation can be organised by simply going back to each of the ISO paragraphs referred to in tier 1, and explain in more detail who controls processes, who is responsible for instrument calibration, who performs final product inspection, etc. There is no prescribed way to write procedures. The choice of format or style is up to the company to decide.

5.3.1 Procedure Writing Process

A well written procedure will clearly state the action necessary to implement a stated policy in the quality manual. The first step in documenting a system, process, or a program is to determine how it actually works. It will be a surprise to see how the system actually works in E.S. The best way to start documentation is to make flow charts. The flow charts can then be modified to show how the process needs to be worked. Once this is done, the flow chart is now redesigned and documented in a procedure to meet the ISO 9000 requirements. The following steps can be used to write a more efficient and an effective procedure. [14]

1. Draw a flow chart of the process

2. Collect related documents

3. Compare existing system to requirements; make revisions as needed

4. Draft new procedure; circulate for feedback

5. Update the draft to final form and seek approval

6. Publish new procedure

The procedures can be evaluated by reading it as if you were a new person at E.S. struggling to understand how various tasks are accomplished. Few sample questions a person might ask are;

1. Can I fully understand the task that is required?

2. Can I readily identify the who, what, where, when, and how characteristics?

3. Is the procedure written in a clear and concise manner? etc.

Then the procedure should be compared against two criteria: (i) the selected ISO 9000 standard to make sure that it meets all the requirements (ii) the actual actions taken by E.S. to assure what is stated is also what is done. Checklists can be

developed to verify the first criteria and internal auditing can be done to verify the second one.

5.3.2 How To Flow Chart? [17]

A flow chart is a schematic representation of a process/procedure. Flow charting to document processes is a popular and widely accepted method, but not necessarily a universal method. The easiest way to construct a flow chart would be to brain storm all the activities, rank them in a logical sequence of events and attach the appropriate flow chart symbol to each activity. The last step would consist of all the symbols with arrows, thus indicating the process flow.

5.3.3 Procedure Writing Tips

It is always advisable to keep the procedures brief, and as simple and easy to read as possible. Procedures should be uniform in content, headings, etc. to provide continuity [25]

1. One person should review all procedures for consistency 2. Draft procedures in present tense. For example, `All incoming parts shall be inspected' should be written as `All incoming parts are inspected' 3. Use a consistent template (boiler plate) to write procedures 4. Avoid writing procedures telling how to fill out forms. Forms should be self explanatory. 5. Flow chart procedures where practical. Create the flow chart making sure it is complete then write the procedure.

5.4 WORK INSTRUCTIONS (TIER 3 DOCUMENTATION)

Usually this level of documentation is machine-, task-, or product-specific. As with second tier documentation, there are no third tier style or format standards to follow. However, the preferred method to write work instructions uses step-by-step instructions that follow the logical flow. Many of the rules used for procedure writing will also apply to this level of documentation.

The instructions should be brief, to the point, and clearly written. Work instructions should be written by those who know and perform the tasks. They must be written

so that the person with the lowest skill level involved in the process can read and understand their meaning. These instructions can be tested by giving them to someone unfamiliar with the process and seeing if he / she can successfully complete the task.

CHAPTER 6

SUMMARY OF SIGNIFICANT CHANGES TO ISO 9002

6.1 IN THE 1994 VERSION

As mentioned in chapter 1, the ISO standards were first published in 1987. The ISO requires that the appropriate Technical Committee review these standards every five years. As a result of the first review, the 1994 revised version of these standards was issued in the spring of 1994 with the U.S. version being issued through the ANSI in late spring of 1994. The major revisions have provided further clarification of the 1987 standard or added requirements exceeding those originally issued, but have not altered the intent of the standard. In theory, the standard has been modified to stress even further the purpose of customer satisfaction. In other words, they have been modified to incorporate a number of the principles of Total Quality Management. [13] A brief summary of the primary revisions to the ISO 9002 standard is identified and discussed in this chapter.

6.2 SIGNIFICANT CHANGES

1. All three models (9001, 9002, 9003) have a common numbering system for the quality system elements: i.e., 4.1 through 4.20. In 9002 and 9003 non-applicable clauses are required to be addressed as non applicable. These changes were made to improve the consistency in the interpretation of the elements between standards.

2. The 1994 version of the ISO 9002 will contain 19 elements instead of 18 with the addition of `servicing' and the revised ISO 9003 standard will contain 16 elements instead of 12 with the addition of `contract review', `control of customer supplied product', `corrective action' and `internal quality audits' to the model.

3. A quality manual is now mandatory; this may, or may not, include procedures but is required to reference their existence.

4. Several clauses have been expanded to address additional requirements.

5. The term `Purchaser' has been replaced by `Customer'.

6.3 SUMMARY OF ISO 9002:1994 CHANGES

As mentioned above, `servicing' lies within the scope of the 1994 version of ISO 9002. A brief summary of the changes imposed to the 1987 standard are as follows.

1. The quality policy statement is required to further stresses the importance of customer needs/satisfaction. It is also seen that the importance of management's role in the quality system is enhanced and emphasized with the introduction of the terms `executive management' and `executive responsibility'.

2. Prevention of occurrence of product nonconformity requirement has been expanded to include process and quality system nonconformances.

3. The standard now addresses the requirement of trained personnel for management functions which was not specifically mentioned in the 1987 version.

4. The inclusion of the term `defined intervals' in the management review element indicates that this activity may need to be documented by a schedule.

5. A quality manual is now a requirement, even though the 1987 version did not require one.

6. Greater emphasis is placed on quality planning.

7. The standard now requires a method addressing amendments to contracts and

the way in which such information is transferred to concerned functions be identified.

8. Evaluation of subcontractors is a specific requirement now. Supplier verification at subcontractor's premises is referenced and the confusion surrounding it has been eliminated.

9. Purchaser-supplied product element has been re-titled to control of customer-supplied product. The change was to require documented procedures to address this element if applicable. It also requires the documented procedures for identification and traceability of product where applicable.

10. The maintenance of equipment `to ensure continuing process capability' is a requirement. This would mean the maintenance of equipment such as welding machines, furnaces, and automated processing equipment.

11. Corrective action element in the 1987 version has been expanded to include preventive action. Hence the element has been re-titled to corrective and preventive action.

12. The handling, storage, packaging and delivery element has been expanded to include requirements for preservation of the product.

13. The title of `quality records' element has been revised to `control of quality records'.

14. In the internal audits element, the standard has added the requirement for auditing activities to be carried out by personnel independent of those having direct responsibility for the activity being audited. This requirement was previously addressed in the management responsibility element.

15. The identification of the need for statistical techniques is a stated requirement.

CHAPTER 7

APPLICATION TO AN ENGINEERING SERVICE COMPANY

As mentioned in chapter 4, the quality system's primary aim is to assure that all activities are planned, and done in pre-determined ways and that there are clearly defined channels for communication of information and instructions. According to ISO 9000, a quality system is `the organisational structure, responsibilities, procedures, processes and resources for implementing quality management.' (ISO 9000, Clause 3.3)

According to the understanding of Chapter 4, the sample application of ISO 9002 to an Engineering Service Company, MUGESAN Engineering and Marine Specialist Co. Inc. , is given in this chapter.

Quality Assurance Manual QAM	**Document No:** MGSN-0.01
Issued By: Quality Assurance Manager	**Approved By:** General Manager
Title: Revision Page	

7.1 REVISION SHEET FOR QUALITY ASSURANCE MANUAL

Revision No.	Chapter/ Section No.	Page No.	Date	Remarks	Signature

Quality Assurance Manual QAM	**Document No:** MGSN-0.02
Issued By: Quality Assurance Manager	**Approved By:** General Manager
Title: Distribution	

7.2 QUALITY ASSURANCE MANUAL DISTRIBUTION LIST

Distributed Document No.	Date	Holder	Signature

Date of Issue: 01.05.1998	**Rev No:** Original Copy
Page No:	**Rev Date:**

7.3 COMPANY PROFILE

MÜGESAN Engineering & Marine Specialist Co. Inc. is a major marine service and engineering company in Turkey. MÜGESAN Engineering & Marine Specialist Co. Inc. was founded in 1980, and come today with one change in 1992. The major activities of the company are as follows;

- M/E & D/G Overhauls, General Repairs & Services,
- M/E Lining & Epocast 36 Epoxy Resins Applications Services,
- In-situ Crankshaft Grinding Services,
- Ultrasonic Digital Thickness measurement services,
- Hardness Testing Services,
- Boom test Services.,

As the company working with a philosophy of a leader in the market, Mugesan A.Ş., is in activity with the Worldwide known Major Companies for the performed services. In briefly, Some of these Worldwide known Major Companies are as follows:

- MAN B&W DIESEL / DENMARK & GERMANY, Authorised Repair Shop & Reconditioned Spare Parts Stock (Since '95)

  The biggest builder of the Main Engines and Diesel Generators worldwide.

- MITSUBISHI HEAVY INDUSTRIES / JAPAN, Authorised Repair Shop (Since '96)

  The biggest builder of the Main Engines and Diesel Generators worldwide.

- SPRINGER Marine & Industrie Service GmbH. / GERMANY, Distributor & Service (Since '93)

  The producer of EPOCAST 36 Epoxy Resins for chocking compounds of Main Engines, Diesel Generators, propulsion Plants and Propulsion units.

- LONGUEVILLE Gebr. / BELGIUM, Distributor & Service (Since '95)

  The in-situ Crankshaft grinding & repair company, giving services worldwide.

The personnel of the company is about 13, which includes Marine Chief Engineer, Mechanical engineers , Naval Architect and Marine Engineers and technicians.

Quality Assurance Manual QAM	Document No: MGSN-2.00
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Definition and Abbreviations	

7.4 DEFINITION AND ABBREVIATIONS

7.4.1 Definitions

Definitions given in the International Standard ISO 8402-1988 and TS 90005-1991 are used in this Quality Assurance Manual. However there are special terms related to servicing call for more precise definition.

7.4.2 Abbreviations

QAM	Quality Assurance Manual.
MÜGESAN	MÜGESAN Engineering & Marine Specialist Co. Inc.
Q.A	Quality Assurance.
Q.C	Quality Control

7.4.3 Abbreviations of Data Sheets

KK Data Sheets For Quality Control

7.4.4 Abbreviation Of Quality Assurance Documentation And Records

KKK Office Quality Control Books
KKD Office Quality Documents
DD Auxiliary Documents
GT Personal Definition
KP Working Procedures
IT Operating Instructions
ED Training Documents
KD Calibration Documents
SKD Order Acceptance Quality Control
TS Technical Specifications
MSD Customer Complaints
MB Mechanical Maintenance
SA Purchasing Dept.
SD Sales Dept.

7.5 CUSTOMER'S RIGHT TO FIND OUT THE QUALITY SYSTEM AND COPYRIGHT

7.5.1 Customer's Right To Find Out The Quality System

If requirements of the International Standard ISO 9002 are related to in customer's order, The customer or his representative has the right to examine the Quality Assurance System of MÜGESAN Engineering & Marine Specialist Co. Inc. This includes the right; to inspect service and supervise testing, to have to documents related to the Quality Assurance.

Special point classified as service secrets are not available for inspection,

Also the right to inspect the systems and production processes is restricted about to order concerned.

