A CASE STUDY!
FORMING AN EFFECTIVE QUALITY MANAGEMENT SYSTEM
ACCORDING TO ISO 9000 STANDARDS

A THESIS
Submitted to the Faculty of Management
and the Graduate School of Business Administration
of Bilikent University
in Partial Fulfillment of the Requirements
For the Degree of
Master of Business Administration

By
Orhan Zalayapen
June 1995
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I certify that I have read this thesis and that in my opinion it is fully adequate, in scope and in quality, as a thesis for the degree of Master of Business of Administration.

Assistant Professor Selçuk Karabatı

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

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Assistant Professor Serpil Sayın

Approved by Dean of the Graduate School of Business Administration

Professor Sübidey Togan
ABSTRACT

In today's world, companies which adopt themselves to certain internationally recognized standards are one step ahead of their competitors. ISO 9000 Quality System Standards captured the most attention among all. The aim of the standard is to provide an international benchmark for in-house quality practices. In order to get the most benefit out of it, the standards should be tailored to the specific requirements of the facility. Otherwise, companies trying to adopt this Quality Management System (QMS) may find themselves in a mass of useless work which could easily lead them to great inefficiencies.
ÖZET

ACKNOWLEDGMENTS

I greatly acknowledge patient supervision and helpful comments of Assistant Professor Selçuk Karabati throughout the preparation of this study.

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

I also wish to express my thanks to the distinguished members of Işık Makina İmalat ve Pazarlama A.Ş.
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CHAPTER 1
INTRODUCTION

Quality, like beauty, is in the eye of the beholder. Customer perceptions are typically the only true measurement of quality. If they are satisfied the quality is good enough.

However, there has been a push in recent years to quantify quality, particularly through the ISO 9000 series of international standards sponsored by the International Organization for Standardization located in Switzerland. This set of generic standards gives guidelines for establishing and maintaining a quality system within a company, for manufacturers and service entities alike. The intent is to provide an international benchmark for in-house quality practices, be they in Istanbul or Düsseldorf, and allow at least some degree of comparison on a global basis.

ISO 9000 says nothing about the quality of the end product. In fact, the intent of the standards is not to ensure product quality—the marketplace determines if a product is good or bad. Rather, ISO 9000 merely tries to ensure that quality is consistent, that the product is the same from batch to batch, from one day to the next.
Implementing a quality system is a difficult task for any facility. Even for those with TQM quality practices in place, implementing an ISO 9000 system can take many months. For those starting from scratch, ISO can take years. No facility would dream of undertaking such a task without expecting a significant return on the investment, benefits in other words.

There are two levels to these benefits, depending partly how the standard is applied. Most often, facilities implement ISO 9000 for contractual reasons because a customer has made ISO 9000 a condition of its contract with the facility. This application of the standard obligates the facility to acquire ISO 9000 certification. Other facilities adopt the ISO 9000 standard for non contractual reasons simply as a model for an ideal quality system.

1.1.1. What is a "quality system"?

The aim of a quality system is to assure, through the application of quality assurance and quality control, that the facility's product or service meets the quality requirements of the customer.

To arrive at a workable explanation of a quality system, we need to define some terms more closely:

Quality, in the context of this discussion, consists of the features and characteristics which collectively determine the extent to which output satisfies the customer's needs. The definition is customer driven at both ends. The customer determines what the features and characteristics are; the customer determines the extent to which the features and characteristics of the output satisfies his or her needs.

Quality assurance is the collective term for planned, formalized activities intended to provide confidence that the output will meet required quality levels. In addition to in-process activities, quality assurance includes activities external to the process, including activities by means of which customer needs are determined.
Quality control is the collective term for in-process activities and techniques intended to create specific quality characteristics. These activities include monitoring, reduction of variation, elimination of known causes, and efforts to increase economic effectiveness.

A quality system, then, is a facility and process-wide program of plans, activities, resources and events. This program is implemented and managed with the aim of ensuring that process output will a) meet customer quality requirements, logically assuring that b) return on investment (ROI) goals are met.

An effective quality system unites all elements of the facility including employees, plant, equipment, procedures, etc. with suppliers at the front end and customers at the output end.

