ISO 9000 IMPLEMENTATION IN A MIDDLE-SCALE TURKISH ORGANIZATION

MBA THESIS

İSMAİL BURAK UZKAN

Ankara, January, 1996

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A THESIS

SUBMITTED TO THE DEPARTMENT OF MANAGEMENT

AND

GRADUATE SCHOOL OF BUSINESS ADMINISTRATION

OF BILKENT UNIVERSITY

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MASTER OF BUSINESS ADMINISTRATION

By

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January, 1996

I certify that I have read this thesis and it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Business Administration.

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ABSTRACT

ISO 9000 IMPLEMENTATION IN A MIDDLE-SCALE TURKISH ORGANIZATION

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M.B.A. Thesis

Supervisor: Assoc. Prof. ERDAL EREL

In organizations of every kind, quality is regarded as a means to an end customer satisfaction in all aspects of a product or service. ISO 9000 Standards aim customer satisfaction in that respect.

In this study, a real life case which analyses a middle-scale Turkish firm trying to adopt ISO 9001 is presented. Each facility should tailor those standards according to its specific requirements, otherwise it may become a mass of useless work.

ÖZET

ORTA ÖLÇEKLİ BİR TÜRK İŞLETMESİNDE ISO 9000 UYGULAMASI

İSMAİL BURAK UZKAN

M.B.A. Tezi

Tez Yöneticisi:Doç. Dr. ERDAL EREL

Tüm organizasyonlar için kalite, ürün veya servisin tümünde müşteri memnuniyeti sağlamanın bir aracıdır. ISO 9000 Standardları bu kapsamda müşteri memnuniyeti sağlamayı amaçlar.

Bu çalışmada, ISO 9001 Standardına adapte olmaya çalışan orta ölçekli bir Türk firması analiz edilmiştir. Her işletme, bu standardları kendi gereksinimlerine göre yorumlamalıdır, aksi taktirde olay bir yığın kullanışsız iş haline dönüşebilir.

ACKNOWLEDGMENTS

I would like to acknowledge my thesis supervisor Assoc. Prof. Erdal EREL for his hepful comments, suggestions and his invaluable supervisions throughout the course of study. I would also like to thank Assoc. Prof. Dilek ÖNKAL and Assist. Prof. Serpil SAYIN for their kind interests to the subject.

Special thanks to my family and to my fiancee for their love and support.

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CHAPTER 1

INTRODUCTION

The world faced a significant change in the second half of the twentieth century. With the end of the second world war, world peace became more important than ever as people became aware of the possible results of a third world war. Also during this period, the rise of mass production resulted in the formation of mass consumption trends around the world.

As mass production developed into the early 1960s, consumer tastes around the world began to converge to make international trade more important than ever. Nations realized that the future world balance would be established on the growing economic powers. During this time US was the biggest economic power in the world with a large amount of world trade constituted by American firms. On the other hand, Japan was one of the least respected countries in world trade. This changed quickly and almost amazingly so that Japan today is seen as one of the big players, maybe the biggest, in world trade. Japanese products are known for their exceptional quality and cheaper prices.

Against this Japanese success, each European Community member states had established their own quality standards. Because of this in 1979, a group from International Organization for Standardization (ISO) is established to define those series of standards which coincide with each other. In this group, there were representatives of different nations including the United States. The objective of this group was, to define a general Quality Standard for all types of organizations. Those standards had to be neither so rigid that only a few number of firms nor so

easy that many firms could adopt. At the end, this group had established the ISO 9000 Quality Standards.

At the beginning, ISO 9000 Standards had widely spread in England and Holland. Further on, other European countries had translated those standards into their languages and respected those standards. Today ISO 9000 Standards are respected in more than fifty countries throughout the world with different names; e.g. BS 5750 in England, NFX 50 -121 in France, DS/EN 29000 in Denmark, GB/T 10300-88 in China and ANSI/ASQC- QB in United States.

1.1. OBJECTIVE OF THESIS

The objective of this thesis is to transfer our experiences in designing and implementing a Quality System at a firm according to the requirements of ISO 9000 Standards. A real life case of a middle-scale Turkish firm from electronics industry trying to adopt ISO 9000 Standards is presented in the thesis. Employees working in ISO 9000 studies in their firms may take this thesis as a base line, however each firm would tailor the requirements of the Standard by deleting or adding certain quality requirements for specific contractual reasons.

1.2. SCOPE

This thesis is for the people who need to learn the basic concepts related with ISO 9000 Standards. In this thesis, one can find what ISO 9000 Standards are, what those standards require and why they important are. At the end of the thesis, the reader will have the necessary background to be involved in the Quality System studies at their firms.

CHAPTER 2

UNDERSTANDING QUALITY

In this chapter some quality related terms like 'Quality', 'Quality Assurance', 'Total Quality Management' are defined. . At the end of this chapter one can differentiate 'Quality Control' and 'Quality Assurance' . Besides, in this chapter, one can find what ISO 9000 Standards and what the basic differences between ISO 9001, 9002 and 9003 are . At the end of this chapter, one can define the importance of ISO 9000 Standards and the relation between those standards and Total Quality Management.

2.1. QUALITY, TQM AND IMPLEMENTATION

As other nations began to search for ways to compete with Japanese and regain power, they realized what lay behind the Japanese myth: Total Quality Management. At first it was said that this management system was unique to Japan and could not be implemented successfully anywhere else. Firms that had attempted using Quality Circles (QCs), Statistical Process Control (SPC) and other elements of the 'Japanese system' actually failed in their efforts and reported that trying to implement Total Quality Management (TQM) was both useless and incredibly costly. This was of course a result of the lack of total understanding of TQM.

Today it is recognized worldwide that there is much more to TQM than Quality Circles or Statistical Process Control. It is in fact a management philosophy and a way of life. Also the successful completion of TQM implementations in the west and the great improvements achieved

by these firms prove that a systematic and planned way to TQM is possible. There are some basic principles underlying success with TQM.

In organizations of every kind quality can be regarded as a means to an end customer satisfaction in all aspects of a product or service. It should be all pervasive, covering not only the design, performance and reliability of a product or service but the constant improvement of what is on offer.

When it comes to quality, there is often too much emphasis on statistical process control, quality circles, automation, CAD/CAM and robotics. All are important but at most provide gloss to the total quality program within an organization. Quality is about attitudes, culture and commitment within an organization. It applies in all organizations: manufacturing, service or public sector, including government. However, quality is also an achievable, measurable and profitable entity that can be introduced into an organization once there is commitment and understanding.

Quality is defined to be the 'totality of features and characteristics of a product or service that bear on its ability to satisfy a given need'. On this basis it is possible to evaluate quality first on the criteria of 'fitness for purpose' and second on the ability to 'satisfy a given need', which may include availability, maintainability, reliability and design. In the past, the terms quality assurance, quality control and quality management tended to be used synonymously. Quality assurance was defined to be 'all activities and functions concerned with the attainment of quality'. This is now widely referred as total quality control, and the related quality systems as total quality management.

There are many definitions of TQM but it is best explained as ' a management philosophy that builds customer driven learning or organizations dedicated to total customer satisfaction with continuous improvement in the effectiveness and efficiency of the organization and its processes'.

To follow this philosophy, management must develop a system where all the members of the organization must be set to have a mind-set that is focused on satisfying customers' needs and wishes. Such a mind-set leads to concentration on value-added activity directed at total customer satisfaction. Other things being equal, the better the system functions, the more the company's profit and market share will grow.

The required support systems include continual education and training systems, tailored recognition and reward systems, accessible information systems, and feedback systems. If a TQM system is built without an underlying quality system, it will ultimately fail.

A successful total quality program must be based on certain basic principles. Underlying the whole approach are six fundamental requirements, which are:

- top management commitment,
- attitude change,
- continuous improvement,
- strengthened supervision,
- extensive training,
- recognition of performance.

Determining whether the organization is meeting the criteria for success, can be achieved quickly by asking the following questions under the main headings of the strategy development-

planning-operating elements (S-P-O) approach action list. This action list is completely taken from Corrigan, Quality Progress, May 1994.

Strategy Development:

- Do you know what the costs of quality are within your organization?
- Do you know what the costs of quality are within your particular area of responsibility?
- What changes for the better or worse have been achieved in the cost of quality over the past 12 months?
- What systems have been put into place to measure the cost of quality on a regular basis?
- When did you last measure the organizational climate within the organization?
- What views do management and work force have on the total quality program?
- What management organization has been put in place in order to meet the requirements of the total quality program?
- What are the prevailing attitudes towards customers/clients?
- How would you define the customer requirements in terms of external customers?
- How would you define the customer requirements in terms of your immediate internal customers?
- When did you last carry out a market survey to determine the customer requirements?
- When did you last meet your customer/clients?

- How would you define your customers'/clients' view of the organization and your own department?