7.5.2 Copyright

Quality Assurance Manual QAM	Document No: MGSN-3.00
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Contents	

7.6 CONTENTS

Policy Statement Number	ISO 9002 Requirement	Section Description	Quality Procedures
P.S. 01	4.1	Management Responsibility	QP01
P.S. 02	4.2	Quality System	QP02
P.S. 03	4.3	Contract Review	QP03
P.S. 04	4.4	Design Control (Not Applicable to Company)	QP04
P.S. 05	4.5	Document and Data Control	QP05
P.S. 06	4.6	Purchasing	QP06
P.S. 07	4.7	Customer Supplied Product / Service	QP07
P.S. 08	4.8	Identification and Traceability	QP08
P.S. 09	4.9	Process Control	QP09
P.S. 10	4.10	Inspecting and Testing	QP10
P.S. 11	4.11	Control of Calibration Equipment	QP11
P.S. 12	4.12	Inspection Status	QP12
P.S. 13	4.13	Control of Non-Conformance's	QP13
P.S. 14	4.14	Corrective and Preventive Action	QP14
P.S. 15	4.15	Handling, Storage, Packaging, Preservation and Delivery	QP15
P.S. 16	4.16	Control of Quality Records	QP16
P.S. 17	4.17	Internal Quality Audit	QP17
P.S. 18	4.18	Training	QP18
P.S. 19	4.19	Servicing (Not Applicable to Company)	QP19
P.S. 20	4.20	Statistical Techniques (Not Applicable to Company)	QP20

7.7 ISO 9002 QUALITY SYSTEMS

7.7.1 Management Responsibility

7.7.1.1 Quality policy

Management of MÜGESAN Engineering & Marine Specialist Co. Inc. determines and implements quality policy in all activities pertaining to quality of a service which involves all phases from initial identification to final satisfaction of requirements and customer expectations which may include, marketing, procurement, process planning, service inspection and storage sales and distribution.

The company is totally committed to achieve the highest management standards with particular emphasis placed upon assuring quality and the protection of the environment.

Our personnel at all levels is responsible to meet customer's demands and expectation of the order to provide it on time with cost effective operations and economic profitability.

Quality system is planned to meet the requirements of standard ISO 9002: 1994, All the quality policies are understood, maintained and implemented at all levels of the organisation.

7.7.1.2 Organisation charts

7.7.1.2.1 General

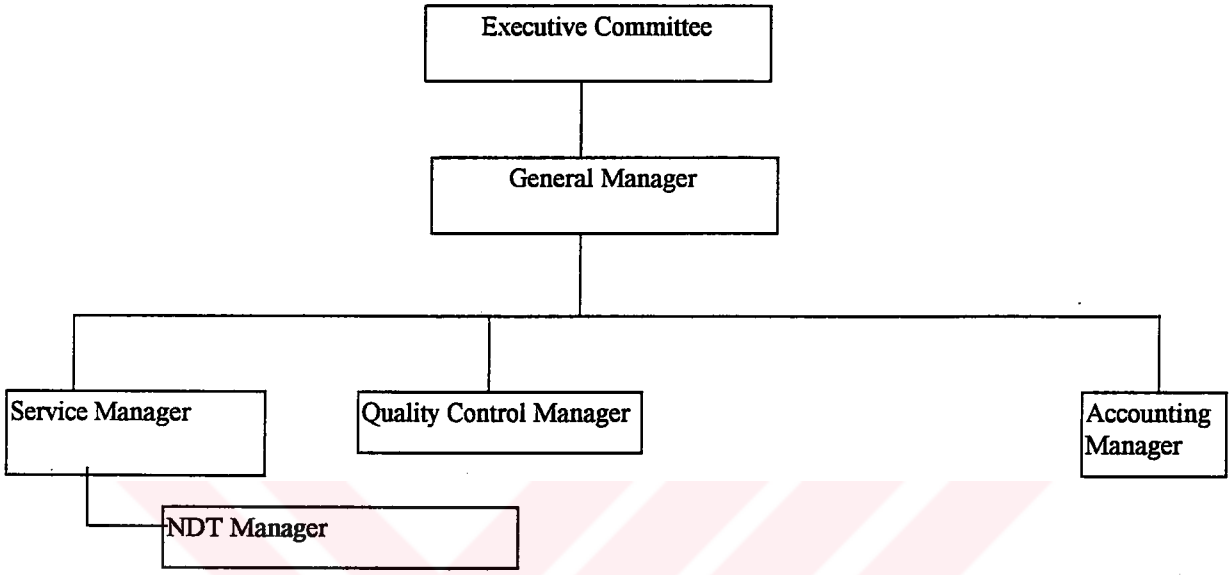
The organisation charts and functionaries confirmed by directives from the General Manager of the works are described. Each department is responsible for the renewal of its own organisation chart, when the organisation is reformed. General Manager with his signature.

7.7.1.2.2 Overall organisation chart of MÜGESAN ENGINEERING & MARINE SPECIALIST Co. Inc.

The overall organisation chart of the MÜGESAN is shown on page 2.

Quality Assurance Manual QAM	Document No: MGSN-4.01
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Management Responsibility	

GENERAL ORGANISATION CHART



7.7.1.3 Responsibility and authority

Organisation of the department and functions is defined and issued by a directive from the General Manager at MÜGESAN. Division of jobs, responsibilities and authorities refer to activities affecting quality are explained in a general way in this Quality Assurance Manual and more detail in the descriptions and directions pertaining to the different activities.

Personal responsibilities and authorities are defined in the job descriptions of salaried employees.

7.7.1.3.1 Resources

Service is carried out in accordance with documented procedures and operation instructions with trained personnel at all levels is responsibility and authority is defined to meet the requirements of standard ISO 9002.

Quality System verification activities is carried out by personnel independent of those having direct responsibility for the department an internal audits.

7.7.1.3.2 Management representative

Levent IŞIK (Mech. Eng. Msc.) is the management representative having authority and responsibility for ensuring that the requirements of quality matter at MÜGESAN.

7.7.1.3.3 Quality responsibility

Quality responsibility is not separated in the organisation of MÜGESAN. Each department and each individual section shall be responsible for quality. Quality system is reviewed January & July a year by the senior management to ensure its continuing suitability and effectiveness. Quality Assurance Coordinator shall be responsible for the quality purpose at the senior management level.

Quality control responsibility & Overall inspection responsibility for the final approval of product lies with the Quality control Department of MÜGESAN. This functions is carried out by giving planning servicing, and inspection instructions, by carrying out absolutely free from other departments.

7.7.1.4 Management review

The quality system are reviewed by the management February and August per year in MÜGESAN.

The purpose of the management review of this quality system is done by reviewing of the quality system and quality feedback to ensure the necessary improvement in the quality system.

Generally following items will be considered:

1- Review system and effectiveness to reach the aims.
2- Verify that corrective and preventive action procedures are effective
3- Type of customer complaints.
4- Non-confirmed services
5- Results of internal and external audits.
6- Feedback of the system performance.
7- Development of new technology and the market strategy.
8- Checking the other necessary subjects.

7.7.2 Quality System

7.7.2.1 General

Quality system of MÜGESAN Engineering & Marine Specialist Co. Inc. was established in 1997 and Originally based on the service purposes. Later the present system was improved as a means of ensuring that services conforms to specified requirements of ISO 9002.

It means,

- Quality Assurance Manual (QAM) is prepared.

- The organisation charts prepared and personnel duties was carried out.

- Work's activities affecting the quality of services was carried out for each unit in the service chain as Equipment Working Procedures and Instructions.

- The identification and preparing of quality records such as the file and active systems are improved to fulfil on the order acceptance, service planning, process control, inspection and testing.

Quality Assurance and Certificate etc.

The establishment of a Quality System Intends systematic development of all the activities of the works.

7.7.2.2 Quality system procedures

Quality System Procedures are established and maintained to control all activities affecting the quality to meet the requirements of standard ISO 9002, 1997.

7.7.2.3 Quality planning

Quality Planning in work's activities affecting the quality of services was carried out according to the work's process flow chart as given in section 4.09

7.7.2.4 Arrangement of quality system

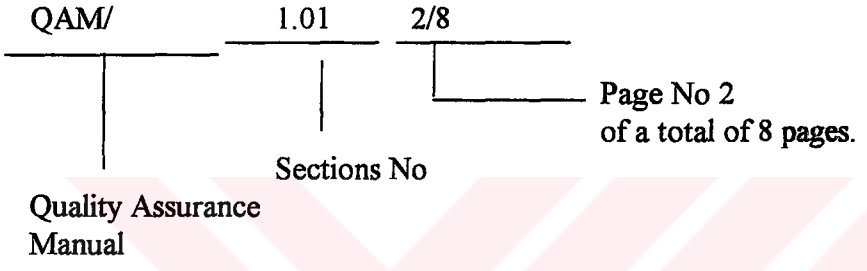
The quality system of MÜGESAN is organised in such a way that adequate and continuous control is exercised on all activities affecting quality. System arrangement can be described by means of manuals, computer based documentation, service planning, manufacturing and quality control.

7.7.2.5 Numbering of quality system documents

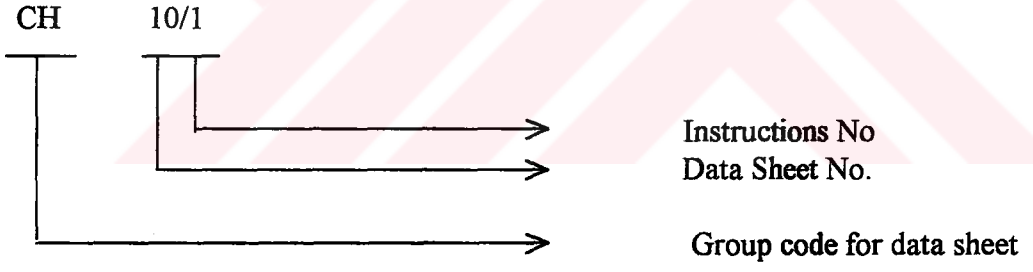
All Quality Documents are numbered on a base of friendly using. The section of the Quality Assurance Manual are numbered in accordance with the requirements of ISO 9002.

Other documents have identified alphabetically for each specific purpose and are not having capacity to changes in standards or organisations.

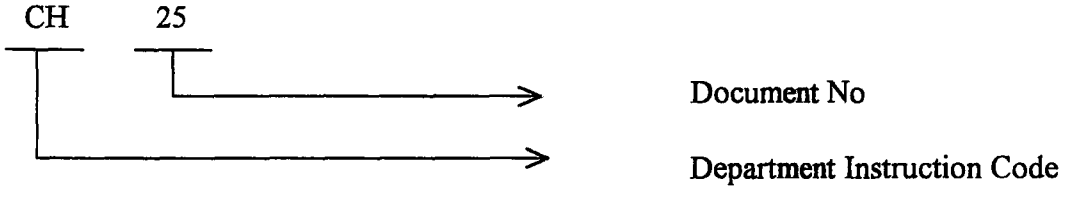
Example 1 " Manual Page"



Example 2 "Quality Data Sheet"



Example 3 "Work Instruction "



Identification of service is made on the base of heat no and remain intact from the time of initial receipt to delivery to final destination. Detail of service identification is given in section.