Facilities with dynamic quality systems tend to exhibit the following attributes:
- Philosophy of prevention rather than detection.
- Continuous review of critical process points, corrective actions, and outcomes.
- Consistent communication within the process, and between facility, suppliers and customers.
- Thorough record keeping and efficient control of critical documents.
- Total quality awareness by all employees.
- High level of management confidence.

These attributes inevitably lead to the following tangible benefits:
- Informed, competent management decision making
- Dependable process input (supplier control)
- Control of quality costs
- Increased productivity
- Reduced waste
1.1.2. What is ISO 9000 certification?

A facility seeks certification to ISO 9000 either because one or more customers require it by contract, or because the facility expects such contractual requirements to be imposed upon it at some point.

Unlike non contractual applications of ISO 9000, which need not involve firms outside the facility, certification requires that the facility establish a relationship with an outside body. These bodies, which are called registrars, are specially accredited for this purpose.

ISO 9000 certification is awarded on a per-facility, rather than per-firm basis. Therefore, a firm with 10 facilities may need to acquire 10 certifications. Certification is conferred when the registrar, by means of audits of the process and its documentation, decides that the facility:
- Has a quality system which meets the ISO 9000 standard;
- Uses that system actively in its daily course of activities

The facility actually becomes certified to a particular part of the ISO 9000 standard. These parts called ISO 9001, 9002, 9003, are actually quality system models. The facility becomes certified to the model which most closely fits the scope of its operations:
- ISO 9001, the most comprehensive part, applies to facilities which design/develop, produce, install and service products or services to customers who specify how the product or service is to perform.
- ISO 9002 applies to facilities which provides goods or services consistent with designs or specifications furnished by the customer.
- ISO 9003 applies to final inspection and test procedures only.

The facility's quality system must include each element specified in the standard. The system must also be documented by means of a "quality manual".

Certification, once awarded, is reinforced by means of semi-annual unscheduled on-site audits.
1.1.3. Benefits of ISO 9000 certification

There are two important benefits: access to markets and competitive advantage. Another benefit of certification is that the facility regularly undergoes objective assessment by skilled outside professionals.

Access to markets is the most critical benefit of ISO 9000 certification. It enables facilities to maintain or create customer relationships in situations in which ISO 9000 certification is required. As quality becomes an increasingly vital differentiator in the marketplace, ISO 9000 certified facilities will enjoy a clear competitive advantage.

These, along with the quality system benefits cited above, make achievement of ISO 9000 standards a powerful strategic tool.

1.2. Preliminary Audit

The preliminary audit can be done in-house or by an outside consultant. (If in-house, someone must be assigned to the task for a week or two and relieved of other duties.) Following study is a result of such an audit. The first thing to do is to buy copies of the ISO 9000 series of standards from the local national certification agency or standards authority. These should be secured in a solid ring-binder and become the first and master set of documents in a documentation system which will form part of the final quality assurance scheme.

The aim of the audit is to check whether the existing Quality Management System meets the requirements of ISO 9000. This will result in:

- Establishing the conformity or non-conformity of the products or processes within the existing system;
- Establishing the degree of success or failure of the existing system, including both the degree of success in meeting customer requirements and of meeting any regulatory requirements.
The Preliminary Audit should reveal how far we have to go to install the desired quality management system. The following study contains an appropriate application of the QMS elements of ISO 9001 and an action plan. The study is completely based on a Preliminary Audit.

1.3. Which standard to choose

The firm İşık Makina İmalat ve Pazarlama A.Ş. is audited according to the requirements of ISO 9001 since the company:
- Has full control of the design and development of the product.
- Ensures conformity to customer requirements through the process of design/development, production, installation and service.
- Manufactures a complex or newly developed product and the related employees are the active participants in the design/development work.
- Has a contractual obligation to provide servicing of his product.
CHAPTER 2
QUALITY SYSTEM REQUIREMENTS

2.1. Who is responsible for the quality of a facility's products?

Ultimately, one person at a facility is vested with overall responsibility for the quality of the facility's products. This person, as the management representative, is a person possessing sufficient rank and authority within the facility to be able to develop, monitor and change elements of the quality system in concession with the responsible staff of the related function. The duties of the management representative should be clearly defined; the overall objective of the function is to assure that the facility's products meet the customer requirements.