Planning:

- Who is the board level person responsible for the total quality program? How would you define his/her responsibilities?
- Who is the full time senior manager with specific responsibility for the total quality program? How would you define his/her responsibilities?
- Is there a steering committee within your organization? Who are the members?
- What are the training programs that have been set up as a direct result of the total quality program?
- Do they cover training and development of top management, management, task group leaders, improvement group leaders, facilitators?
- Has a detailed timetable for implementing the total quality program been established? What are its main components?

Operating Elements:

- What are the details of the briefing program?
- What are the components of the briefing pack?
- Does the briefing program involve everybody from top management down to the shop floor?

- Does the main training program incorporate training in concepts of quality, interpersonal skills, statistical and systematic problem solving techniques?
- Is there a facilitator responsible for the improvement group process? What are his/her main responsibilities in terms of task and improvement groups?

In the improvement groups:

WHO manages, teaches, leads, belongs and does not belong to them; selects the members, selects the leaders; identifies problems for the groups; measures their performance?

WHAT are they and what do they do; will it do for the organization and the people in it; times do they meet; training is involved; commitment is needed; problems are worked on?

WHY should they meet; are improvement groups voluntary; are improvement groups lead by supervisors; do they meet in company time; are they so training oriented; are they so structured; should they be measured?

WHEN do they meet; are they measured; are they stopped?

- What arrangements are there for evaluation of progress including a review of cost of quality, people and attitudes, improvement group/ task group performance?

- What are the arrangements for publicizing the successes in the total quality program?
- Are there any special awards associated with the total quality program?

In simple terms TOTAL QUALITY is about attitudes, a way of life, achieving excellence.

2.2. THE TURKISH QUALITY AWAKENING

The changing trends around the world also inevitably effected Turkey. There are very good examples to TQM implementation programs in our country as well, even though they may be few when compared with US. Quality has been the major certificate that a certain enterprise is better than its competitors for a long time. Consumers in countries with developing industries who have less buying power than those in developed countries, generally give more importance to price than quality. The fact that supplies in such countries are usually much lower than demand, also supports the rise of price as the primary criterion of purchase. Turkey has a similar picture. However, especially since the end of the 1980's, as Turkish market began to open up to foreigners and exporting gained speed there has been a shift toward quality as the purchasing criterion. Much of this was a result of consumers' becoming more knowledgeable and aware of the market.

Today the Turkish industry faces the major challenge of producing at world standards and at lower or comparable costs. Thus, the major movement toward TQM and Quality Assurance of the last 10 years has also affected Turkey.

The first serious steps toward the TQM philosophy in Turkey were taken in the early 1980s by a few big holding companies. They were the first to implement Quality Circles.

By the end of 1980s, interest in Quality Control due to its ineffectiveness which resulted from improper implementation has decreased. During the same time Statistical Process Control practices gained attention.

The full philosophy and idea of TQM began to get wide-spread recognition by early 1990's. However the rise of ISO 9000 standards during that same period, slowed down and literally prohibited development of TQM applications in Turkey. ISO 9000 looked like a shorter path to quality improvement and thus managers lost interest in the long-term hard-work practice of TQM.

As we reach the mid 90s, especially since the last 2-3 years we can clearly observe that interest in ISO 9000 is declining and the Turkish National Quality Award is getting more attention and importance. This award was first presented and is still supported by the joint efforts of TÜSİAD and KALDER.Today the hottest question in business circles is really, whether to practice TQM or Re-engineering. It is exactly the same situation, Europe and the US are also confronted with.

Looking back on this brief history, there are three things worth noticing. First of all except for quality circles the rest of the concepts were introduced and first practiced by the Turkish industrial circle and not the academicians.

Secondly the path followed by Turkey to TQM parallels that of the West. Concepts have reached us in exactly the same order. Furthermore, although QC was first recognized in Turkey with a delay of 10 years, TQM with 7 years and ISO 9000 with 3 years delay, today we are at the same point on the road as the West (as far as recognition of concepts are concerned). This simply

shows that Turkey has moved with accelerating speed on the quality highway. (Akın, Endüstri Mühendisliği, July 1994)

Although big steps have been taken toward quality recognition and improvement, it cannot be denied that on the average, Turkish firms need to improve on a lot of issues before trying to implement TQM.

First of all we must be aware that the idea of controlling quality is at its infant stages in Turkey and downstream quality inspection is the major method used. Statistical Process Control is only used in a few number of firms and operations research techniques or quality improvement engineering are hardly known.

Stocks are abundant. Inventories for finished, semi-finished products, raw material and resources are huge. Stocks often stay full for weeks or even months. Zero-inventory models are not found anywhere. There is almost no use of a Material and Resources Planning Program (MRP) or Kanban.

Most Turkish firms are not involved in the designing stage of their products. When they are, they have either never heard of Quality Function Deployment or conditions do not allow for its practice. Firms with design policy and committees are very few. Planned maintenance is not wide spread. Repairs are done when breakdown occurs.

Training in Turkish firms does not exceed a few hours per employee per annum. Compared to 200 hr./employee per annum in Japan, this is almost non-existent. Even the financial analysis tools to guide top management in decision making are overlooked. Organization structures are usually either pre-Taylor or Taylor like, with fixed job definitions and rigid hierarchy of authority.

2.3. CONCEPTS MOST ARGUED ON

As TQM began to draw attention, there were also many conflicting interpretations as to what it really was and how it should be practiced. Therefore it is worthwhile to clarify certain points about TQM practice.

The management model of a firm does not necessarily have to change with TQM application. Every firm is free to choose and use any management model. Likewise there is not one fixed model for implementing TQM. Often trying to describe TQM is said to be like trying to understand the shape of an elephant eyes closed. Everyone seems to have their own self-tailored model for TQM, and although the basic principles do not change one implementation is never the same as another. No one would expect an Olympic champion and a novice athlete to follow the same self improvement program. Similarly it is inappropriate to expect all organizations to follow the same path to quality improvement.

A major assumption when talking about TQM, is of course that the organization is in a free-economical environment with fierce competition. TQM is a long term management model and if there is no competition firms tend to go after short term profit realization models.

TQM guarantees long-term continuous quality improvement and profit maximization that is supported by a democratic work environment where respect for both employee and customer prosper.

Another much debated issue is the relationship between quality circles and TQM. In short, TQM can exist without quality circles but quality circles do not guarantee that TQM will follow or exist in an organization. However it cannot be denied that a healthy quality circle practice does a great deal in strengthening TQM applications. Mainly because quality circles are a very good way

of bringing management and employees closer, and verifies employee participation, they are only a small part of the whole TQM system.

There has been growing debate about the relationship between ISO 9000 and TQM in the last years. However, this issue is explored further in the next section.

2.4. ISO 9000 STANDARDS AND TQM

The quality assurance models, set out in the three International Standards; ISO 9001, 9002 and 9003, represent three distinct forms of quality system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

ISO 9001 is a model for quality assurance in design, development, production, installation and servicing. ISO 9002 is a model for quality assurance in production, installation and servicing. ISO 9003 is a model for quality assurance in final inspection and test. Those standards are generic and independent of any specific industry or economic sector. The design and implementation of the quality system is influenced by the varying needs of the organizations, its particular objectives, the products and services supplied, and the processes and specific practices employed.

Most important benefits of ISO 9000 Standards are access to markets and competitive advantage. ISO 9000 Standards enable facilities to maintain and create customer relations for situations in which ISO 9000 certification is required; that is for contractual reasons. Another benefit of certification is that the facility regularly undergoes objective assessment by skilled outside professionals.

ISO 9000 and TQM supplement each other. A successful TQM effort will have a quality system that is similar to ISO 9000 quality system. Therefore, a corporation that has successfully woven TQM into the fabric of its business should need only minor changes to meet ISO 9000 registration requirements.

Although ISO 9000 and TQM supplement and support each other, they do have different objectives, evaluation and improvement processes, and management and success goals. ISO 9000 standards define the requirements of a prevention based quality assurance system. If the system is adhered to the suppliers, they will always produce and deliver a predictable product or service. These standards are essentially paper driven. All of the appropriate elements must be documented, the documentation must cover all requirements and the company must do what it has documented. Adequacy of the system and the company's adherence to it, is measured by auditing against the standard. Therefore, ISO 9000 standards measure neither the efficiency of the system nor how good the product or service is.

ISO 9000 might not be *'the path'* to TQM, but it could be *'a path'* to TQM. (Corrigan, Quality Progress, May 1994). ISO 9000 as a path to TQM is incomplete. For example, ISO 9000 does not have a sufficient customer focus, does not address how good a product or service is, does not focus on continuous improvement and the scope of the support systems and processes needed for continuos improvement and does not call for an ongoing evaluation and improvement of the quality system elements. These however are not deficiencies because ISO 9000 serves a different purpose.

Any organization starting a TQM effort should assess the adequacy of its underlying quality system. It becomes a base line to start from. Using an ISO 9000 standard for this

assessment would provide excellent measurement criteria and a structured approach to periodic evaluation of the quality system.