7.7.2.6 Dealing with complaints

Responsible service receives Customer complaints. Customer complaints is sent to Quality Assurance Coordinator as soon as the complaints arrives. Quality Assurance Coordinator carefully analysis the complaints by using the quality records. Final decision is given after comparing services quality with the requirements specified in the customer's order. Two possibilities are available in this case;

- The case Customer is right: In this case Quality Assurance Coordinator gives a summary report to the General Manager and Service Department about the type of the cause of the complaint, for information and corrective action in order to prevent recurrence.

- The Customer is not right: Quality Assurance Coordinator gives a clear report to the Service Department about the complaint in order to make a contract to the customer.

7.7.3 Contract Review

7.7.3.1 General

The Sales Department shall receive the pre-order specification from abroad & domestic customers. For an ordinary quality service's and product's order confirmation shall be given to the customer by Responsible Sales Department and Service Manager.

If customer's pre-order requirements need on additional technic verification at that time the Quality Control Department shall be received the Customer's requirements and determine whether servicing or manufacturing is possible in accordance with the order specification. The Quality Control Department Manager shall transmit the determination status to the Sales Department through the Service Manager to inform the customer.

7.7.3.2 Review

The main order confirmation of works is given with in the flow chart as;

- Order receive from foreign & domestic customer (on page 2/2)

7.7.3.3 Amendment to a contract

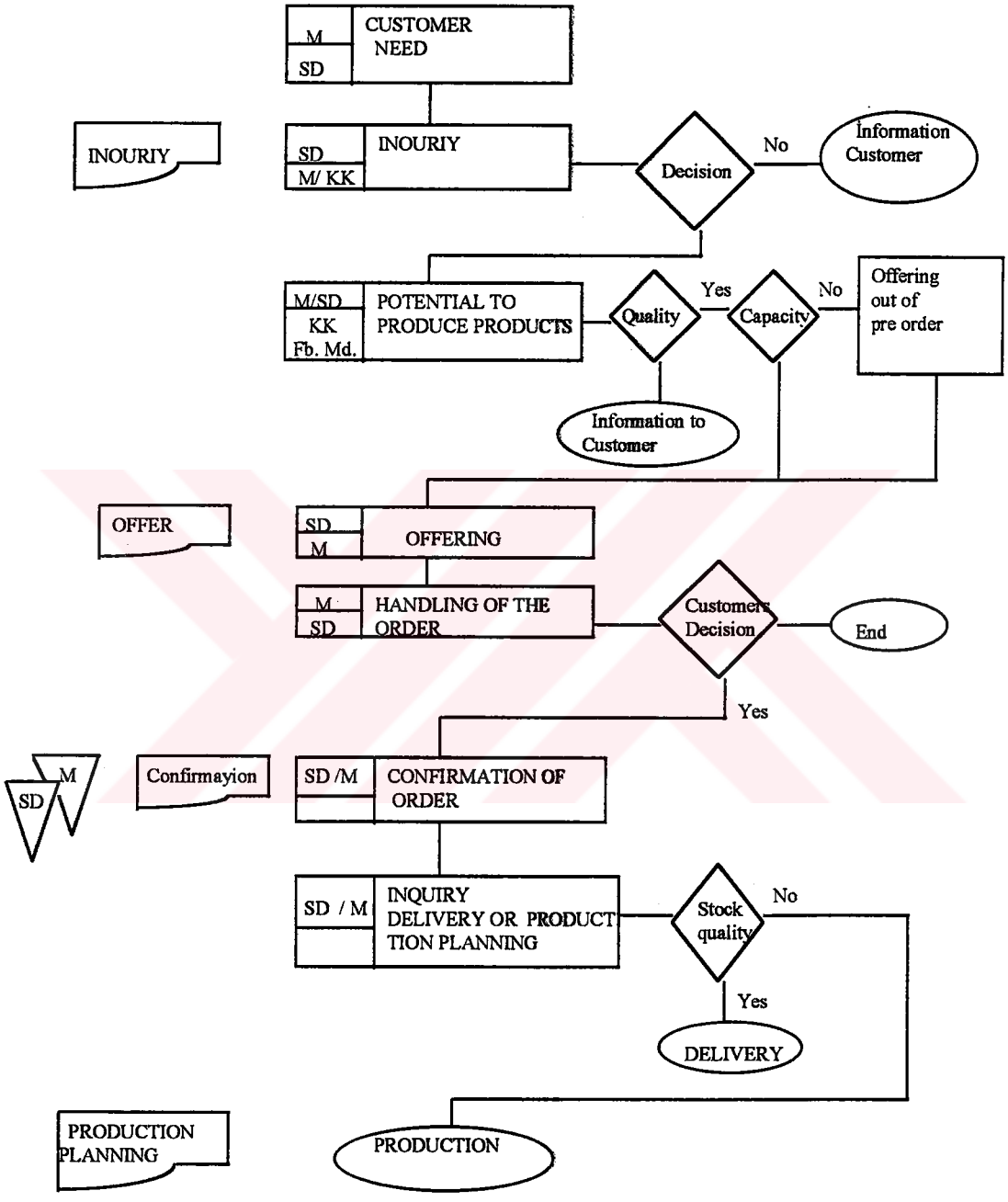
When the amendment is made an contract, the Sales Department correctly transferred it to the Quality Control Department through the Service Manager.

7.7.3.4 Records

Sales Department contract review records are saved in files and kept at least for 1 year.

Quality Assurance Manual QAM	Document No: MGSN-4.03
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Contract Review	

- The flow chart of the contract review for on order receive from foreign & domestic customer



Quality Assurance Manual QAM	Document No: MSN-4.04
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Design Control	

7.7.4 Design Control

The scope of design control is not used in our quality system and this action of ISO 9002 does not apply.

7.7.5 Document And Data Control

7.7.5.1 General

The procedures are established and maintained to control all documents and data that relate to the servicing activities affecting quality. Most of the time the following principles are applied:

- Service Manager is responsible for maintaining and identifying the documents concerned with quality.

- The responsibility of a document preparation changing, revision, cancellation and distribution is belonging to the person who has prepared and approved the original review and approval unless specifically designated otherwise.

-Documents are filed according to MÜGESAN Regulation in folders for one year.

- All the quality documents are reviewed and controlled yearly.

7.7.5.2 Permanent control of document and data

7.7.5.2.1 Quality assurance manual

The QAM shall be reviewed and controlled by Management Representative If necessary, changes are made to the relevant sections. When revised sections are issued holders of the copies are revised and updated absolute pages are requested to return to the Quality Department to ensure that no absolute versions are in use.

7.7.5.2.2 Quality data records

All quality instructions are maintained and kept in concerned department for specified period.
Quality Department is responsible for all quality instructions which are used at MUGESAN A.Ş.. The instructions are reviewed and approved for adequately by the quality Department and by the Department involved to issue.

7.7.5.2.3 Procedures

The procedures of MÜGESAN give more detailed description of the activities than the Quality Assurance Manual. They are included the description of activities affecting the quality for each unit is the service chain such as Working Procedures.

The procedures are prepared by the organisation Co-ordinates the activity and approved. Procedures copy are sent to the Quality Department.

7.7.5.2.4 Work instructions

Each Department has the responsibility for the preparation, approval and updating at work instructions. Work instruction folders kept by the departmental offices and The Quality Department office. Each Department Manager is responsible for maintaining and identifying the work instructions.

7.7.5.3 Control of order documents

Responsible Sales Department feed the customer's requirements into the works information system as described in section 4.03 Inquiry, offers and quality specifications are filed by related Sales Department.

Sales Department supplies the customer using the order confirmation from the information system. At the same time, internal works order is made for internal use by the Quality Department. Work's order, order confirmation and shipping documents are filed by the Sales Department.

7.7.6 Purchasing

7.7.6.1 General

The Quality System of MÜGESAN is considered that purchase materials, components and assemblies directly affect the quality of services. So MÜGESAN Quality System ensures that purchased products and service shall confirm to specified requirements, services and delivery accuracy of the subcontractor products and services.

Generally the following materials are acquired from the suppliers

- Product materials,
- Measuring and testing equipment
- Engineering Services
- Transportation Services
- Educational Services

A clear definition of the technical specification of purchased product and service are filed by Account Department and Service Department and Quality Department.

Responsible department gets contact to the subcontractors for acquired materials and services through Department Manager.

7.7.6.2 Specifications of requirements of product and service to of required

The Quality requirements for purchase materials are defined by pertinent Department which will virtually utilise the materials assisted by Quality Department.

7.7.6.3 Evaluation of subcontractors

Selection of Subcontractors shall be made in accordance with to secure competition at least between two subcontractors at any time by the purchasing department in consideration of the quality price and delivery

In long term the approval of subcontractors has done with the combination of the following information.

- Evaluation of subcontractor capability
- Evaluation of test results of similar subcontractor
- Past history with similar subcontractor
- The service experience

Before getting into the approved list, each subcontractor to answer an inquiry about his quality. Also certain products such as alloying elements and additions is assured by using reliable agent with receiving inspections.

On the basis at information collected from user experience, receiving inspections, and delivery accuracy is followed the decisions about the subcontractor and changes to receive inspection quality agreement are made in purchasing files.

7.7.6.4 Purchasing data

The main purchasing are made on a long-term basis. The technical specifications of purchased product and service are defined by the plant. The technical specifications are written and approved by the relevant department.

The offers of sub-contractors are examined by the Purchasing Department commercial basis and by the Plant on the technical basis.
All purchasing data are recorded in the information system to make inquiries to potential subcontractors which are used to select to subcontractor new purchase orders.

7.7.6.5 Verification of purchased product and service

Appropriate receiving inspection is established to ensure that purchased product and services which have been received are properly controlled by different organisations with adequately trained personnel, depending on the type of materials.

Most of the foreign purchased product and service verification are made by an independent inspection company due to the contract.

When the purchased product and service is not confirmed to specified requirement on the order a complaint is made after that the product and service is returned to the suppliers or used for another purpose.

The Purchasing Department is in charge of contacts with the subcontractor about a complaint.

The customer verification of subcontracted product and service item is not used by MÜGESAN.

Quality Assurance Manual /QAM	Document No: MGSN-4.07
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Customer Supplied Product	

7.7.7 CONTROL OF CUSTOMER SUPPLIED-PRODUCT

Customer-supplied product is not used by MÜGESAN and this action of ISO 9002 does not apply.

7.7.8 Product Identification And Traceability

7.7.8.1 General

All services & materials identified from initial stage to final product delivered to the customer. The control of the identification system established and maintained procedures for identifying the products during servicing. These systems may include the following checks:

- Correct identification occurs during manufacturing

- Materials are use correctly

- The planned production and inspection are taken

- Packaging, handling and storage are done according to the given instructions.

The Quality Control Department is responsible the control the identification system.

7.7.8.2 Identification during servicing

Purchased materials, equipment, goods and services are identified by and traceable to; purchase orders, requisitions, delivery notes and commercial invoices.

The degree of traceability is dependent upon the specific items and its importance with regard to quality, vessel operations, safety and the environment.

Equipment requiring certification is clearly identified in order to provide ready traceability to the appropriate certificate.

7.7.9 Process Control

7.7.9.1 General

The Service planning, manufacture, inspections and despatch activities are carried out under controlled conditions at MUGESAN A.Ş.. Control of production and despatching are carried out by production planning. Data changing from item to item are input by he order and inspection of products, reporting of non-conformance, control of corrective action are defined.