The management representative has ultimate responsibility for creating and implementing facility's quality policy. The quality policy is management's stated public commitment to the quality of the facility's products, and is expressed in terms of quality objectives, policies and practices. Responsibility for carrying these out is vested in a clearly defined quality organization consisting of all personnel whose duties effect quality in any way. That the quality policies and practices are being carried out effectively must be verified by trained personnel (auditors) on a regular basis.

Periodically, the facility's quality system must undergo through management review. This is done under the authority of the management representative. The schedule for quality system review can be adjusted in accordance with experience and results. Each quality system review should consider, at minimum:
- The results of internal quality audits;
- Management effectiveness;
- Defects and irregularities;
- Resolution of customer complaints;
- Solutions to quality problems;
- Implementation of past solutions;
- Handling of non-conforming product;
- Results of statistical score keeping tools;
- Impact of quality methods on actual results.

2.2. What are the elements of the facility's quality system?

The facility's quality system is a direct result of management's philosophy and decisions concerning quality. It is a documented system whose chief aim is to assure that the facility's products meet customer requirements.

The elements of the facility's quality system include:
- A quality manual which addresses the appropriate segments of the Standard;
- Documented quality system procedures and instructions to support the specifications contained within the Quality Manual;
- Documented means for identifying customer requirements, both objective and subjective, and for translating those customer requirements effectively into the design, production and delivery of product;
- Measurement, testing and control equipment for assessing quality which utilize recognized procedures and meet documented external standards, as appropriate to the process(es) in question;
- A system for evaluating process capability that allows sufficient lead time for anticipated capability requirements to be met.

The facility's quality system must be accessible to and easily understood by all personnel whose duties and activities have any bearing upon quality. It should take into account all facility functions and should provide for the keeping of pertinent records.
2.3. How should the facility manage its contracts?

The facility must establish documented procedures for creating, coordinating and reviewing customer contracts. These procedures must specify a contract review system which verifies that:

- Customer requirements are clearly documented and understood;
- Any variances are satisfactorily resolved with the customer in advance;
- All contract conditions are well within the facility's capabilities.

Records shall be maintained of all contract reviews.

2.4. How shall the facility manage the design function?

The purpose of the facility's documented design system is to assure that the facility's products meet specified customer requirements. To that end, the design system shall include:

- A documented organizational structure that clearly specifies responsibility for each design and development activity;
- Clearly defined interfaces among the design/development function and its constituencies;
- Means to assure that the design/development function has all necessary training and resources;
- A system for gathering design input, documenting it, resolving ambiguities and translating it into the design process;
- A system for assuring that product designs meet input requirements, include acceptance criteria, meet all relevant laws and regulations, and anticipate appropriate safety standards;
- A system for verifying the appropriateness of designs for products by means of design reviews, laboratory and field tests, comparative studies and the like;
- Procedures for reviewing and adjusting the design and development system as necessitated by circumstances.
2.5. How should the facility control and revise quality-related documents?

The facility will administer a documented system for the creation, publication, distribution, use and revision of all documents related to the quality system and the requirements of the Standard. These documents specifically include the Quality Manual, all referenced procedures and operating instructions and other documents central to the design, production, and distribution of products. The system shall include the following elements:

- Up-to-date editions of all relevant documents shall be readily accessible by the personnel who need them;
- Superseded documents shall be promptly removed from circulation and discarded;
- All document reviews, changes and updates shall be performed by the same functional personnel who created them, and shall undergo the same review and approval process as the originals;
- A master list of quality related documentation shall be maintained, clearly denoting the edition numbers and dates of the up to date issues.

2.6. How shall the facility control the purchasing function?

The facility shall maintain a purchasing control system which assures that purchased products meet specified requirements. The system shall provide the following:

- All purchasing documents shall include data which thoroughly describes the products concerned, including, where appropriate, name, specifications, drawings, technical data and the like;
- All purchasing documents shall undergo specified reviews for adequacy, completeness and accuracy;
- All sub-contractors shall be chosen on the basis of a documented capability, past experience and demonstrated ability to meet specifications;
- Records of acceptable subcontractors shall be maintained. The facility shall include in its purchasing contracts the right to inspect purchased products either at the supplier's site or
upon receipt to assess its conformance to published requirements. In so doing, the facility shall not: a) relinquish its right to reject purchased product, b) absolve suppliers of the responsibility to furnish products that meet specifications, or c) take responsibility for the quality within a supplier’s process.