An alternative is to integrate the ISO 9000 standard into TQM from start. This integrated approach could accelerate the TQM process. It would give quality councils immediate strategic plans. It could also provide greater assurance of early success and help simplify the cultural acceptance. The integration should result in a mutual strengthening of both efforts and ensure that neither effort detracts from the other.

Companies seeking ISO 9000 registration that already have a successful TQM system can manage the activity by making it a quality improvement project. Even 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 as this will increase quality awareness.

CHAPTER 3

ISO 9000 QUALITY SYSTEM REQUIREMENTS

In this chapter, the key characteristics of ISO 9001 Quality Assurance System are defined. ISO 9001 consists of twenty elements. This chapter explains the requirements of ISO 9001, but since 9001 covers both 9002 and 9003, organizations tailor those requirements according to their own needs.

3.1. MANAGEMENT RESPONSIBILITY

ISO 9001 starts with top management commitment to quality. The success of the quality system is up to top management. If top management supports the activities and gives importance to quality, then it will be much easier to establish the quality system. Top management has the responsibility to support the quality activities by defining quality policy and the organization chart, by appointing a management representative and by assessing the system periodically.

3.1.1 Quality Policy

Management shall define and document its policy for quality including the objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. Management shall define its objectives with measurable targets and state its policy to reach these objectives so as to guide the operational activities. The quality policy shall be relevant to the company's

organizational goals, expectations and needs of its customers. Management shall also ensure that this policy is understood , implemented and maintained at all levels of the organization.

3.1.2 Organization

There shall be a defined and documented organization chart stating the responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality. An official organization chart shall be established, particularly for the personnel who need the organizational freedom and authority to:

a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system,

b) identify and record any problems relating to the product, process and quality system,

c) initiate, recommend or provide solutions through designated channels,

d) verify the implementation of solutions,

e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

3.1.3. Management Representative

A member of supplier's own management who, irrespective of other responsibilities shall be appointed as 'Management Representative' and shall have defined authority for;

a) ensuring that a quality system is established, implemented and maintained in accordance with ISO 9000,

b) reporting on the performance of the quality system to the company management for review and as a basis for improvement of the quality system.

The Management Representative shall be out of all kinds of operational activities directly related with production.

3.1.4. Management Review

There shall be quality audits assessed by management. Management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of the stated quality policy and objectives.

3.2. QUALITY SYSTEM

3.2.1. Documented Quality System

The detailed quality system shall be defined and documented as a means of ensuring that product conforms to specified requirements. The Quality System shall be authorized by top management and the structure of the established Quality System shall be announced to the personnel involved in carrying out the activities.

Documented procedures shall be prepared to implement and control all the activities affecting quality, efficiency and cost, through the line beginning from the preparation of product and process specifications till finished goods. During the preparation of the procedures, contribution and coordination of all the related departments is a must for effective implementation and application of procedures. Work instructions shall be prepared to

implement production operations according to the demands and specifications. A Quality Manual covering the requirements of ISO 9000 including the Quality System procedures shall be prepared.

3.2.2. Effective Implementation

Control and audit functions shall be established to ensure that the activities are run according to the procedures and work instructions that are documented. For that purpose, an audit system shall be established to assess the implementation of the procedures. This audit mechanism shall also ensure that the implementations are always kept up to date and optimum.

3. 3. CONTRACT REVIEW

The company shall establish and maintain documented procedures related with taking and evaluating customer demands and orders. To assess the relevancy of orders with regard to the specifications, all the essential data shall be defined. Records of contract reviews shall be maintained. Channels for communication and interface with the customer's organization in these contract matters should be established.

3.4. DESIGN CONTROL

Among ISO 9001, 9002 and 9003, only 9001 includes this requirement. The main objective of this requirement is to control and verify the design of the product in order to ensure that the specified requirements are met. In order to do this, the company shall establish and maintain documented procedures related with design control.

The company shall prepare plans for each design and development activity, including defined responsibility, and describe or reference these activities. At appropriate stages of design, formal documented reviews of the design results shall be planned and conducted. All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their realization.

3.5. DOCUMENT AND DATA CONTROL

To be certified by one of the ISO 9000 Standards, a lot of documentation is required. ISO 9000 requires from the firms to establish some methods to control all those documents and data. The company shall establish and maintain documented procedures to control the documentation.

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise and the records of these changes shall be maintained. Invalid and/or obsolete documents shall be removed from all points of issue or use.

3.6. PURCHASING

The objective of this requirement is to ensure that purchased product conforms to specified requirements. This main objective is supported with three subheadings which are quality records of acceptable subcontractors, specific and detailed purchasing data and effective quality control systems.

Procedures concerning the acceptance criteria for subcontractors shall be documented. The company shall evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and quality assurance requirements and keep the records of those acceptable subcontractors. Purchasing documents shall contain data describing the product type, class, grade or other product identification. An effective quality control shall be established that the subcontracted product conforms to specified requirements.

3.7. CONTROL OF CUSTOMER SUPPLIED PRODUCTS

This requirement covers the situation of customer supplied products that shall be used in the production or that shall be used as a part of the product. This part requires documented procedures for the control of verification, storage and maintenance of customer-supplied products. Any such product that is lost, damaged or unsuitable for use shall be recorded and reported to the customer.

3.8. PRODUCT IDENTIFICATION AND TRACEABILITY

Sometimes product traceability is a need, but generally it is a contractual requirement. Procedures for identifying the product for suitable means of receipt during all stages of production, delivery and installation shall be documented. Where it is a specified requirement, unique identification of individual product or batch and records of those shall be maintained. An other important factor that shall be handled is to define how much traceability is needed. These factors shall be defined and documented in the procedures.

3.9. PROCESS CONTROL SYSTEMS

An other important element of ISO 9000 Quality System is Process Control Systems. The company shall document procedures defining the manner of production shall. Work instructions shall be written for production, installation and servicing processes where the absence of such instructions could adversely affect quality.

Production processes shall be carried under controlled conditions, like use of suitable production, installation and servicing equipment, suitable working environment, compliance with reference standards, quality plans, documented procedures.

3.10. INSPECTION AND TESTING

ISO 9000 aims to reach the high quality level by controlling the whole process rather than inspecting and testing. But since inspection and testing ensure the quality of product performance, it requires inspection and testing for incoming products, in-process inspection, final inspection and testing and records of those.

Incoming product shall be inspected before it is used or processed or otherwise verified as conforming to specified requirements. Products shall be inspected and tested during the production process for conformity to specified requirements. Definitions of nonconforming products shall be made. The company shall carry out all final inspection and testing in accordance with the quality plan and no product shall be dispatched until all the activities specified in the quality plan are completed. Records which provide evidence that the product has been inspected or tested shall be established and maintained.

3.11. CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

To ensure that the product conforms to specified requirements, all inspection, measuring and test equipment including measuring devices that can affect product quality shall be identified and calibrated at prescribed intervals against a certified equipment having a known valid relationship to internationally or nationally recognized standards. Inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and consistent with the required measurement capability. Procedures defining actions to be taken when the calibration results are unsatisfactory shall be documented.

3.12. INSPECTION AND TEST STATUS

ISO 9000 requires a documented system for maintaining continuous identification of the test status of the products as they proceed through the process by appropriate means. Procedures shall define the authorized personnel responsible from the dispatch of conforming products. Conformance or nonconformance of each product with regard to inspections and tests performed shall be indicated from the records.

3.13. CONTROL OF NONCONFORMING PRODUCT

This part is related with control of nonconforming products and identification of nonconforming products. The objective of this system is to ensure that nonconformances do not inadvertently reach to the customers.

Procedures ensuring product that does not conform to specified requirements is prevented from unintended use or installation shall be documented . The responsibility for

review and authority for the disposition of nonconforming product shall be defined. Nonconforming product shall be reviewed in accordance with the documented procedures.

3.14. CORRECTIVE AND PREVENTIVE ACTION

It is important to establish systems ensuring that corrective and preventive actions are taken in case of nonconformances. Procedures for implementing corrective and preventive action shall be documented.

The cause of nonconformities relating to the product, process and quality system shall be investigated and the results of the investigations shall be recorded. The system may include risks versus return analyses of corrective actions. Corrective action needed to eliminate the cause of nonconformities shall be determined and controls to ensure that corrective action is taken shall be applied.

3.15. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

If the products are damaged after passing all the inspection and test stages, the processes that are established as required by the standard are of no use. Thus the company shall maintain a documented system to ensure the protection of products at all phases until installation. ISO 9000 requires documented procedures for handling, storage, packaging, preservation and delivery of the products.

3.16. CONTROL OF QUALITY RECORDS

This part explains the responsibilities of the company for managing the documents. Records of design control, contract review, acceptable subcontractors, identification of products, inspections and tests, calibrations, nonconforming products, corrective and preventive actions, internal quality audits and training shall be maintained. There shall be documented procedures for creating, maintaining, distributing, using and disposing of those records at prescribed intervals.