7.7.9.2 Service planning

Appropriate written procedures are available to all relevant personnel in order to ensure that those activities appertaining to their respective responsibilities, are carried out in a uniform and consistent manner at all times. These procedures and instructions describe the core activities of Service operations.

Where necessary, and to ensure that quality and safety services are maintained, formal work instructions and guidance notes have been issued to personnel to assist in the performance of their duties.

Instructions and guidance documentation supplement the quality and safety procedures and may be generally or specifically, applicable to the requirements of operations, maintenance, safety, manning, contracting and other related activities.

All personnel are responsible for ensuring their work is in accordance with Company quality Assurance management procedures and instructions.

Department Managers have specific responsibilities for checking and verifying work or services for which they are responsible as specified in Company procedures and instructions.

7.7.10 Inspection And Testing

7.7.10.1 Service inspection and testing

All material properties are inspected, by comparing taken based on the specified requirements of the purchasing documents.

Each purchasing materials which is used for production should be controlled before using. Materials are ordered according to specification and quality which is determined.

7.7.10.2 Inspection and test records

The measurements made in servicing process are kept in the test records.

Materials supplier certificate are given in addition to internal report. The chemical composition and mechanical test results, supplier, buyer, material type are written on quality documents.

Also a copy of the certificates are kept in the Quality Department records.

Material certificate type and material standards will determine the inspections and testing amount. Inspection and testing requirements are specified in the standards.

7.7.11 Control Of Inspection, Measuring And Test Equipment

7.7.11.1 Measuring and test equipment

All chemical and mechanical analysis are made in the Quality Control Laboratories.

7.7.11.2 Registration, storing and using

All measuring equipment used in servicing & production which effects the service & product quality is recorded in lists. On these lists, the equipment type calibration frequency, measuring range and accuracy is indicated along with the responsible person for calibration.

Quality Department is responsible for records and recordings, use, calibration of test equipment and storing. Usage of equipment and training of users are done according to written instructions.

Measuring and testing equipment is used by only qualified personnel.

7.7.11.3 Measuring and test equipment calibration

7.7.11.3.1 General

The equipment for the measurement of the properties of semi and final products and before and after servicing are ensured to fit for use by Quality Control Department.

The Quality Control Department is responsible for systematic equipment calibration and record.

7.7.11.3.2 Mechanical workshop equipment

The mechanical properties of product are tested in Quality Mechanical testing Laboratory. The annual calibration of mechanical testing machine is made by Turkish Standard Institute.

The calibration records are filed by the Department. In addition, internal calibrations are carried out at prescribed intervals.

7.7.12 Inspection And Test Status

7.7.12.1 Record inspection

The record inspection status of equipment is readily available by reference to the appropriate survey certificates, inspection reports, planned maintenance data, records, logs, and results of internal quality and safety audits.

The inspection status of purchased goods, materials, equipment and services is readily available by reference to receipt records.

Quality Assurance Manual QAM	Document No: MGSN-4.13
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Nonconforming Product	

7.7.13 Control Of Nonconforming Product

7.7.13.1 Control of nonconforming product

The main idea is to keep the specification of intermediate and final services and products are based on customer request in order. Services or Products which do not comply with the specified requirements at semi or final inspections are directed to reinspection regarding. All rejected products are recorded and deleted from the order and Quality Control Department starts the production of a substitute product.

Inspection staff has got the sufficient instructions about the correctness of acceptance and rejection limits from Quality Control Department.

The reason for rejection is recorded. Also minor defects do not effect in rejection are reported. Related order information is got out from the rejected product, by cancelling the quality and inspection tags. The instruction for regarding are in the responsibility of the Quality Department.

Finding nonconformities during testing are held in accordance with resetting rules according to the standards. If a product has a minor defect which does not essentially effect its quality such a dimensional deviation and surface quality, Sales Department will contact to the customer to find out whether such a product is useable or not. Further action will be taken according to the customer decision.

7.7.14 Corrective And Preventive Actions

7.7.14.1 General

It is important that the causes of nonconformity are investigated for MUGESAN Works. Recurrence of non-conformities are only prevented by eliminating and detecting the causes of non-conforming service.

As soon as the individual non-conformities are seen which is given serious economic results are immediately deal with at meetings between related departments for searching the causes. After investigating the cause and statues of non-confirming the usual procedures is to written a report to take a paper action for correction. The suggesting report is gives to the related units.

All non-conformity reports are deal with at regular monthly quality meeting.

7.7.14.2 Work process and analysis of processes

Quality of products are partly dependent on the condition of production equipment. Related Departments are responsible for process control, control of process parameters and corrective action. The Quality Control Department is responsible to ensure the necessary requirement placed on the manufacturing process parameters for the controlling the product quality according to the customer requirements.

If the corrective action is required the decision about investigating the cause of nonconformity and the corrective actions is made by the person in charge of the activity together with the responsible Quality Control Department person.

7.7.14.3 Corrective action

7.7.14.3.1 Corrective action on services

Reporting, corrective action and the planning to repair for service equipment have been done with using the preventive information system.

Service operation defects come into existence in working process due to wrong work methods and faulty instructions from unknowledgement. Necessary corrective activities are decided in a meeting between the Quality Control Department and related Department. Related Department is responsible for the preparation, checking, approval and implementation of a new instructions and procedure.

7.7.14.3.2 Corrective action on products

The functions of effected quality and relevant instructions are usually done by the Quality Control Department. The function of Quality Control Department is to start the corrective action and ensure that the necessary changes are carried out. Changes are planned and carried out by the personnel who is responsible in the production organisation. Big changes are planned, decided and documented in co-operation with affinity departments of the works.

7.7.14.4 Preventive action

The quality-related problem or causes are determined before occurring the nonconformities on product This required careful analysis of the product specification and all related processes operations, quality records, and customer complaints.

Appropriate steps are taken and used to eliminate potential causes of nonconformities. The results of the investigation is recorded.

Quality Assurance Manual QAM	Document No: MGSN-4.15
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Handling, Storage, Packaging Preservation and Delivery	

7.7.15 Handling, storage, packaging, preservation and delivery

7.7.15.1 Handling

Handling methods and equipment for services and products are chosen safety. The basic handling equipment are crane or lifting machines as such as forklift.

7.7.15.2 Storage and packaging

Storage areas for finished products are located under the crane area for easy delivery. Storage is controlled and reported.

Packaging is done partly by automatic machines and manually.

7.7.15.3 Preservation

Stored product are controlled for preservation at product according to quality and safely in closed area.

7.7.15.4 Delivery

Delivering of products is based on agreed delivery orders. Quality Department is responsible for planning to delivery. The execution of deliveries is the responsibility of affinity.

Delivery documents and loading instructions can only be obtained when all the planned inspections and tests have been carried out.

Quality Assurance Manual QAM	Document No: MGSN-4.16
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Quality Records	

7.7.16 Control Of Quality Records

7.7.16.1 General

Mugesan has placed definite necessary requirements on documentation. Documentation's will show that,

- The service and product has been manufactured in conformity with order specifications.
- The qualified personnel, work methods and equipment meet the requirements
- Corrective or other actions on non-confirming products have been taken it right away
- Necessary attention has been paid to prevent the products defects.

The quality dairies are recorded

The summary reports are made systematically at agreed intervals.

General directions for the filling at documents are given in the company's filling works.

7.7.16.2 Service records

Servicing to the marine industry are of a continuous nature, so the control systems must have continuos reporting facilities. Also Reports include Quality data. Inspected records are used servicing process to control and development.

The servicing records are saved in files by date sorting and are kept for minimum 5 year.

7.7.16.3 Quality inspection and assurance records

The direct surveillance and measurement results are recorded on paper documents. The information needed id find out easily from the list of the jobs performed. These records are kept for 5 year. Surveillance and rejections due to nonconformity are registered analysed and reported.

The most important data for the customer's is inspection and testing data which show that the specified requirements are met. The Quality Control Department is responsible for the collection and filing data.

Quality Assurance Manual QAM	Document No: MGSN-4.16
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Quality Records	

7.7.16.4 Educational records

The educational records are at the each personal departments.

The material certificate and the surrounded inspection reports show that the material meets the specified requirements. the material certificate is kept 1 year as copy paper.

Calibration records are filed by the Quality Department. also the reports of external quality audits are filed by Quality Department.

Quality system is planned to meet the requirements of standard ISO 9002: 1994, All the policies are under stood, maintained and implemented at all levels of the organisation.

Quality Assurance Manual QAM	Document No: MGSN-4.17
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Internal Quality Audits	

7.7.17 Quality Audits

7.7.17.1 Planning of internal audits

Internal quality audits at MUGESAN are planned to be carried out in conformity with an annual plan made for each year. In the audit plan according to be Work's activities are made once year for each department

The Corporate Quality Coordinator is responsible for the preparation of internal audit annual plan and the audit personnel is selected by evaluation panel which consists general manager, Quality Control and management representative. The audit will be carried out upon the basis of Quality Assurance Manual ISO 9002 1st August, 1994 dated and ISO 10011 1992 dated Standards.

7.7.17.2 Conduct of audits

Internal quality audits are usually provided in Co-operation with the department audited.

During the audit the departments are visited and working methods and work instructions evaluated in practice. Internal audit are normally carried out in working time.

During the internal audit deficiencies are found and identified. Then an audit reports is written and given to the affinity department.

7.7.17.3 Follow-up corrective action

The Quality Control Department find out effectiveness of corrective action is not taken by the time fixed, a new schedule is agreed upon and the corrective action concerned will be put under special monitoring. A lot of delayed corrective is prepared and disturbed to the managers of the responsibility concerned and where necessary presented at the general manager.

7.7.17.4 Evaluating auditor candidates

Evaluating auditor candidates at MUGESAN are made after at least four audits together with lead auditor.

7.7.17.5 External quality audits

An audits of the Quality System of MUGESAN are carried out annually by certified persons, authorities and customer's. This societies carry out regular audits of the whole Quality Assurance System.

Quality Assurance Manual QAM	Document No: MGSN-4.18
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Training	

7.7.18 Training

7.7.18.1 Basic education and initiation

Basic Education and initiation the workers of MUGESAN, especially those having jobs in production or quality inspection have received basic occupational education.

Before starting independent work, a new worker who is changing jobs is given occupational guideline by a trained engineer.

7.7.18.2 Further training

A training strategy for different categories of personnel is prepared annually by the Quality Control Department. Training is given partly by external trainer organisation and partly within the company. The number of training days varies from 5-10 days a year depending on the personnel category.

Quality Assurance Manual QAM	Document No: MGSN-4.19
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Servicing	

7.7.19 Servicing

Servicing is not used by MUGESAN and this action of ISO 9002 does not apply.

7.7.20 Statistical techniques

7.7.20.1 Statistical sampling

Product's samples are taken according to the Customer requirements and Standards. Mechanical testing and chemical analysis are determined by using these samples.

Mechanical test results such as, tensile strength, yield strength, elongation, bending are carried out according to the rules of the standards are used in a manufacturing program.

7.7.20.2 Analysis of quality data

All the test results and measurement explanations for the reject of the product are recorded. The statistical analysis which is got from these records are summarised monthly and yearly reports.

Quality Control cards which are held for daily purposes are statically analysed and used for monitoring process and quality control.