2.7. How should the facility handle product supplied by its customer?

Facilities which incorporate customer-supplied products into their own end-products must operate a system which controls and secures such products. The system shall provide for the following:
- Procedures must exist for ensuring the suitability of the products for the intended purposes;
- All products, where appropriate, must be kept safe and secure;
- All occurrences of non-conformance, shrinkage, damage, etc. to supplied products must be reported promptly to the customer.

2.8. What actions should the facility take to assure identification and traceability to its products?

Identification and traceability is an especially vital issue for those facilities supplying products that may be subject to recall if found to be non-conforming, hazardous or in conflict with laws, regulations or statutes. Where appropriate, the facility shall maintain a system which provides identification and traceability throughout the process: from the design through production, delivery, installation and use. This system may be on a lot or an item basis. In all cases, records of the identification system and documentation of traceability shall be carefully maintained.

2.9. How should the facility control the production process?

The facility shall carry out all production processes which affect the quality of products under a system that specifies thorough planning and control. This system shall include:
- A documented quality plan covering each step of the process which includes clearly understood quality criteria;
- Documented and updated work instructions which specify the steps required for each task, where the absence of any of those steps would negatively effect quality;
- Provision of appropriate equipment, facilities and supplies;
- Periodic review and approval of quality methods, processes, systems and equipment;
- Adherence to published standards, laws, codes and regulations;
- Monitoring of identified crucial product characteristics at appropriate points in the process;
- Careful attention and control of special processes, the results of which cannot be objectively assessed until after the resulting product is in use.

2.10. What procedures shall the facility follow for inspection and testing?

The facility shall maintain a documented system for inspection and testing at each appropriate process phase. This system shall provide for the following:
- Facility shall operate a receiving inspection process to assure that all incoming product is inspected or verified as being in conformance with requirements;
- The system shall ensure that any and all products exempted from the receiving inspection procedures for reasons of urgency or otherwise shall be clearly identified and made traceable should retrieval become necessary or prudent at any point in the process;
- In-process testing requirements shall be clearly documented by procedures and work instructions. These shall specify inspection points, methods, standards and equipment, as well as a system for handling non-conforming product (see below);
- The final inspection process shall be documented by procedures and work instructions. It shall verify conformance to requirements and shall be designed to ensure that non-conforming products are prevented from reaching the customer;
- Facility shall utilize a clearly documented procedure for storing, correcting and/or disposing of non-conforming products regardless of the point at which they are encountered in the
process. The facility shall maintain a record keeping system to document the inspection and test process, including outcomes in all categories.

2.11. What is required with respect to measuring and test equipment?

The purpose of measuring and test equipment is to aid in making an objective assessment on the conformance of products to specified requirements. Where appropriate, the facility shall acquire, maintain and use measuring and test equipment in keeping with the following:

- Equipment shall be acquired to meet identified and documented requirements with respect to measurement, accuracy and precision;
- Facility shall operate a documented system for ensuring that measuring and test equipment is checked, calibrated and kept consistent with a) devices known to be consistent with a nationally recognized standard, or b) a clearly documented basis for calibration. The system shall include procedures for calibration, methods for calibration, required actions in the event of non-conformance, and means for clearly identifying the calibration status of each piece of equipment;
- Facility shall also have procedures that provide for the safety and security of inspection, measurement and test equipment. The facility's procedures shall ensure that all measuring, test and inspection equipment is capable of detecting non-conforming products at all times under all foreseeable circumstances, and shall provide for the keeping of records sufficient to document a satisfactory level of control.

2.12. How shall the facility identify the inspection and test status of products in production?

The facility's procedures shall include a documented system for maintaining continuous identification of the test status of products as they proceed through the process. This system may be visual (i.e. tags, labels, markings, etc.), or it may be organized by physical location or some other clearly documented means. The inspection and test status of products should
thereby be easily ascertainable in order to prevent non-conforming products from being released to dispatch, installation or use. The facility's procedures shall include record-keeping methods adequate to document this system and the persons responsible for its administration.