3.17. INTERNAL QUALITY AUDITS

When a company passes from the external quality audit carried out by an accredited body, then the company is certified by that International Standard. Internal quality audits have the same objective with external quality audits. The objective of internal quality audits is to ensure that the activities related with quality are in conformance with the requirements of the Standard.

The company shall document the procedures for planning and implementing internal quality audits. The results of the audits shall be recorded and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take corrective action on the deficiencies found during the audit.

3.18. TRAINING

The company shall implement a training program to ensure that all personnel can carry out their duties in a way that is consistent with the objectives of the quality system. The company shall document and maintain procedures for identifying training needs. Documented procedures shall also define how to carry out those training activities.

3.19. SERVICING

Where servicing is a specified requirement, procedures for performing, verifying and reporting that the servicing meets the specified requirements shall be documented. Servicing needs must be taken into consideration in the design phase, i.e. training needs of servicing personnel. Companies must give importance to process control systems and training because process control systems decrease servicing needs. On the other hand, training not only supports process control systems, but also ensures that required servicing is supplied correctly.

3.20. STATISTICAL TECHNIQUES

The company shall maintain a documented system for evaluating the need for statistical techniques as well as systems for creating, implementing and monitoring statistical techniques deemed to be appropriate for the effective operation of the quality system. In the documented procedures, the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics shall be identified.

In this chapter, twenty elements of ISO 9001 are explained. The objective of this chapter is to help the reader in designing and establishing a quality system which conforms with the requirements of ISO 9001. This part contains some basic information about design, implementation and certification of the quality system that shall be built in the company.

CHAPTER 4

A CASE STUDY: ELİMKO LTD. CO.

In this chapter, ELİMKO Ltd. Co., an industrial electronic control devices manufacturing company is presented. Elimko has decided to organise its Quality Assurance System with the requirements of ISO 9001. The quality system activities are being designed by top management. Before designing the quality system, top management had appointed a quality committee and this committee had performed an audit through the whole company according to the requirements of ISO 9001. Throughout the chapter, the company profile including its history and general information about Elimko's operations are presented. At the end of the chapter, the results of the preliminary-audit is presented. In the next chapter, a detailed action plan for achieving the ISO 9001 requirements will be suggested.

4.1. COMPANY PROFILE

4.1.1. History:

Elimko is located in its own building in the Emek quarter of Ankara since 1989. The building consists of 2000 m^2 covered area including 500 m^2 of mechanical workshop.

Elimko was established in Ankara in 1976 by its present shareholders, for the purpose of producing a range of electronic measuring, recording and process control instruments along with certain sensors needed for these instruments, e.g. thermocouples and resistance sensors.

The period from start in 1976 onto 1978 was a crucial period, in which a range of prototypes were developed and field tested at and in close co-operation with several selected companies, resulting in a range of basic instruments with proven references for good performance and reliability.

Elimko became a limited corporation in 1978 and started up mass production of control equipments with analog indicators. At the same time it was developing and field testing equipments with numeric indicators, which were released for mass production of board type recording equipments in 1982.

In 1983, Elimko started to produce equipments equipped with microprocessor, e.g.: Programmable Control Equipment, Textile Computer, Mixing Computer, Alarm Computer, Data Collection Station, Flowmeter Computer , etc.

4.1.2. Elimko of today:

Elimko is today the leading company in design, production and supply of complete turn-key Process Control Systems. It is also the leading producer of a wide range of measuring and control equipments and sensors such as: Thermocouples, Resistance Sensors, Speed Sensors, Relative Humidity Sensors, Location Sensors, ...

Elimko, beside production of its own products, is since 1985 the exclusive representative of ABB-Asea Brown Boveri Kent-Taylor Group, responsible for marketing,

production and after-sales technical service together with representation of some other foreign companies.

4.1.3. Quality Assurance System

Elimko has decided to organise its Quality Assurance System in conformity with the requirements of ISO 9001 for the purpose of, through third party certification, demonstrating its effective implementation. Anyway, the primary purpose of operating a formal Quality Assurance System is to provide management an effective management system, ensuring that all activities are carried through in a planned and consistent manner.

The Quality Assurance System of Elimko shall ensure that Elimko's products are always in full conformity with stated product specifications, in a way which will continuously satisfy the customers at minimum production costs.

The structure of the Quality System shall be worked out to ensure maximum motivation, involvement and efficiency by those who shall ensure the quality of work and output. The Quality System documentation shall be structured with consideration to all parts of Elimko.

4.2. PRELIMINARY AUDIT

The Quality Committee appointed by top management had performed a preliminary audit through the whole company. The elements of the standard have been tailored to the specific needs of the company in order to form an effective Quality Management System. In this

part, the nonconformances will be analyzed and in the next chapter, a detailed action plan suggesting the corrective actions will be developed.

There is a well-defined quality policy of the company, but it is not officially stated and documented. The organizational structure is well-defined, but it is not documented and explained in detail. No 'audit ' system exists evaluating the quality control activities. There are well-implemented quality control activities related with finished goods and last stages of production, but the quality control activities during production process are not enough.

A management representative, ensuring that a quality system is established , implemented and maintained does not exist. There are neither documented procedures nor work instructions.

The procedures related with the requirements for Contract Review are generally well applied, but documented guides and work instructions are not existing. The applied procedures are not always relevant to define adequately the specifications of the products. The order requirements are not always confirmed by the customers. Generally no written statement of a requirement is available for an order received by verbal means. Delivery time is sometimes defined as the time when the production is finished and sometimes it is defined as the time when the product is sent to the customer. Although the products are defined within various product specifications, the existing coding system is not always enough to define all the characteristics of the products; for that reason additional codings are done. Different coding systems are applied in Production, Purchasing and Sales departments according to their own needs.

There is no document control procedure identifying the current revision status of documents. Serious misleadings are met in the documentation and usage of existing documents

through production line. Some products are being produced without a production plan. There are no documented plans regarding to any design and development activity. The design and development of new products are released without the approval of General Manager.

Purchasing activities are not documented. There is no systematically applied system of purchasing orders. Coordination between Sales, Production, Stock and Purchasing departments is not strong.There are no records of acceptable subcontractors. Subcontractors are selected on the basis of previous experiences of purchasing personnel. There are no procedures concerning the evaluation and selection of subcontractors. System assessing the quality performance of purchased products does not exist. There are no quality records of the previously demonstrated capability and performance of subcontractors.

There is no documentation system regarding to the identification of products and components, e.g. material entrance data, lot size, lot number, controller, records. Production process is not defined with specifications, e.g. process parameters, quality control points, reporting, etc. Work instructions are not established for specific production operations. Special processes are not defined with related parameters such as welding operations, etc.

Incoming product is neither inspected nor verified as conforming to specific requirements before it is used or processed. There are no documented procedures defining what to do in the event of nonconformity to specified requirements. Nonconforming products are not separated from the conforming ones, they are stored together without any marks on them. Although final inspection and testing is carried out in accordance to the procedures, those procedures are not documented.

Measurement uncertainties of the test and control equipments are not fully known. Although some of the instruments are being calibrated, there are no documented procedures for controlling the calibration system. Records of calibration results are not maintained. Required accuracy and measurement capability of measuring and test equipments are not defined systematically.

Calibrations are carried out in unsuitable environmental conditions, e.g. lacking humidity and temperature control. System uncertainties affecting the calibrations, inspections, measurements and tests being carried out are not known. While indicating the inspection and test status of the products, some indirect methods are applied; e.g. red mark on the adjusting pot, etc.

Products, work-in-process goods, purchased materials/products are stored without any records monitoring the test status. Rejected, scrapped, accepted or regraded products are stored together without any marks on them.

A planned and documented audit function of the quality system is not established in Elimko.There is no authorized training program in the company. Although servicing is crucial for Process Control Systems Department, there are no written procedures relating to the servicing activities.

The results of the Preliminary Audit performed by the Quality Committee are presented in this chapter. In the next chapter, a detailed action plan suggesting the corrective actions will be developed.

CHAPTER 5

IMPLEMENTING ISO 9000 QUALITY SYSTEM

TO ELİMKO

In this chapter, according to the results of the Preliminary Audit, a detailed action plan is suggested. While suggesting the action plan, the requirements of ISO 9001 are tailored according to the needs of the company. In parts 5.1 and 5.2, the Quality Assurance System that is going to be established in Elimko is defined. In 5.1, the quality objectives, quality policy and the organization is explained. In 5.2, the structure of the Quality System is summarised. The other parts suggest corrective actions according to the requirements of the standard.

5.1. MANAGEMENT RESPONSIBILITY

ELİMKO will always be committed to ensure that the quality performance of the company is in conformity with the expectations of the customers.To be in conformity with its quality goals continuously, ELİMKO shall work out and implement its Quality Assurance Systems in conformity with ISO 9001.