7.7.20.3 Statistical quality control

Specific statistical quality control methods have been used for each servicing and production stage by the Quality Control Department. By having statistical quality control get feedback about the works and so that most productive work is done for the achievement of qualify products.

Quality Assurance Procedures	Document No: MGSN-501
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Management Responsibility & Authority	QP01

7.8.1.1 Purpose

To set the Company quality objectives and establish an organisation structure which identifies key personal, ensures that adequate resources are available and ensures that reviews take place to verify the effectiveness of the system.

7.8.1.2 Scope

The procedure covers all system elements determined by ISO 9002 (1994).

7.8.1.3 Responsibility

General Manager hold joint responsibility for the quality, safety and organisational policy of the Company and ensures that those within it are formally identified and the system reviewed for effectiveness.

The Company Quality Assurance Manager ensures that the content of the quality system is maintained, operated and updated as necessary and all employees are aware of its requirements.

7.8.1.4 Procedure

7.8.1.4.1 Quality policy

The Company has drawn up and published a Quality Assurance Policy Statement which addresses the needs of the organisation and demonstrates the Company's commitment to these objectives. This statement is signed by the General Manager.

7.8.1.4.2 Responsibility and authority

Personnel have been appointed who have the responsibility and authority for controlling key areas of the quality assurance system.

The position and status of these persons is illustrated on the Company's organisation chart.

Authorities and responsibilities of all personnel who manages, performs and verifies their duties in the Quality Assurance System are clearly stated in this procedure and have been drawn up and agreed by the respective individuals.

The main aim of configuring job descriptions can be defined as follows:

1. The control and maintenance of the Company's Quality Assurance System with emphasis on preventive measures.

2. Control of non conformance's and corrective actions with emphasis on preventing recurrences of quality system deficiencies.

3. Measures to ensure that any implemented corrective action is effective.

4. Management reviews which identify system weaknesses eliminate such weaknesses and ensures the effectiveness of the Quality Assurance System.

7.8.1.4.3 Responsibilities

The responsibilities and authority of each designated position in the management system which has particular influence on the quality of service and the effectiveness of the Quality Assurance System is defined below.

7.8.1.4.3.1 General manager

1-) Responsible to the Main Board of The Company for the efficient and economical running of the Company.

2-) Responsible for the Quality Assurance Policy and providing the infrastructure required to enable the Company to meet its desired objectives and stated aims of providing a quality service to its Customers.

3-) In liaison with the other Managers producing and developing projects, budgets and determining the training requirements for all personnel.

4-) Representing the Company's interests on official occasions.

5-) In order to implement the Quality Assurance System effectively, he shall provide the necessary resources (including personnel) and support for the Quality Assurance Manager to carry out his functions.

6-) In order to evaluate the performance and improve the Quality Assurance System, he shall review the system.

7-) In order to configure the proper implementation of Quality Assurance System, he shall select and arrange the adequate personnel.

In the absence of the General Manager, Service Manager shall act on his behalf depending on the nature of the business to be attended.

7.8.1.4.3.2 Service manager

Responsible to the Managing Director for the efficient and economical operation and maintenance of the Company's jobs, including planning, technical support and agency operations.

The Service Manager has been nominated as the Quality Assurance Manager and as such has direct access to the General Manager for all matters relating to quality.

7.8.1.4.3.3 Secretary

Responsible to the Service Manager for handling the social requirements relating to personnel, attending to all communications in and out of the Company and indexing and organising department files and records. Also responsible for the electronic recording of data in the department.

7.8.1.4.4 Verification of resources and personnel

The Company identifies resources for verifying that the services provided are in accordance with the Company's quality objectives.

Adequately trained personnel are available to carry out verification checks on contracts and orders, safety and internal quality and safety auditing.

7.8.1.4.5 Management review

The Quality Assurance System is reviewed at six monthly intervals.
The Management Review is carried out at a meeting convened by the General Manager who chairs the meeting and ensures the attendance of appropriate key personnel.
The Agenda for the meeting is prepared by the Quality Assurance Manager and circulated in advance, accompanied by summary records or reports which are to be part of the discussion.
The Agenda includes but is not limited to the following items:-

-Review of the Minutes of the previous meeting and progress on the actions carried forward.
-Review of the reports on internal Quality and Safety audits.
-Review of summaries of non-conformance's.
-Review of corrective actions taken since the previous meeting.
-Review of suppliers and sub-contractors performances.
-Review of training and training requirements.
-Review of any complaints from Customers

7.8.2.1 Purpose

To ensure that the Company establishes and maintains control of its activities through the operation of a formalised and documented Quality System.

7.8.2.2 Scope

All activities performed by and operated by the Company to provide the prescribed services which fall within the scope and field of application of the Company's Quality System Registration.

7.8.2.3 Responsibility

The overall responsibility for the policy and administration of the Quality System is that of the General Manager, whilst the Quality Assurance Manager, is responsible to the General Manager for the day to day operation and maintenance of the system.

All employees bear individual responsibility for the quality of their work and this is adequately defined in the Procedures Manual and third level documentation.

7.8.2.4 Procedure

The Quality System is designed to :

a) Satisfy the Company's objectives to attain and maintain the desired quality at optimum cost.

b) To meet the Customer's needs for confidence in the ability of the Company to provide the desired quality of services and support as well as consistently maintaining that quality.

This is achieved by the implementation and maintenance of a documented Quality System which provides objective evidence that the Quality System is operating effectively.

The Quality Assurance Manual sets out policy and gives an overview of the Quality Assurance System with reference in each section to the relevant procedures.

Quality Assurance Procedures	**Document No:** MGSN-502
Issued By: Quality Assurance Manager	**Approved By:** General Manager
Title: Quality System	**QP02**

The Company's Quality and Safety Procedures Manual gives details of working practices and systems at all levels of the Company's core activities. The format of the Procedures follows these headings and each will describe :

1. PURPOSE
2. SCOPE
3. RESPONSIBILITY
4. THE PROCEDURE
5. RECORDS

The Procedures are numbered and indexed and all associated documentation is given be spoke reference numbering.

Key elements which provide further work instructions and training are defined in the various third level documentation.

The documented Quality Assurance System is an integral part of the Company's Management System and is designed to ensure that all services meet the Customer's specified requirements. To achieve this, the following actions are taken:

1. The identification and acquisition of any controls, equipment or skills that may be needed to achieve the desired quality.

2. Updating and development of inspection and testing techniques as found necessary.

3. Clarification of standards of acceptability for all requirements.

4. Identification and preparation of Quality and Safety Records.

7.8.3.1 Purpose

To ensure that all Customer requirements will be adequately documented and reviewed in order to fully understand the specification and to ensure any requirements differing from the original agreement are resolved.

7.8.3.2 Scope

This procedure defines the activities and controls necessary to carry out a review of the contracts which include Management Agreements with Principals, Contracts with Suppliers, Sub-contractors and personnel.

7.8.3.3 Responsibilities

The General Manager in liaison with the departmental Managers is responsible for negotiating on behalf of the Company and signing major Agreements. Departmental Managers are responsible for conducting and signing Agreements with capital values as determined from time to time by the Managing Director. All Managers are responsible for ensuring that contracts and agreements are regularly reviewed to ensure continued compliance by both parties to the agreed terms.

7.8.3.4 Procedure

7.8.3.4.1 Introduction

Reviews of major contracts will be conducted annually and Principal concerns will be discussed and minutes will be taken.

The Company will be required to comply with such contracts or agreements as are current and this compliance will be monitored by the senior management.

Where requirements are sub-contracted to second parties, these are also closely monitored to ensure that the Company's standard of service is not compromised.

Quality Assurance Procedures	**Document No:** MGSN-504
Issued By: Quality Assurance Manager	**Approved By:** General Manager
Title: Design Control	**QP04**

7.8.4 Design Control

The Company is not concerned with Design Control and therefore this requirement of the standard is not applicable and is not addressed in the Quality and Safety Management System.

Quality Assurance Procedures	Document No: MGSN-505
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Document and Data Control	QP05

7.8.5.1 Purpose

To ensure that all documentation relating to the Company's Quality System is promptly reviewed and properly controlled.
This will be achieved by :
This procedure is intended to facilitate the preparation, issue, distribution, upkeep, revision, and abolition of management documents and the distribution, custody, and verification of other documents and drawings in accordance with Document Management.

a) Ensuring that documentation is approved prior to its use.

b) Making certain that the issue status of the documented Quality Management System is known by all custodians of the Quality Management System documentation.

c) Informing and issuing all custodians of controlled Quality Management System documents with changes to the system which they will be responsible for inserting in the relevant manual and entering a record of the action.

d) Ensuring that all obsolete documents are withdrawn from use.

7.8.5.2 Scope

Quality Assurance Documents shall include internal company regulations procedures, circulars, and other official documents; publications related to Quality Assurance System, other documents and drawings.

7.8.5.3 Responsibilities

The Company's Quality Assurance Manager is responsible for the issue of Quality Assurance System documents and their retrieval when obsolete.
The Quality Assurance Manager shall be responsible for the control of all quality management documents. The establishment, upkeep, revision, and abolition of management documents must be carried out only with the Quality Assurance Manager's approval.

Each Department Managers is responsible for ensuring all drawings, plans circulars and material that affect the Quality Management System are controlled from issue through to disposal.

Each departmental Managers is responsible for identifying the need for the revision and amendment of documentation.

7.8.5.4 Procedure

7.8.5.4.1 Quality System

The Quality Management System has been documented in two levels,

LEVEL 1 Quality Management Policy Manual.
LEVEL 2 Quality Management Procedures Manual

Company shall ensure that all valid documents are available at all departments of the company. The provision or lending of management documents or copies thereof to unrelated persons shall be prohibited.

The custody and control of each management document shall be the responsibility of the manager of the department that proposed the document and is directly connected with it. The custody location shall be determined by the relevant departmental manager.

Any queries about the contents of a management document shall be communicated to the Quality Assurance Manager in writing and resolved. The answer(s) shall be retained in writing.

Every document and publication related to Quality Management System shall be distributed together with a Distribution Notice and the accompanying receipt. Upon receipt of a document, each departmental Manager shall promptly sign or affix his seal to the receipt and return it to the Quality Assurance Manager. The Quality Assurance Manager shall treat this receipt as proof that the relevant document was distributed correctly.

The retention period of the management documents is only a year. After the expiry of retention period, the documents will be stored in the archives.

If any document related to Quality Assurance System is revised or abolished, Quality Assurance Manager shall enter the necessary items on a Revision/Abolition Notice. For documents whose revision or abolition has been approved, the necessary items shall be entered in a Revision Record and the Revision Record shall be distributed together with the revised document.

Every document transmitted from the company (including documents sent by facsimile) shall bear the abbreviated names of departments followed by the year and a communication number.

A Document Distribution Notice of each copy of the Company's Quality Management System is maintained to ensure effective control of the distribution and to provided traceability for updating.

Quality Assurance Procedures	Document No: MGSN-505
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Document and Data Control	QP05

Procedures will only be issued to third parties other than an appropriate accreditation body, with the express permission of the Quality Assurance Manager who will first seek the permission of the General Manager.

The Quality Assurance Manager is responsible for ensuring that appropriate Procedures, associated documents and forms technical references national rules and regulations and any operating instructions are available at the required point of use.