2.13. How shall the facility control non-conforming product?

The facility shall maintain a documented system for the control of non-conforming products. The objective of this system is to ensure that such non-conformances do not inadvertently reach customers. Elements of the system may include the following, as appropriate:

- Means of identification shall be used to differentiate non-conformances from other products;
- Procedures shall exist for effecting correction of non-conformances, inspection and integration into the process stream;
- Procedures shall also be documented for obtaining customer approval of non-conformance in cases of urgency. Records of detection and disposition of non-conformances shall be maintained, as appropriate.

2.14. What type of corrective actions shall the facility implement?

The facility shall maintain a documented procedure to detect the causes of non-conformances, formulate corrective actions, implement them and monitor the results to ensure that the corrective actions have had a salutary effect. The system may include, as appropriate, ongoing process studies to anticipate potential causes of non-conformances and risk versus return analyses of corrective actions. Records of corrective actions shall be maintained, as appropriate.

2.15. What shall the facility do to protect the quality of its products?

The facility shall maintain a documented system to ensure the protection of products at all phases for which the facility is responsible, from inception through installation. Elements of this
system may include, as appropriate:
- The maintenance of secured storage areas to protect products from deterioration, theft, misuse or other misfortune, including regular audits to assess the effectiveness of storage measures;
- Systems for tracking products throughout the process, including identification, tagging or other means to prevent unauthorized custody or use;
- Packaging and marking systems that assure accurate identification and robust tolerance against anticipated handling during the delivery process;
- Use of delivery systems, where appropriate, that ensure that products are received by the consignee in a manner that is consistent with requirements. This procedure shall be documented by appropriate records.

2.16. What quality system records are required?

The quality system shall be thoroughly documented by quality records. A procedure shall exist for creating, maintaining, distributing, using, and disposing of records at prescribed and managed intervals. The procedure shall specify:
- Persons responsible for quality records system;
- Types of records to be maintained;
- Secure storage systems;
- Retrieval procedures that ensure access by authorized persons;
- Retention intervals;
- Means of disposal;
- Systems for making quality records available for inspection by authorized customers, outside assessors, etc.

2.17. How shall management monitor the quality system?

The facility shall maintain a documented procedure for conducting regular internal audits of the
quality system. These audits shall ascertain the degree to which promulgated quality activities are being conducted as specified, the effectiveness of the quality activities, areas of non-conformance and action items. The frequency of audits in any particular area of the facility shall be appropriate to a) the importance of the area in question; b) results of past audits; and c) number, magnitude and seriousness of non-conformances traceable to the process area. Audits shall be carried out by trained and authorized personnel whose regular duties entail no responsibility for the areas being audited. Results of internal audits shall be made available to the persons involved and management of the affected areas shall be made responsible for responding to audit flags with the appropriate corrective actions. All internal audits will be thoroughly documented based upon established procedures.

2.18. What type of training programs are required?

The facility 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. This documented program shall:

- Identify skill shortages by means of examination or other techniques;
- Secure the appropriate training resources;
- Implement the training;
- Verify training effectiveness by means of examination or other techniques;
- Conduct post-training monitoring, as appropriate;
- Include records of training and competence levels of employees.

2.19. How shall the facility provide service to customers?

The facility shall maintain a documented system for monitoring the post-transaction service needs as well as systems for creating, implementing and monitoring service that is appropriate to the needs of the customers and the marketplace. Appropriate records shall be maintained of all service related activities.
2.20. What are the requirements for statistical techniques?

The facility 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 particular, procedures for selecting samples, acceptance rules, process capability, lot screening and classifying of characteristics shall be formulated and documented. Records of statistical evaluation programs shall be maintained in accordance with documented procedures.
CHAPTER 3
THE COMPANY AND ITS OPERATIONS

3.1. Name of The Company

Işık Makina İmalat ve Pazarlama A.Ş.

3.2. Location of The Company

Tel: (0312) 278 08 48

3.3. History of The Company

The company was originally established as Işık Unlimited Co. in 1960 specializing in the production of construction equipment. Later, it diverted its occupation to the production of all kinds of cranes and dam equipment systems. The company then changed its corporate status and adopted its present corporate name in 1983.

Activities originated by the late Orhan Işık in 1956 in an 18 sq.mt. workshop are presently located on an area of 39000 sq.mt. 9500 sq.mt. of which constitutes the workshop and 4000 sq.mt. as open assembling area.