The management of Elimko is committed to respect the stated, authorised and implemented quality system and to allocate the resources necessary for ensuring its optimal function.

5.1.1. Quality objectives:

5.1.1.1. Company:

It is the objective of ELİMKO:

- To develop, produce and market electronic measuring and process control equipment and systems, with characteristics that, as a minimum, will fulfil the requirements of authorities and customers, at the lowest possible cost,
- To be known as a reliable and trustworthy supplier with the shortest delivery time, compared to alternative suppliers.

5.1.1.2. Design quality:

The quality of the products shall be defined as optimal function, where optimal functionalism is expressed in terms of :

- compliance with agreed customer specifications,
- compliance with agreed configurations,
- actual use and application of the product.

The level of quality is achieved through the development/design phase by showing high attention on:

- Legal requirements, customer needs and the technologic state of the art,

- Precise and realistic requirements in terms of specifications for realistic functional characteristics, environmental approved materials, realistic production methodology and environmental sound production.
- Careful attention to choice of materials and production methodology, with consideration to functional requirements and cost.

5.1.1.3. Product Quality:

It is the objective, through the quality system, to ensure:

- that existing relevant legal requirements are fulfilled,
- that products as a minimum are in conformity with all stated requirements and specifications,
- that the customer will experience the product as having a satisfying quality by :
  * fulfilling the customers expectations and being in compliance with relevant standards and legislation,
  * producing at the lowest possible costs,

    (Lowest possible cost is defined as the cost necessary for maintaining the determined quality level.)

5.1.1.4. Market Quality:

It is the objective, through close contact to the user, field experience and constant showing high attention to indicated and expressed needs, to achieve that:

- the products shall be ranked in the upper part of the market concerning quality,

  the company shall be known through a good reputation for reliable delivery of best quality products along with good customer service,

- that technical advice given under the authorisation of the company is always honest and reliable.

5.1.1.5. Quality of product information:

It is the objective, through careful attention to the need and situation of the individual user, to ensure that they receive valid and correct information concerning the product, by means of comprehensive technical advice and guidelines for use. User Manuals are worked out with emphasis on satisfying the users need for good and comprehensive guidelines for use and maintenance of received equipment and systems.

5.1.2. Quality Policy:

Conformity with stated quality objectives are ensured by reliable design and concentrating on preventive methods and motivation of all personnel to aim for ***"right first time"***, those preventive methods are based on carefully planning and definition of how performed quality related activities shall be controlled and verified.

Preventive methods are executed through objective evaluation of the performance of the established quality system, continuous relevant revision and adjustment of the quality system, supervising that established procedures are followed, relevant training of personnel with influence on achieved quality, investment in necessary process technology and looking for reliable and quality minded subcontractors and suppliers.

It shall be stimulated by, each individual is responsible for the quality of his own work, and he is entitled for receiving sufficient facilities to control it. However, the responsibilities of the individuals are not limited to his own tasks as far as quality is concerned. Every employee of the company is obliged to report any divergencies to the responsible concerned, even if this should be beyond his own field of responsibility.

Continued improvements of quality and productivity performance shall be accomplished through establishment of detailed plans for improvement of quality performance and productivity on basis of various quality reports and improvement plans that shall be expressed in, and made measurable against a yearly "Quality and Productivity Improvement Plan", worked out and authorised by top management.

5.1.3. Organization

Organization chart is documented and the responsibility, authority and the interrelation of the personnel who manage, perform and verify work affecting quality is defined in the Quality Manual. The organization chart is given in Appendix I.

5.1.4. Management Representative

A Quality Assurance Manager is appointed by top management with the following responsibilities and authorities;

Responsibilities:

- To describe, implement and maintain a quality assurance system in accordance with the stated quality objectives and ISO 9001,
- To supervise, and carry periodic planned audits through the company to determine whether routines and activities are followed in accordance with approved procedures and work instructions, and report to management,
- To act as consultants, concerning quality matters, to all departments of the company,
- In co-operation with the Quality Control Department, specification and co-ordination of measurements, tests, verification and registrations concerning quality matters,
- In co-operation with the Quality Committee, establish new quality activities in accordance with outside and inside requirements and reasonable needs,
- Assist Marketing Department in handling of customer claims and evaluating causes, and report to management.
- Assist the Procurement Department in carrying through pre-qualification of sub-contractors,

- Handling of activities concerning documentation and approval of 'first off' test.

Authority:

- Initiate random audits due to observations,
- Stop of activities which obstructs the quality system, and immediately report to top management concerning corrective actions to be taken.

A Quality Committee is established. The participants in the Quality Committee are; General Manager, product related department managers, Quality Assurance Manager and selected supervisors of production departments. Quality Assurance Manager arranges and calls for the meetings and the results are recorded in the minutes of the meeting. The responsibilities and the authorities of the Quality Committee are;

Responsibilities:

- Ensuring maintenance and improvements of the quality system as a result of gained experience and development,
- Evaluates quality data from Quality Assurance Department, for the purpose of deciding on eventually corrective actions or other initiatives,
- Authorise new or changed procedures,
- Functioning as co-ordinator and source of initiatives concerning quality matters,
- Initiate quality analysis and corrective actions,

- Evaluate consequences of concessions concerning production methodology,
- Evaluate quality reports and initiate eventually actions needed to correct/ improve quality characteristics,

Authority:

- Authorisation of procedures, approved by the Quality Department,
- Based on approved claims, initiate needed quality actions to be executed by the Quality Department,
- Evaluate, and eventually, grant concessions for raw materials, activities and products which has been stopped because of deficiencies,
- Initiate changes in the quality system if found necessary for keeping the decided quality level.

5.1.5. Quality report for management

Once a month, Quality Assurance Manager reports to the General Manager, concerning various quality activities. The report is discussed in the Quality Committee meetings.

Top management will discuss the quality report and evaluate the combined Quality Assurance System, for the purpose of ensuring that the system is current adequate and efficient. Handling of the quality report is documented and filed at the Quality Department.

5.2. QUALITY SYSTEM

The Quality Assurance System of Elimko is documented in the Quality Manual and a series of Procedure Books. The documentation is deviated into 3 parts (Appendix 2). Part 1 is the Quality Manual. In the Quality Manual, guidelines for compliance with the elements of ISO 9001 with reference to documented procedures worked out for relevant activities are documented. Part 2 is the Procedure Books. Documented procedures describe and define general and transverse guide-lines for activities and co-operation and co-ordination between individual organisational functions. Procedures are controlled by the Quality Assurance Manager, who is responsible for approval from a system point of view and for ensuring approval for functionalism by the manager responsible for the procedures' application area, before applying for authorisation by the General Manager. The Quality Assurance Manager is responsible for ensuring distribution of valid procedures. Issue, structure, approval and authorisation of procedures are based on defined guidelines. Part 3 is the Work Instructions. Instructions for how to carry out and control specific activities and operations. Work instructions, such as drawings, part lists, guide- lines for specific operations, check-lists, etc. are filed at, and distributed from various relevant departments. Documents are drafted by relevant parties, approved by relevant technically qualified persons and authorised by the General Manager.

5.2.1. Internal Distribution of Quality Manuals

Part 1, the Quality Manual, is subject for all activity areas of Elimko, whereas Part 2, which covers transverse activities as well as general activities and operations within identified organisational sections, are divided into several sub-parts.

Part 1, is filed at the Quality Assurance Department, and a registered copy is distributed to all managers as well as to selected customers. Part 2, is in total filed at the Quality Assurance Department, whereas individual departments have copies of those relevant to the department.

5.2.2. Maintenance of Quality System

Procedures and instructions are subject to continued revision on behalf of input from the departments, management and from outside coming requirements, as well as on the basis of experience from quality observations and registrations from internal and external audits. Quality Manual is revised once a year at a minimum.

5.3. CONTRACT REVIEW

Elimko shall establish and maintain documented procedures related with taking and evaluating customer demands and orders. In the procedures, the way of taking orders for products against standards shall be defined. Documented procedures shall also define the routine to pursue the delivery time agreed in the contract. Documented procedures shall define how it is ensured that customers always will receive a product/service in conformity with

written agreements, as well as in conformity with documented or implied promises. The procedures shall ensure that customer inquiries and requirements are carefully evaluated in view of the capability of Elimko to fulfil specified requirements. Customers shall at any time, on request, be granted access to inspections, test methods, results and documentation in relation to their product.

The success of Elimko in satisfying customer demands shall be assessed by top management. All the documentation, records of internal and external memorandum and records of communication by verbal means shall be saved in the related customer files.

Elimko shall ensure that the order requirements are agreed before their acceptance. It shall also identify how an amendment to a contract is made and correctly transferred to the functions concerned within the organization.

5.4. DESIGN CONTROL

General Manager shall carry the superior responsibility for products offered by Elimko. New, or significantly modified products, shall only be released after documented approval by the General Manager.