Record sheets and forms raised by the Company not clearly titled or referenced previously, will if used within the Quality Assurance System carry the unique reference number which identify the procedure number.

The Quality Assurance Manager holds the master copy of the system and on receipt of a document change request checks, the issue status of such request against the master copy for compatibility.

The Quality Assurance Manager allocates the request a sequential number from the request. Quality Assurance Manager then processes the request and alter discussion with relevant involved personnel, decides upon a course of action.

If the request is approved, the appropriate pages are amended and distributed to all holders of the affected documentation.

Where request are rejected, the person initiating the request will be notified of the reason for rejection.

The document request changes is replied by the Quality Assurance Manager who files the original and forwards a copy.

It is the responsibility of the holders to insert updated pages on receipt and send the abolished ones to Company.

Quality Assurance Procedures	Document No: MGSN-506
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Purchasing	QP06

7.8.6.1 Purpose

The purpose of this procedure is to describe the responsibilities and actions necessary for the appropriate control of purchasing, to ensure that purchased goods, materials or services conform with the Company's specified requirements and that appointment of suppliers/ sub-contractors is controlled, approved and reviewed by the Company.

7.8.6.2 Scope

This procedure covers the control of purchasing of goods, materials and services from suppliers and sub-contractors providing services to the Company.

7.8.6.3 Responsibilities

Department Managers are responsible for ensuring that this procedure are fully complied with, as they apply to their departments and personnel.

The Quality Assurance Manager is responsible for ensuring the requirements of this procedure are effective and are maintained.

7.8.6.4 Procedure

7.8.6.4.1 General

The main objectives of this procedure are :

a) To ensure the Company is able to exercise control in the purchase of goods or services that are instrumental to the Company's quality objectives.

b) To produce a mechanism for quality assessment and ongoing monitoring of performance of all suppliers/ sub-contractors and the maintenance of the approved suppliers/ subcontractors by the responsible Department Head.

c) To ensure that orders are placed where possible only with those companies on the approved Suppliers List and purchase orders are issued in a controlled manner.

7.8.6.4.2 Purchase requisitions

The Accounting Department will arrange payment of supplies or services in accordance with the Company's agreed terms of payment after receiving signed authorisation by the Service Manager that the goods have been received by the Company.

7.8.6.4.3 Assessment of suppliers / sub-contractors

The Company will maintain a list of approved suppliers which will include

Details of address, contact, phone and fax numbers
Scope of supply
Assessment category (A, B or X)
Approved by

Assessment of suppliers will be made to determine the suppliers ability to meet the Company's requirements including Quality requirements.

Established suppliers have been categorised and approved by the relevant Managers and appear on the current Approved Suppliers List.

All suppliers other than those utilised in an emergency will be approved by the relevant Manager. Where a supplier/ sub-contractor not on the approved list has to be used in an emergency, the degree of monitoring of their service will be increased to ensure the Company requirements are met.

The down grading of a supplier as a result of poor performance may be carried out by the responsible Manager at any time either as a result of his own experience or as result of feed back from a Company employee.

Biannual Management Review meetings will address the poor performance of suppliers and sub-contractors to relevant departments and appropriate action will be taken to ensure the maintenance of MÜGESAN standards.

7.8.6.5 Record

Stores Indents
Purchase Orders
Delivery Notes
Invoices
Approved List of Suppliers/ Sub-contractors

Quality Assurance Procedures	Document No: MGSN-507
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Customer Supplied Product/ Service	QP07

7.8.7.1 Purpose

To describe how the Company shall take care of all Customer supplied goods services, information/ data and maintain and care for it until returned to the Customer or declared obsolete by the appropriate Department Manager.

7.8.7.2 Scope

This procedure covers Customer's supplied goods/ services and information relevant to specific operations in the management of vessels.

7.8.7.3 Responsibility

Each Department Managers are responsible for ensuring that all employees are aware of their responsibilities with regard to this requirement the Quality Assurance Manager is responsible for monitoring this procedure to ensure that it is consistently complied with and that the Company's Quality Assurance System remains effective.

7.8.7.4 Procedure

In order to comply with the requirements, the Company will operate a Quality System which will ensure that all employees know what is expected of them and will provide, objective evidence of such compliance.

Adequate records of all information or data supplied by the Customer will be maintained.

7.8.7.5 Records

Trading Certificates
Maintenance Reports
Company Instructions

Quality Assurance Procedures	Document No: MGSN-508
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Identification and Traceability	QP08

7.8.8.1 Purpose

To ensure documented procedures are established for all operational activities provided by the Company to ensure an adequate degree of identification and traceability of all services provided.

7.8.8.2 Scope

This procedure describes all services which the Company provides to its customers all stages of these services.

7.8.8.3 Responsibility

The General Manager will be responsible in liaison with the relevant Departmental Managers for establishing the system for determining and identifying relevant documents and files. All employees will be responsible for ensuring that records are identified in accordance with the Company's Procedures and the Quality Assurance Manager will ensure that the Company Procedures as they apply to this requirement are correctly followed and monitored for effectiveness.

7.8.8.4 Procedure

Services will be traceable to log books, inspections and reporting forms issued by the Company and by external parties.

7.8.8.5 Records

Purchase Orders
Delivery Notes
Personnel Records
Reporting Forms

7.8.9.1 Purpose

To ensure that all operations that have an affect on quality and safety are carried out under controlled conditions and where appropriate to specific working instructions.

7.8.9.2 Scope

The range of core activities identified in Procedures QP09.1

7.8.9.3 Responsibility

The General Manager in liaison with the Department Managers is responsible for the overall operation of the Company's services.

Each employee is responsible for the tasks for which they have been engaged to perform.

The Quality Assurance Manager will be responsible for monitoring the Quality System and ensuring that it is effective and continues to remain effective

7.8.9.4 Procedure

Appropriate written documentation as detailed in QP02 level two documentation will be available to all relevant personnel in order to ensure that those activities for which they have a responsibility are carried out safely, correctly and consistently.

Where necessary and in order to ensure that the quality of service is maintained, formal rules, instructions and relevant data are issued to personnel to assist in the performance of their duties. These instructions supplement procedures and may be generally applicable or specifically applicable to the requirements of a contract.

Although each member of the Company is responsible for ensuring that their work is in accordance with the International and National Rules, procedures, and instructions, the Department Managers have specific responsibility for checking work carried out for which they have overall responsibility.

The Company will ensure that all personnel delegated to perform any activity are qualified and competent to do so.

7.8.9.5 Records

The records generated in each Process Control procedure are identified in the procedure and filed within the Company filing system.
QP05 and QP16 summarise the system of filing and record keeping, where records are located, their retention period and method of disposal.

7.8.9.1.1 Purpose

To establish a system which ensures that taking Ultrasonic Thickness Measurement Work is carried out in an efficient and effective manner.

7.8.9.1.2 Scope

This procedure describes the activities and controls identified with taking Ultrasonic Thickness Measurement work.

7.8.9.1.3 Responsibility

The General Manager is responsible for ensuring that adequate resources are available to meet the requirements of the Company's Quality Management Policy and related maintenance procedures with special emphasis on safety and pollution prevention.

It is the responsibility of Quality Assurance Manager to revise/update this document whenever there is need to do that. However, all registered holders are obliged to inform her/his superior or general manager. Whenever she/he feels that a change shall be effected to this QM for improving routines/systems described here in relevant to his duties.

7.8.9.1.4 Procedure

7.8.9.1.4.1 General

The Company's objective is to maintain all vessels in a consistently safe, efficient and cost effective manner in compliance with all current international, national, classification and Company rules and regulations.

7.8.9.1.4.2 Thickness measurement of hull structure

Company gets order from the owner. After that manager appoints an operator who is on the queue to the next job or available. According to the operator available, the thickness measurement are accepted.

7.8.9.1.4.3 Survey preparation guidance

There may be a meeting can be organised between Manager or Operator, superintendent of the ship and class surveyor. The vessel condition, some recommendation, if available, original thickness, acceptable minimum thickness or maximum acceptable diminution of the subjected steel thickness diminution, in order to see the result on the thickness measuring forms, safety precautions , access

instructions and other important things, which may be mentioned by the other persons, can be discussed in this meeting.

Procedure of work can be considered as special survey period, intermediate survey period, annual survey period and recommendation survey to be taken from hull structure. Bulk carrier and tankers need more attention then general cargo ship or small tonnage of ships..

Operators gets necessary drawings from the vessel / shipowner / manager office and prepare copies of them in order to put figures on it. If there is missing drawing, operator prepare sketch for the same. Manager and operator check all possibilities and difficulties on the drawings, operator listen to the manager carefully. If he has any question, discuss with manager. If it is necessary, they both discuss solutions with the surveyor and what the surveyor needs additional.

Every operator follows forms during their work on board that all papers are taken from classification rules and briefly all contains same procedure.

Operator is ready to go board and start his job after discussion according to the readiness of the vessel.

7.8.9.1.4.4 Liaison with surveyors

Manager or operator discuss extend of the job with classification surveyor and ask surveyor the amount of acceptable minimum thickness or maximum acceptable diminution in order to see the result on the thickness measuring forms.

Beside this annex, surveyor may ask additional thickness measurement according to the condition of the vessel, age of vessel and the condition of the coating. Diversely if the vessel condition, the coating condition or the thickness gauged are found satisfactory, surveyor may ask reduce at the amount of the thickness measurement.
If age of vessel, is getting old, needs more check and more thickness measurement and operator must be very carefully.

7.8.9.1.4.5 Selection of points for measurement

According to the Thickness measurement requirements, detailed in the tables of survey condition of the classification societies, the plates and other structural members, which is going to be measured, are selected. This points will be noted by the operator and will be printed on place.

The details of how the measure are also given in the tables TT-01 ~ TT-10.

7.8.9.1.4.6 Safety aspects

First the personal safety is the most important factor to be protected. The safety precautions must be taken into consider in all kind of vessels. The health and safety precautions, which the vessel crews and officers take care, must be given and explained to the operator by the safety officer before beginning of the thickness gauging.

In case of emergency situations, one of the crew must attend the operator to prevent any damage. The safety controls must be done before the entrance of enclosed spaces by the vessel, like checking of the explosiveness of the tanks, the air quantity in the tanks etc. and the operator must inform the safety officer or the related persons before entering of enclosed spaces, ballast tanks and cargo tanks especially oil / chemical tankers.

The safety shoes, safety hat and glove must be used always by the operator on board of the vessel. If there is a need for use of the ladder, which must be supplied by the vessel. the safety belt must be used by the operator. The slippage of the ladder must be restricted by the helper. In order to gauge the members in the cargo tanks of tanker. the boat can be used. In this case the operator must wear life-jacket.

7.8.9.1.4.7 Access Instruction

The necessary access, like cherry-picker for the area of the upper part of the hold frames and longitudinals under the topside tank bottom, boat for the transverse members in the area of cargo and ballast tanks of the oil tankers, etc. will be supplied by the ship.

7.8.9.1.4.8 Preparation of fitted or corroded surfaces

If there is to much scale or pitting on the surfaces, the vessel will be informed to clean the surface and the condition of the surface must be informed to the surveyor. If there is a pitted or corroded steel in small size, the surface will be cleaned and grinded by hand tool, which is prepared for the thickness measurement. After gauging, this measurement must be noted on the steel and by the operator to warn the surveyor / superintendent in order to be less than acceptable minimum thickness.