3.4. Scope of Supply

Işık Machinery Production and Marketing Co. Inc. is a heavy equipment manufacturing
company with its own systems and design technology specializing in hoisting/handling machinery and in hydro-mechanical equipment for large irrigation projects and electric power generating dams.

The company concentrated all of its efforts in hoisting/handling machinery for a couple of years because of the instability in hydro-mechanical equipment need which completely depends on Government Policies and Tenders.

3.5. Hoisting and Handling Machinery

Işık has been involved in manufacturing hoisting and handling machinery since the beginning of the industrial development in Turkey. The company has been the supplier of more than 1500 hoisting and handling machinery to various installations throughout the country. The major fields of industry where Işık products well regarded are:

- iron and steel industry
- hydroelectric and thermal power plants
- construction and manufacturing industry
- mining industry
- cement industry
- paper industry
- shipyards
- harbors.

The company manufactures the following hoisting and handling machinery:

- overhead traveling cranes
- general purpose and powerhouse cranes
- heavy duty steel mill cranes
- gantry and semigantry cranes
- derrick cranes
- harbor cranes
- shipyard cranes
- electrical hoists
- transfer cars for steel mills
- grabs and special attachments.

3.6. The Process

Government tenders, inquiries of companies from the private sector, direct orders of the customers constitute the work potential of Işık Machinery.

3.6.1. Preparing a Quotation

After receiving an inquiry, the first step in preparing a quotation is the investigation of customer requirements and specifications. This is done in cooperation of Engineering and Production Planning Departments and the Project Manager.

Technical requirements and material need is determined by the engineering department after performing the basic engineering calculations. Production planning department determines the existing extra man and machine hour. The need for the subject project is compared with the current excess capacity and finally the project manager investigates the financial soundness and profitability of the project.

With the help of all of these information, if it is decided to submit a quotation to the customer a cost analysis is performed by the project manager in order to do the pricing of the project.

3.6.2. Receiving the Order

After receiving the order, the project manager informs the production planning department
with the following:
- customer name
- invoice address
- delivery address
- brief description of the job
- delivery date of the order
- terms of delivery (free on truck, ex-works, cost & freight, etc.)
- payment schedule (advance payments, installments, deferred payments, etc.)

According to the above mentioned information production planning department issues a Work Order and distributes it to the:
- engineering department
- manufacturing department
- accounting department

3.6.3. Planning the Job

At this phase of the process, design engineers finalize the raw material and sub-assembly parts need. The components that should be imported are segregated from the ones which are supplied domestically.

A time schedule for the supply of raw materials (steel plates, forged round bars, profiles, cast material, etc.) and sub-assembly parts (motors, bearings, geared couplings, hooks, etc.) is determined by the engineering department. This information is forwarded to the production planning department. Production planning department, after checking the stocks informs the purchasing department about the need. Meanwhile, the production planning department includes the new order to the current Production Schedule and determines an approximate production time for the new order. If a lack of capacity is determined, the chief of the department takes the necessary action by
increasing the number of employees, shifts, etc. All of these activities are carried out in coordination with the chief of the manufacturing department.

If the order is a standard product, there is neither a need for a basic, nor a detailed engineering. The product is manufactured according to the existing standard designs.

3.6.4. Design

After getting the information of an order, the engineering department prepares its own working schedule and makes its departmental job distribution. The past designs and calculations that has been documented are investigated for their suitability of usage in the new order. Basic engineering study and customer specifications are checked again and detailed engineering is performed accordingly.

The first thing to do is the determination of standard components that are going to be used on the product (gearboxes, brakes, hook blocks, sheaves, etc.). This information is immediately conveyed to the manufacturing department so that production could at once start.

After performing the detailed design calculations, design engineers inform the constructors about the necessary dimensions and construction practices according to the allowable standards (DIN, FEM, CMAA, etc.). The constructors, after making the assembly drawing begin the detailed drawings of the project (like hoisting and traveling units, girder sections and assembly parts).

Meanwhile, electrical design is carried out by the electrical engineering department in order to determine the panel sizes, electrical equipment and cable need and etc. Circuit diagrams are drawn and current supply to the product is enhanced accordingly.

Mechanical and electrical engineering departments perform the design in coordination. After the completion of the design work, the managers of these departments check the functionality
of the design and control the dimensioning on the drawings and send them to the customer for approval (if required).