Design and development of new and existing products shall continuously ensure that Elimko can offer products of a high innovative standard by using good and reliable technologies.

Documented procedures shall ensure that products of Elimko are always in conformity with applicable legislation, relevant standards and customer specifications. Well planned

procedures shall further ensure that resources for development and design are optimal utilised to create good and flawless functioning products.

Documented procedures related with how the process will be arranged, beginning from the *product idea* stage till *production* shall be established. The procedures shall control and verify the design of the product in order to ensure that the specified requirements are met. Procedures shall describe or reference each design and development activity and define responsibility for their implementation. A *Design Manual* shall be established defining the main guide lines related with design input for both standard and out of standards design and development activities carried out by Elimko.

Procedures determining the affects of design changes shall be established. All design changes and modifications shall be identified, documented, reviewed and approved by authorized personnel before their implementation. Documented procedures related with invalid and/or obsolete documents because of design changes like technical drawings, materials list, etc. shall be established. The methods that shall be applied in the case of deviation from standards and the related responsibilities, authorities, reporting and documentation shall be determined in those procedures.

The coordination, responsibilities and authorities of design and production functions shall be defined clearly. For products that are produced in project basis, like process control systems, quality plans shall be prepared and those plans shall be approved by customers.

5.5. DOCUMENT AND DATA CONTROL

Documented procedures for issuing, approving, authorisation and control of documents effecting the product, quality, organization and productivity, e.g. procedures, product specifications, process specifications, work instructions, data lists, brochures and catalogues, etc.; shall be established. Documented procedures shall also define the forms and documents to be used or to be removed from points of issue or to be filed. Documented procedures effectively ensure that any kind of documents for Quality Assurance, marketing, customer relations, purchase, production, quality control, delivery, reporting, etc., are valid and approved by authorised personnel. Handling of documents and data is an integrated part of various procedures and work instructions.

The quality system shall ensure that procedures / work instructions are distributed so that valid issues are present at selected locations, and that use of outdated issues are prevented. The Quality Assurance Department ensure adequate systems for control of filing and reclaiming of crucial data and documents.

Each document shall have a revision number and the sources of revisions shall be recorded. Certain rules shall be determined by documented procedures for approval, authorization, format, recording, filing and distribution of documents. All the documents shall be approved before authorization.

Procedures for removing invalid and/or obsolete documents from all points of issue or use shall be established. Document and data control shall ensure that any obsolete documents retained for legal and/or knowledge-preservation purposes are identified.

5.6. PURCHASING

Elimko shall establish and maintain documented procedures defining all the purchasing functions and activities. Clear and specific procedures shall be documented for how products from customer is safeguarded against any harmful influences and/or un-planned usage.

Procedures for receive inspection shall ensure whereas customer products are in conformity with specifications at the time of receive. Documented procedures shall ensure that purchase of goods and services are carried through so that goods will be acquired in conformity with relevant specifications from competent and reliable suppliers at most beneficial prices.

Capability of potential suppliers of essential goods and services shall be carefully evaluated before approval for a first time supply. Selected supplier's data shall be registered in a designated file before placing of order. The supplier's process and inspection capability and personnel qualifications shall, when relevant, be a part of the supplier evaluation. Realised supplier performance shall be registered in relevant supplier files, and be the basis for determining conditions of possible further purchases, as well as extent of receive inspection.

Purchase of essential goods and services shall only be made on behalf of written requisitions, specifying technical, quality and financial related requirements. Organizational functions having the authority of purchasing shall establish a product / material list defining who will buy which product / material. In the documented procedures, forms used for purchasing orders, personnel having purchasing authority, subcontractor approval criteria shall be determined. For all types of products / materials, list of subcontractors shall be established. This list shall also include alternative subcontractors.

5.7. CONTROL OF CUSTOMER-SUPPLIED PRODUCTS

Customer-supplied products shall be identified clearly, documented procedures preventing unsuitable usage or damage shall be established. Documented procedures shall ensure that the customer-supplied products are stored and used as stated in the contract. Documented procedures, where ever relevant, ensure unambiguous traceability between related documents, materials, processing and results.

Any kind of products; stored, to enter production, during production, processed, stored and ready for shipment, are at any time be clearly identified concerning type and status. Identification of products and status are clearly visible by means of markings, labeling or storage.

The control activities that shall be applied to those products and the related documentation system shall be defined in the procedures. Any nonconformities met during control usage shall be recorded and reported to the customer. Responsibilities related with customer-supplied products shall be defined clearly.

5.8. PRODUCT IDENTIFICATION AND TRACEABILITY

Although there is no obligation for recording the work-in-process goods required by the customers, critical parts shall be identified and recorded to follow the operations applied to finished goods. When this method is applied, the sources of quality problems related with the products shall be easily determined.

'Product Follow-up Cards' System shall be the most simple and effective way for tracing and controlling the product, production process and operator relations. Records of quality control activities during production shall be maintained. Those activities shall be defined in the documented procedures. Planned and documented procedures shall ensure that processing and production is carried through in a well planned and cost effective way, without compromising from delivering a correct and satisfying product at the right time to the right customer.

Written procedures and work instructions shall exist for all such activities and operations where mode of activity and/or operation is not simply obvious, or where lack of written instructions might result in reduced quality or increased costs.

5.9. PROCESS CONTROL

For each product type, production flow shall be defined with procedures supplied by work instructions. In the procedures and work instructions, all the tolerances shall be defined. Procedures and work instructions shall include the actions to be taken when the parameters fall out of tolerances. All incoming products and documents, with influence on quality of production and products shall be subject for conformity inspection, versus specified requirements, before release for use.

The extent and type of inspection depends on the situation, e.g. supplier capability, type of received product, products, production stage, etc. and might consist of check of relevant certificates, visual examination, measuring, chemical analysis or performance test. .

Procedures shall be established for controlling and documenting cases of exemptions and/or concessions. Inspection and testing, in accordance with documented specifications, shall be carried through during the complete production flow to document level of conformity with product and process specifications. All products are subject for documented final inspection and approval before release for delivery.

Special processes shall be determined, parameters related with those processes shall be defined and documented. Special process is the one in which all the characteristics of the product can not be controlled and tested at the end of the process, for that reason those processes can be controlled only by tracing the process parameters.

5.10. INSPECTION AND TESTING

Detailed work instructions shall be established for various kinds of quality control activities. Before the incoming product is used or processed, they shall be inspected with proper inspection techniques, e.g. document control, sampling, etc. All the test and measurement equipments shall be identified and records of those equipments shall be maintained. In-process inspection and testing points shall be determined and the responsible personnel shall be defined in the documented procedures.

All the activities and assessment criteria related with the inspections and tests determined in the quality plans shall be documented in the procedures. In the event of nonconformity, records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria.

5.11. CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

Elimko shall determine the measurements to be made and the accuracy required for the test and measuring equipments. For all test and measuring equipments; information like type, brand, supplier name, measurement capability, accuracy, calibration results, repairs and location shall be recorded and maintained in a separate file.

Documented procedures defining the calibration activities carried out in Elimko shall be established. All relevant inspection, measuring and test equipment shall unambiguously be identified and registered in terms of: identity, type, brand, supplier, capability, location/use and history.

All equipments for establishing objective measuring and test results shall be subject to documented and traceable periodic calibrations, ensuring that capability are in conformity with specified requirements.

All equipments for measuring and testing shall be marked to indicate calibration status. Equipment outside valid calibration status shall be protected against any use related to products, production or process control. If calibration shows that equipment is out side required measuring capability, the effect on previous released products shall be investigated, and if relevant, the customer shall be informed.

Elimko shall identify all inspection, measuring and test equipment that can affect product quality and calibrate and adjust them at prescribed intervals or prior to use, against certified equipment having a known valid relationship to internationally recognized standards. On the test and measuring equipments, final calibration status and its validity period shall be clearly shown.

5.12. INSPECTION AND TEST STATUS

Documented procedures shall define the identification of inspection and test status. Inspection and test status shall continuously be identified through all stages of the production flow by means of registrations, labels, markings or protected area of storage. Procedures for identification of inspection and test status shall be an integrated part of relevant procedures and work instructions.

Work-in-process goods shall be marked with small forms monitoring the final inspection and test status. On the specific parts constituting the final product, identifications regarding to the inspection and test status shall be present.

Authorized personnel responsible from the delivery of the products to the following process or to dispatch shall be determined and the qualifications of those personnel shall be defined.

5.13. CONTROL OF NONCONFORMING PRODUCT

Documented procedures and work instructions shall be established regarding to the nonconforming products. There shall be clearly defined and documented procedures for control of any kind of nonconforming products and processing, ensuring against unplanned usage.

Nonconforming products, e.g. materials for production, processed products, packaging, faulty processed documents, etc. shall be clearly separated from other products by means of physical separation and/or clear and unambiguous marking.