7.8.9.1.4.9 Preservation of coatings

After the checking of the points, by the surveyor, if there is no need to renew or cut the plates or members, the vessel crew must paint these points in order to preserve the coatings.

Quality Assurance Procedures	Document No: MGSN-509-1
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Process Control (Ultrasonic Digital Thickness Measurement)	QP09-1

7.8.9.1.4.10 Measurement through coatings

If there is a low scale on the surfaces and these are accepted by the surveyor, the measurement will be done by our equipment, ECLIPSE TG-2, without removing the coatings. All the plates must be measured by the equipment, ECLIPSE TG-2. The other equipment are not capable to measure through coatings.

7.8.9.1.4.11 UT equipment calibration, annual & on site

The equipment calibration will be done according to the manufacturer information by the institutes or the manufacturer, which is capable to calibrate. Also the certificate must be sent to the class societies.

On site calibration, must be done by the calibration block on every 20 measurement and every entry through the tanks / holds and checked every exit of the tanks / holds.

The calibration block temperature and the measured surface temperature must be equal, in order to have the right calibration.

7.8.9.1.4.12 Derivation of original thickness

If there is a big derivation between the measured thickness and original thickness, the surveyor must be informed. According to the instructions given by the surveyor. The measurement will be continued.

Operator makes enough copies of thickness measuring forms, which are to be used to prepare computer file or ship's history for classification or owner.

7.8.9.1.4.13 Thickness measuring forms

Operator makes enough copies of thickness measuring forms which are to be used to prepare computer file or ship's history for classification or owner. The operator will note the gauging points to his records and the records, which is taken on site by the operator, will be kept separately like thickness measurement forms.

All total 10 different forms, excluding cover page, as company presentation letter page and index page. All forms are computerised. When operator prepares work copies, himself or computer man copy the pages into the computer and print the pages and make 4 (Four) edition. Computer man get copies to the vessel's classification society. The society keeps 3 (Three) copy for their procedure and after approval gives last copy back for company's file.

Quality Assurance Procedures	Document No: MGSN-509-1
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Process Control (Ultrasonic Digital Thickness Measurement)	QP09-1

Form identifications are starting with first letter of thickness measurement (TM) and numbers in the ANNEX II. these are:

TM -Is to be used for reporting general particulars of the vessel.

TM1 -Is to be used for reporting the thickness measurement of deck plating, bottom shell plating and side shell plating.

TM2(A) -Is to be used for reporting the thickness measurement of the transverse section shell plating and deck plating (one, two or three section dependant upon the age of the vessel)

TM2(B) -Is to be used for reporting the thickness measurement of the transverse section shell plating and deck plating (one, two or three section dependant upon the age of the vessel)

TM3 -Is to be used for reporting the thickness measurement of the transverse section longitudinal structural members (one, two or three section dependant upon the age of the vessel)

TM4 -Is to be used reporting the thickness measurement of the transverse structural members in the cargo oil or water ballast tanks with in the cargo tank length.

TM5 -Is to be used reporting the thickness measurement of W.T./O.T. transverse bulkheads with in the cargo tank length.

TM6 -Is to be used reporting the thickness measurement of miscellaneous structural members.

TM7 -Is to be used reporting the thickness measurement of cargo hold/tank transverse frames where appropriate.

TM8 -Is to be used reporting the thickness measurement of topside and bottom area assessments. (Some of classification society does not ask for this form. In this case, this form is out of question.)

Quality Assurance Procedures	Document No: MGSN-510
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Inspection and Verification	QP10

7.8.10.1 Purpose

To ensure that appropriate and adequate certification inspection and monitoring is conducted to establish compliance with defined requirements and these inspections and tests are clearly recorded.

7.8.10.2 Scope

This procedure defines the activities and controls required to monitor the operational efficiency and safety of all departments.

7.8.10.3 Responsibility

The General Manager is ultimately responsible for the safe and economical operation.

The Quality Assurance Manager is responsible for ensuring that the Company's Quality and Management System remains effective.

7.8.10.4 Procedure

All incoming goods, materials, items and services shall be checked on receipt for condition and compliance with the purchase order.

The verification of incoming goods, data and services shall be made by the manager.

Services supplied by sub-contractors shall be monitored for errors, omissions and any non-conformances reported by the manager to the Quality Assurance Manager.

Quality Assurance Procedures	Document No: MGSN-511
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Measuring and Test Equipment	QP11

7.8.11.1 Purpose

To ensure that all equipment and instruments, which are utilised for measurement of critical parameters, are at all times in a state of known calibration and capable of giving meaningful information.

7.8.11.2 Scope

This procedure refers to (but is not confined to) the following equipment:

Micrometers, torque wrenches, ultra sonic equipment

7.8.11.3 Responsibility

The Managers and Engineers are responsible for ensuring that all such equipment is listed and where necessary certificated and in a known state of calibration.

7.8.11.4 Procedure

All measuring and test equipment, which is not already covered by the rules of the classification society or other governing body will be listed and records kept of its status with regard to accuracy and certification. Such equipment may be tested and certificated by the manufacturer or a recognised test establishment or it may be subjected to A test prior to each time it is used.

All equipment should he checked before use whether or not it carries a valid manufacturer's or tester's certificate.

Where repair, servicing, or calibration of measuring or test equipment has been carried out, the technician or competent authority will be requested to produce a certificate or report on the status and accuracy of the item.

7.8.11.5 Records

List of Measuring and Test Equipment
Reports of Calibration

Quality Assurance Procedures	**Document No:** MGSN-512
Issued By: Quality Assurance Manager	**Approved By:** General Manager
Title: Inspection and Test Status	**QP12**

7.8.12.1 Purpose

To ensure that the inspection and test status of each stage of the services provided by the Company are as identified and comply with the Quality Management System.

7.8.12.2 Scope

This procedure identifies the status of inspections and checks at each stage of the Quality Management system and includes the status of :

1. The equipment
2. Progress to planned operations

7.8.12.3 Responsibility

All Department Managers are responsible for ensuring that the aspects of the Company's Quality Management System are adequate to meet the Company's Policy.

The Quality Assurance Manager is responsible for ensuring that the Quality System is constantly monitored and remains effective.

7.8.12.4 Procedure

The indication of inspection and test status of each department, its equipment is readily available by reference to the specific trading and classification certificates, survey reports, test certificates and log books. Originals are retained with equipment and copies held in the office.

The indication of the Company's Quality System is as per the bi-annual audit reports conducted by the Service Manager monthly report to the office.

7.8.12.5 Records

All Company's standard reporting forms
Classification Record
Certificates

Quality Assurance Procedures	Document No: MGSN-513
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Non-Conformance's	QP13

7.8.13.1 Purpose

To ensure that any services, procedures, work instructions or equipment which do not conform to agreed specified requirements are not allowed to be used.

7.8.13.2 Scope

All activities and controls which are required to maintain the quality of performance of service provided by MUGESAN

7.8.13.3 Responsibility

All members of the Company are responsible for identifying and reporting non conformances.

The Quality Assurance Manager is responsible for monitoring of service performance and analysing reported non-conformances. He is also responsible for reviewing the existing systems for any necessary changes and for monitoring the effectiveness of corrective action.

7.8.13.4 Procedure

7.8.13.4.1 Introduction

The Company recognises the need to provide the resources to operate the following necessary controls to ensure that a nonconformance of any nature is identified and actioned:

Recording, analysing and actioning situations which result in customer complaints.

Provide methods to achieve correction of identified non-conformances.

Review and update Company procedures as found necessary following identification of non-conformances.

7.8.13.4.2 Non-Conformances

Non-conforming goods or services are identified to prevent further use, installation or application by documenting, marking, labelling or quarantine.

Where appropriate, instances of non-conformance will be conveyed to the Customer to enable agreed short term corrective action to be taken.

Such instances will be recorded on non-conformance report form which are held by The Quality Assurance Manager.

Quality Assurance Procedures	Document No: MGSN-513
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Non-Conformance's	QP13

The Quality Assurance Manager will check that the corrective action taken will be effective and if affirmative, "close out" on the form.

Any member of staff may raise a non-conformance report where a customer complaint is received verbally or by letter/ telex/ facsimile.

Where the initiator has not been able to resolve The problem and immediate action is required, the appropriate Department Manager will be informed at the earliest opportunity.

The Quality Assurance Manager will monitor progress of the proposed actions and will evaluate the effectiveness of the action by reviewing subsequent non-conformance report's or carrying out an audit.

Non-conformance report's will be filed in date order in the Reports File.

7.8.13.4.3 Review

A review of all non-conformances is made at the Management Review Meeting and incidents are analysed to identify trends or weak areas in the System.

7.8.13.5 Records

Non-conformance Reports
Internal Audit Reports (Quality and Safety)

Quality Assurance Procedures	Document No: MGSN-514
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Corrective and Preventive Action	QP14

7.8.14.1 Purpose

To provide for the analysis of all non-conformances, accidents, and to monitor trends which may be evidenced and initiate action to prevent recurrence of non-conformance in the Quality Management System.

7.8.14.2 Scope

All incidents where non-conformances have been detected during the process of providing services including the supply of products, materials, equipment and services in the operation of the Quality Management System.

7.8.14.3 Responsibility

The Quality Assurance Manager is responsible for examining and analysing non-conformances, monitoring corrective action and, where appropriate, reviewing existing systems for necessary changes.

7.8.14.4 Procedure

The Quality Assurance Manager shall undertake to identify any operational failures and to correct these as quickly as possible preventing where possible any adverse effects upon the service being provided.

Where non-conformances or complaints are recorded on a non-conformance report as described in QP13 and the corrective action to be taken is entered in Part II by the initiator, the form is dated, signed and copied with the original being passed to the person who will be responsible for ensuring that corrective action will be taken without delay. The first copy is placed in the file held by the Quality Assurance Manager. If required, after copies may be handed to other personnel associated with the required action to be taken.

After due consideration and investigation of the causes of the failure or deficiency, the responsible person will consider and may take the action suggested in the non-conformance report or may authorise or take some other course of action to correct the failure and ensure that by such action there will not be a recurrence.

The course of action taken is recorded on the non-conformance report with the date of completion and signed by the responsible person before passing to the originator for copying to the Quality Assurance Manager.

Quality Assurance Procedures	Document No: MGSN-514
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Corrective and Preventive Action	QP14

Appropriate corrective action may be :

a) Revision of a procedure or instruction
b) Issue of a new procedure or instruction
c)Removal of a supplier or subcontractor from the approved list
d)Ensuring that personnel adhere to Quality Assurance Procedures
e)Further training or education

Regular reviews of the operation of non-conformance's and corrective actions are carried out by the Quality Assurance Manager who also monitors the progress of requests and actions. During those reviews the Quality Assurance Manager will consider the implications to such documents and may, as a result propose modifications, to improve the future effectiveness of the system. Action requests and their outcome will be reviewed at the Management Review Meetings.

Copies of non-conformance's may at times be sent to customers to demonstrate that the required corrective action has been taken.

7.8.14.5 Records

Non-conformance Reports (including corrective actions)

Quality Assurance Procedures	Document No: MGSN-515
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Handling, Storing, Packaging Preservation and Delivery	QP15

7.8.15.1 Purpose

To ensure that goods, materials, spares, equipment and cargoes are carefully handled, stowed, protected, preserved and properly stowed until delivered.