Nonconforming production apparatus and test equipments shall be clearly marked and protected against unplanned usage. There shall be clearly defined and documented procedures for initiation of relevant and appropriate actions whenever there is a case of nonconforming products.

5.14. CORRECTIVE AND PREVENTIVE ACTION

Customer complaints and the nonconformities shall be recorded. Records shall include all elements affecting the product quality like mechanical, physical and functional specifications, delivery time, etc. How to carry out the analyses to eliminate potential causes of nonconformities shall be defined in the documented procedures. Effective and documented procedures shall be established concerning corrective actions against activities with negative effect on product quality or cost effectiveness. It shall be ensured that corrective actions are carried effectively through the company to avoid recurrence of unwanted activities and results.

Guidelines for corrective actions shall, whenever relevant, be an integrated part of various procedures and work instructions, ensuring immediately and efficient corrective actions to be initiated and carried through, whenever needed.

Documented procedures shall ensure and verify the efficiency of corrective actions. Procedures shall ensure that all customer complaints are taken into consideration with the support of Quality Assurance Department.

5.15. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

Activities related with handling, storage, packaging, preservation and delivery of the products shall be defined in the documented procedures. Well planned and documented procedures shall ensure correct and optimal handling of various goods, such as documents, products, packaging materials, equipment, spare parts, etc. Procedures shall ensure that internal transportation and handling of materials are carried through without risk for personnel, product or property. Documented procedures shall define methods and conditions for storage of all products with influence on quality of production apparatus, products and cost effectiveness.

Elimko shall provide methods of handling products that prevent damage or deterioration. The materials used in the isolation of thermocouples shall be prevented from dust and humidity. Specific work instructions shall be written for storage of chemical materials.

5.16. CONTROL OF QUALITY RECORDS

Elimko shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records separate from quality control and quality cost calculations. Well controlled and reliable records shall be established to demonstrate that planned and specified operations has been carried through, when and by whom.

Elimko shall record the results of inspection and tests related to products and applied processes. Documented records shall, where ever relevant, be established to demonstrate that all specified requirements have been accomplished.

Recording of product, process and quality related data, shall be an integrated part of relevant procedures and work instructions. Documented quality records shall demonstrate the efficiency of the quality system and level of conformity between procedures, product and relevant specified requirements. The maintained records shall be converted into quality cost reports and quality cost statistics later on.

5.17. INTERNAL QUALITY AUDITS

An audit mechanism to verify whether the quality activities carried out and the related results comply with the planned arrangements to determine the effectiveness of the quality system shall be established.

Audit system shall be carried out by the Quality Assurance Department and the system shall be able to detect the elements reducing the effects of the quality system. Periodic system audits, covering the Quality Assurance Department shall be carried out by independent auditing firms or people outside the company. Only by that way, effectiveness of the system can be assessed by top management. Those kinds of external audits provide new decisions for corrective and preventive actions to be taken and it will be very helpful for Quality Assurance Department.

Internal audit of the quality system shall be a fundamental tool of Elimko for ensuring the efficiency of its quality system. Internal audits shall systematically be carried through by certified auditors, on a scheme which covers the complete Quality Assurance System within a period of maximum one year, certain crucial activities may be audited more frequently if needed for ensuring optimal quality performance.

Audits shall be organised, initiated and carried through under the responsibility of the Quality Assurance Manager. Audit results shall be documented and reported to top management.

5.18. TRAINING

Procedures for identifying training needs of all personnel shall be established to increase their level of knowledge and motivation. Training methods shall be identified in those procedures. Personnel files monitoring the information about education, experience, training, certificates and technical capabilities shall be established.

Requirements for personnel qualification shall be defined where ever certain specific qualifications are required/needed for achieving the specified level of quality. Relevant need for education and training of staff shall be evaluated by relevant responsible managers. Systematic training within various disciplines shall be carried through to ensure adequate qualification of staff.

Registration of relevant personnel data, concerning educational background, experience and technical competence, shall be filed where they shall be readily available for relevant managers.

5.19. SERVICING

There shall be well planned procedures for ensuring effective and satisfying after-sales service. There shall be documented procedures to control activities concerning technical

information, technical support and advisory in connection with selecting, using or/and developing the right product for specific applications, installing and user training concerning Process Control Systems and repair of products supplied by the company.

Elimko products shall be ensured possibility for effective service over a period of minimum 5 years after delivery to the customer. It is regarded as a natural service to ensure customers a satisfying handling of reasonable claims. High priority shall be shown to reduce customers inconveniences resulting from product failures within the specified guaranty period.

Documented procedures and work instructions determining the extent of servicing activities shall be established. Procedures defining the arrangements of required documentation and user guides for process control systems and electronic devices shall be established. Documented procedures shall ensure that field experiences during servicing activities are recorded and maintained by responsible personnel. Those field experiences shall be analyzed and taken into consideration for design and product performance activities.

5.20. STATISTICAL TECHNIQUES

Elimko shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified. Those procedures shall not only ensure technical applicability of those techniques but also the applications for productivity and profitability.

ISO 9001 does not require statistical techniques to be carried out, but in the event of applying those techniques, the verification of the results shall be evaluated carefully. Statistical

methods shall be used where and whenever needed or helpful for ensuring good process control and/or documentation of conformity with specified requirements. Methods might be selected and applied on basis of experience or as required by the customer. Methods shall be defined in documented procedures, or incorporated in relevant work instructions, which also identifies parties responsible for evaluating results.

CHAPTER 6

CONCLUSION

In the last ten years, industrialized countries have had a ' Cold War ' which had not seen before. It is called ' The Quality War ' which was started with the Japanese attack to the Western markets. After 1980s; Hong Kong, Singapore, South Korea and Taiwan have also taken place in this war and threatened the Western markets.

Because of this, especially in USA, efficiency and quality topics have became the most popular management strategies for the firms. These facts also affected the Turkish firms which are trying to live in today's globalized world.

Total Quality Management is seen as the only management strategy to reach the desired quality level. It became a must for the firms to take place in the market. The requirements of ISO 9000 standards show this very clearly.

Today many Turkish firms are trying to adopt themselves to ISO 9000 Standards. The purpose of increasing efficiency is a good reason for adopting these standards. Many firms adopt themselves to these standards for contractual reasons. It may take months to adopt these standards to the organizations. To shorten this period, the Pre-Audit stage is the most important part of the work. A very good action plan has to be established before doing anything. In this study, Elimko Ltd. Co. is analyzed with the data taken from that Pre-Audit and

the strategies to implement those requirements of the standard to the company have been suggested.

The primary purpose of operating a formal Quality Assurance System in Elimko is to provide management an effective management system, ensuring that all activities are carried through in a planned and consistent manner.

The very first thing to implement the designed quality system in Elimko is top management commitment. Top management has to respect the stated and authorized quality system and allocate the resources necessary for ensuring its optimal function. Top management must be actively involved in training, auditing, leading and identifying quality concerned policies and strategies.

A management representative with executive responsibility have to be appointed and the quality system have to be reviewed by that person at defined intervals. To implement and control all the activities affecting quality, efficiency and cost, documented procedures have to be prepared through the line beginning from the design of the product and process specifications till finished goods. During the preparation of the procedures, contribution and coordination of all the related departments is a must for effective implementation.

Formal training courses and seminars have to be arranged for creating new culture. Friendly visits to work centers by top management and showing interest to the employees and their jobs will encourage their involvement and help to obtain that cultural change.

ISO 9000 Certificate is not an end in itself. ISO 9000 Standards may be used as a base line to start a Total Quality Management effort in an organization. Using ISO 9000 Standards to assess the adequacy of the quality system will provide excellent measurement criteria and a

structured approach to periodic evaluating of the quality system. Even 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 as this will increase quality awareness.

In this thesis, I attempted to present a real life case of a middle scale Turkish firm trying to adopt ISO 9000 Standards. Many firms having ISO 9000 studies in their scope, generally have the same problems in their quality systems as in this case. If top management and the employees working in designing and implementing quality system studies in their firms take the suggestions given in this thesis into consideration it will be a more effective work. However firms have to tailor those suggestions according to their own needs, otherwise they may find themselves in a mass of useless work which could easily lead them to great inefficiencies.

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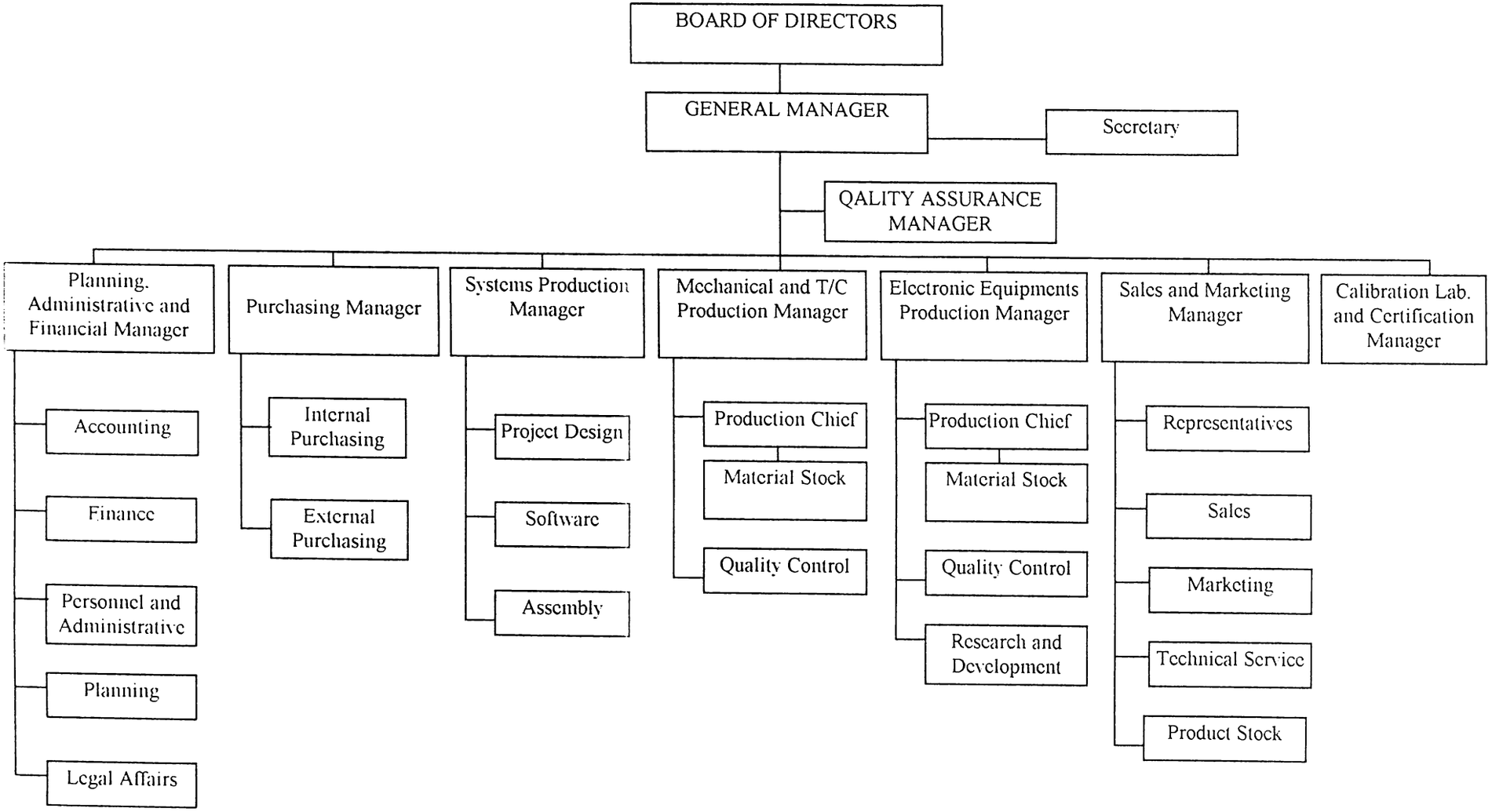
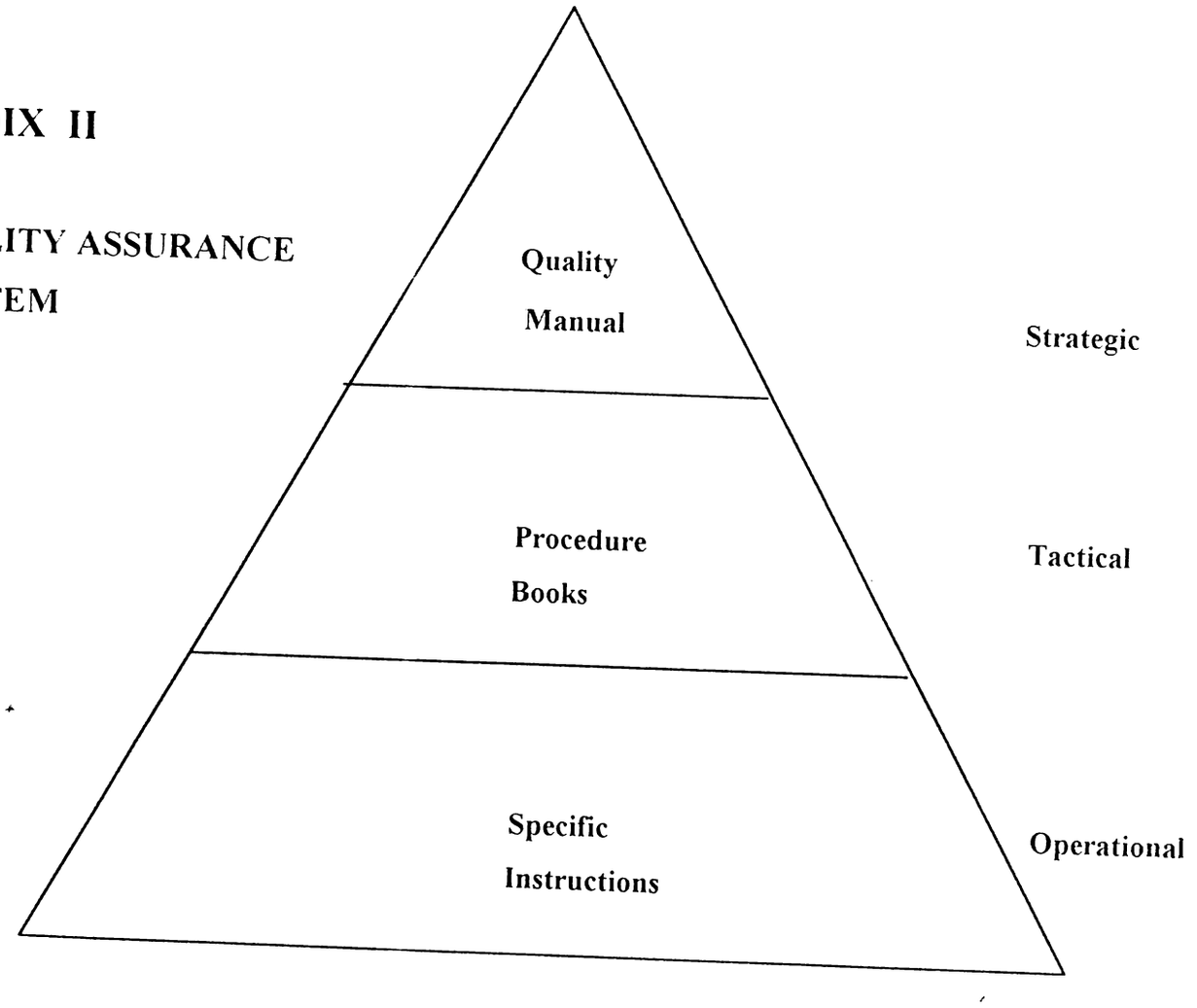
APPENDIX I
ORGANIZATION CHART



APPENDIX II

ELİMKO QUALITY ASSURANCE SYSTEM



APPENDIX III

DEFINITIONS

QUALITY

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

PRODUCT or SERVICE

The result of activities or processes (tangible product, intangible product, such as a service, a computer program, a design, directions for use), or an activity or process such as the provision of a service or the execution of a production process.

QUALITY POLICY

The overall quality intentions and direction of an organization as regards quality, as formally expressed by top management.

QUALITY MANAGEMENT

That aspect of the overall management function that determines and implements the quality policy.

QUALITY ASSURANCE

All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

QUALITY CONTROL

The operational techniques and activities that are used to fulfil the requirements for quality.

QUALITY SYSTEM

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

QUALITY PLAN

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

QUALITY MANUAL

A document setting out the general quality policies, procedures and practices of an organization.

QUALITY AUDIT

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

INSPECTIONS

Activities such as measuring, examining, testing, gauging one or more characteristics of a product or service and comparing these with specified requirements to determine conformity.

TRACEABILITY

The ability to trace the history, application or location of an item or activity, or similar items or activities, by means of recorded identification.

NONCONFORMITY

The non-fulfillment of specified requirements.

SPECIFICATION

The document that prescribes the requirements with which the product or service has to conform.

PROCEDURE

A methodology for carrying through a certain activity or series of operations. Procedures are basically covering general and transverse activities.

DOCUMENTED PROCEDURE

Written and authorised guide-lines for how to handle and carry through a certain activity or series of operations.

INSTRUCTION

A specification of how to execute a specific operation. An instruction is generally covering one, or one of several specific operations subject to a written procedure.

DOCUMENTED INSTRUCTION

A written and authorised specification of requirements to be fulfilled and followed by executing a specific operation or task.

APPROVAL

Confirmation of compliance with specified requirements.