7.8.15.2 Scope

This procedure describes the activities and controls necessary to ensure all goods materials, equipment are properly handled, stowed, preserved protected, carried and delivered to the user or rightful custodian.

7.8.15.3 Responsibility

All employees are responsible for ensuring they comply with this procedure.

The Quality Assurance Manager is responsible for ensuring that the requirements of this procedure remain effective.

7.8.15.4 Procedure

7.8.15.4.1 Handling, stowage, storage

All goods, materials, spares and equipment will be handled stowed and stored such that the possibility of deterioration stowage or storage periods are minimised. They are stowed or stored in accordance with Company procedure, instruction, best practice of the trade, manufacturer's/ supplier's instruction. Critical items (those that may adversely affect the Quality System), goods which have a limited shelf life shall have their "use by" date clearly shown and used or replaced/ reconditioned accordingly. Proper inventory records as appropriate will be maintained.

7.8.15.4.2 Purchased items

Where items are purchased for departments the person in charge of Supply / Procurement will give adequate shipping instructions to the supplier or freight forwarder to ensure items are clearly identified, packed, protected and safely delivered to the department.

7.8.15.4.3 Monitoring

The Quality Assurance Manager will ensure by means of regular internal audits that personnel comply with all handling and safety procedures and instructions.

The condition of all equipment, containment areas and associated equipment will be inspected regularly by department's personnel as instructed by the Company in order to maintain the Company's stated policies and procedures.

7.8.15.5 Records

Supplier's/ Manufacturer's instructions
Certificates

Quality Assurance Procedures	Document No: MGSN-516
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Control of Quality Records	QP16

7.8.16.1 Purpose

To ensure that documents which provide objective evidence of quality performance at all stages in the Quality System are identified and stored in a proper manner for the appropriate and agreed retention periods.

7.8.16.2 Scope

All documents which are specifically referred to in each of the procedures as being quality records.

7.8.16.3 Responsibility.

The General Manager is responsible for ensuring that an adequate system is devised to meet this requirement.

Departmental Managers are responsible for ensuring that proper systems are developed and implemented by their departments.

The Quality Assurance Manager is responsible for monitoring and maintaining this requirement. All employees are responsible for ensuring that they comply with the requirements of this procedure.

7.8.16.4 Procedure

Quality Records are stored so that they are readily identifiable, easily accessed and retrievable. They will be protected from loss, damage or deterioration by those charged with their safe keeping.

The operation of the system i.e revision, distribution, storage, retention and disposal is mentioned in QP05 which is retained by the Quality Assurance Manager.

Each document is identified by name or reference number.

The Quality Assurance Manager assigns responsibility as appropriate for the storage of each category of record. He will determine in consultation with each Department Managers, the appropriate methods of disposal of obsolete and expired records.

The procedure for the care of Quality Records is reviewed as a regular feature of the Management Review.

Where Quality Assurance Records are stored on computer, they are backed-off and retained in a safe place.

Quality Assurance Procedures	Document No: MGSN-517
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Internal Quality Audits	QP17

7.8.17.1 Purpose

To determine the adequacy and effectiveness of the Company's Quality Assurance System and to ensure that it is being applied properly.

7.8.17.2 Scope

All aspects of the Quality Assurance System

7.8.17.3 Responsibility

The General Manager is responsible for ensuring that adequate trained personnel are available to conduct Internal Quality Audits periodically.

The Quality Assurance Manager is responsible for planning and implementing the Internal Quality Audits, for recording the results and ensuring that the corrective action is effective.

The Quality Assurance Manager is responsible for the appointment of auditors on the basis of their availability and independence of the area being audited.

Department Managers are responsible for performing audits of departments as required by the schedule.

The appointed auditor and the Quality Assurance manager shall carry out Company Internal Audits.

The appointed auditor is responsible for reporting details of nonconformance found during audits and ensuring that corrective action is agreed.

7.8.17.4 Procedure

The purpose of Internal Auditing has been conveyed to all staff as the means by which the Quality Management activities can be seen to conform to the procedures laid down and are thus tested to show compliance with the Standard and the Company instructions and their effectiveness.

As a principle, the auditors shall be independent of the areas being audited, in order to make an effective evaluation and review after the audit has been carried out.

The method of Internal Quality Auditing is as follows:

A schedule of Internal Quality Audits is compiled by the Quality Assurance Manager. This schedule identifies which areas or procedures are to be audited and by, whom. This schedule shall also take account of: the importance of each site or activity and

the number of problems being experienced with each particular site or activity. This schedule may be of confidential status where it is required to ensure audits are carried out in an unprompted manner. Normally, however, audits will be announced to the auditee well in advance of the due date.

Internal Audits are conducted using where appropriate Check Lists

Activities to be audited are but shall not be restricted to:

1-) Existence of the controlled Quality Management Policies
2-) Existence of the relevant Quality Management Procedures
3-) Compliance with all the Policies, Procedures and Instructions.

The responses to the questions put by the auditor will be recorded on the Check Lists.

The Auditor and the auditee will sign the audit form when it is completed and the auditor and Quality Assurance Manager will follow up any non-conformances and the necessary corrective action.

The Quality Assurance Manager shall, by January each year, prepare a schedule for the year's internal Quality audits. This schedule shall include all areas and activities which relate to the Quality aspects of Company operations.

All functions of the Quality Management System will be audited twice a year and the results recorded.

Additional or random audits may be arranged by the Quality Assurance Manager whenever found necessary as a result of an adverse trend in Quality Standards or as a result of a Management Review Meeting.

Not less than three weeks before the month in which the audit is scheduled, the auditor shall contact the person responsible for the area being audited and agree a date for the audit

The auditor shall have access to all necessary documentation. If practicable this shall be made available at least two weeks prior to the date of the audit

At the opening meeting, the auditor shall explain the scope of the audit and the method of reporting.

The audit shall be reported by completing a Non-Compliance note. Observations may also be raised to indicate potential risks to the management system.

Any non-compliance raised shall be agreed by the guide and later signed by the person responsible for the area being audited.

A closing meeting shall be held at which the auditor shall present a summary of findings and agree any corrective actions to be taken.

The auditor shall complete an Audit Report Sheet within 2 weeks of the audit The original shall be sent to the Quality Assurance Manager with a copy to the person responsible for the area being audited.

Follow up audits: In cases where serious non-compliances are found, a follow up audit may be necessary. This shall be at the discretion of the Quality Assurance Manager and Department Manager. The purpose of this follow up audit is to ensure that corrective action has been taken and that it is effective. A record shall be made of the decision whether to have a follow up audit

Should a follow up audit be deemed necessary, this procedure will be repeated from step 4.3.

In cases of lesser non-compliances, notification by the person responsible for the area audited that the appropriate corrective action has been taken and is effective will be sufficient to close out the non-compliance.

The Quality Assurance Manager will maintain records of internal audits which will contain the relevant checklists, audit and nonconformance reports and verification of corrective action.

7.8.17.5 Records

Internal Quality Audit Schedule
Internal Quality Audit Preparation Form
Internal Quality Audit Plan
Internal Quality Audit Report
Internal Quality Audit Check Lists

Quality Assurance Procedures	Document No: MGSN-518
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Training	QP18

7.8.18.1 Purpose

To ensure that all personnel have adequate qualification experience and training for the tasks which they are required by the Company to perform.

7.8.18.2 Scope

This procedure defines the activities and controls necessary to ensure that the training needs of all personnel involved directly with the Quality Management System are identified and addressed, that new or newly-transferred personnel are familiarised with their duties and suitable staff are recruited. As a result it applies to all personnel identified with in the Quality Management System.

7.8.18.3 Responsibility

The Quality Assurance Manager is responsible for identifying the training needs of personnel within the Company.

The Quality Assurance Manager is responsible for liaising with Managers to ensure training and training programmes are effective

Each Department Managers will be responsible for bringing to the attention of the Quality Assurance Manager the training needs within their departments.

7.8.18.4 Procedure

Employees new to the Company will be issued with the Company's Quality Assurance Policy Manual, related procedures, and instructions and other relevant documentation to assist in their familiarisation programme.

It is Company policy to employ suitably experienced and qualified personnel to fulfil the diverse functions of the Company. All personnel who are engaged by the Company are required to undergo a period of training under supervision of a person of the same qualification or a senior colleague to ensure that they are adequately familiar with their allotted tasks.

When the Departmental Manager is satisfied as to the trainee's competence, that person will be allowed to fulfil their normal role unsupervised.

Any identified training which has been undertaken, either internal or external will be noted in the Training Record.

Identification of training needs may originate from new legislation raised non-conformances or Management Review Meetings.

Quality Assurance Procedures	Document No: MGSN-518
Issued By: Quality Assurance Manager	Approved By: General Manager
Title: Training	QP18

Periodic examination and refresher training may be conducted by an external third party or in house following agreement with the Quality Assurance Manager as and when determined by the Company's Agreements and Government statutory regulations.

Each Department Managers will carry out on-going appraisal reports of all personnel for whom file are responsible. These reports will be completed for all personnel. At such times the head of departments and the individual will have the opportunity discuss any further training needs.

7.8.18.4.1 Training systems and records

The Company have instituted a programme of further training on board the fleet using audio visual aids.

Records will be kept of all training.

7.8.18.5 Records

Quality Assurance Management Manual Training Record For Personnel
Quality Assurance Management Procedures Training Record For Personnel
Personnel Training Report
Familiarisation Checklist

Quality Assurance Procedures	**Document No:** MGSN-519
Issued By: Quality Assurance Manager	**Approved By:** General Manager
Title: Servicing	QP19

7.8.19 Servicing

The Company do not conduct "Servicing" in the provision of their service to Clients and therefore this element of the standard is not addressed. If there should be a requirement in the future, a procedure will be established and implemented to cover this aspect of this standard.

Quality Assurance Procedures	**Document No:** MGSN-520
Issued By: Quality Assurance Manager	**Approved By:** General Manager
Title: Statistical Techniques	QP20

7.8.20 Statistical Techniques

The Company do not utilise "Statistical Techniques" in the provision of their services to Clients and therefore this element of the standard is not addressed. If there should be a requirement in the future, a procedure will be established and implemented to cover this aspect of this standard.

CONCLUSION

This thesis, provided additional information on the ISO 9000 standards and related issues to readers unfamiliar with some of the new developments in this area. It attempted to answer additional questions on ISO 9000 standards related issues. It also identified sources for further help in this area.

This project's aim was to establish a system that controls the critical activities affecting quality at Engineering Services and to assure the production and delivery of high quality goods and services. This aim has been achieved.

The objective was to design and develop an outline for a quality system in Engineering Services, having the ISO 9000 standard as a framework.

At this point, the objective of the project was satisfied to the fullest extent by writing a guide containing all the necessary information, including a conceptual quality system design to implement ISO 9002 based quality system in the division of Engineering Services, Marine Industrial Company. The conceptual quality system suggested in this guide can be used as a structure through which to implement a Total Quality Management program.

For to keep this object satisfied and usable, the company, MUGESAN Engineering and Marine Specialist Co. Inc.'s Quality Assurance Manuals and Quality Assurance Procedures has been established according to these thesis.

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AUTOBIOGRAPHY

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