3.6.5. Production

After getting approval from the customer, the engineering department forwards the drawings to the production planning department and this department distributes a copy of the drawings to the related work areas in the shop floor.

Production planning department checks the drawings and compares the previous purchase orders with the exact material need which could only be determined at this phase. If a need occurs, an urgent purchase order is sent to the purchasing department.

The time schedule of production is revised according to the current information i.e. detailed drawings and the production of parts which are not standard starts.

The first step in production is the cutting of steel plates and round bars. These raw materials form almost % 90 of a crane on weight basis. The girders (main and end) are constructed by welding steel plates which had been cut to design dimensions to form a box section. They are also used inside the girders and in various sections as supports, in gearbox manufacturing and in the construction of the trolley chassis.

Forged round bars are mostly used in the production of transmission shafts (for example to enable transmission of power from the electrical motor to the gearbox, and from the gearbox to the crane wheel). They are also used in the production of crane wheels, gearbox cassettes, flanges, etc.

An Overhead Traveling Crane depending on its span and capacity is generally formed of two main girders, two end girders and a trolley traveling on the main girders. As described
previously, the girders are constructed from steel plates of certain thicknesses which are determined by their stress carrying capacities.

The assembly of the main and end girders forms the so called bridge of the crane. Bridge traveling is enabled in various ways, however, the logic is the same for all. Power from the electrical motor is transmitted to the crane wheels by the help of a gearbox. This is also the same in trolley traveling.

After the production of the trolley chassis, traveling and hoisting units are assembled on it. The hoisting unit is formed from four main components. Electrical motor, gearbox, brake and a hoisting drum. With the same logic, power gained from the motor is used in activating the drum on which a steel rope is wired. At one end of the rope the hook block exists. The load is hanged on the hook for hoisting and handling purposes.

After describing the crane, its components and very briefly the production process, we can talk about the organization of the manufacturing department which exists informally and the details of manufacturing.

There are seven sections under the manufacturing department:

- raw material preparation
- welding
- chip removal shop
- mechanical assembly
- standard assembly
- thin plate section
- painting
- quality control

Raw material preparation section is responsible from cutting steel plates, round bars, profiles
and etc. to their design dimensions (with enough allowances for machining) and supplying them to the related work area. After cutting of the steel plates they are sanded for the removal of corrosion on them. Then they are painted with initial paint for protection and sent to the welding area. Round bars are also cut to their dimensions with enough machining allowances and sent to chip removal shop for machining.

In welding area, girders and trolley chassis are constructed from the steel plates. Parts like gears, flanges, transmission shafts, wheels and etc. are manufactured from round bars and cast material in the chip removal shop. Steel plates and round bars which had been controlled ultrasonically and tested for their material properties are inspected for their dimensional tolerances after manufacturing. Parts like gears and wheels which require a certain hardness are sent to outside companies for heat treatment after their machining operation is completed. Later, they are brought to the mechanical assembly area. Gears are assembled in the gearboxes and tested for their proper functioning and shafts are assembled to the wheels.

At the same time, standard assembly is carried out. Here, İşik's standard products like hoists of low capacity, brakes (magnetic and electrohydraulic), hook blocks and etc. are assembled.

After the production of these components and sub-assembly parts, it is time to perform the main assembly works. Traveling and hoisting mechanisms are mounted on the chassis, trolley wheels are assembled to it and the operation is completed for the trolley. In order to construct the bridge, end girders are assembled to the main girders. Before doing this, crane traveling wheels should be mounted on the end girders. Next, the traveling units of the crane are assembled to one of the main girder and the crane is now ready for painting and electrical installation.

While all of these operations is going on, in the electrical engineering department electrical panels of the crane are manufactured. Thin plate section constructs the cable ducts on the crane and manufactures the cable drums which carry the electrical cables. After the installation
of electrical panels on the platforms welded to the main girder and current carrying cables into the ducts, the crane is ready for the final tests. Dimensional controls and performance tests are carried out and the crane is dis-assembled to its main sections for delivery to the customer.
4.1. Management Responsibility and The Quality System

Management Responsibility is the keystone requirement of ISO 9000 standards and requires the most attention among other requirements. Without strong, demonstrated commitment by the management, it is not possible to pass this element of the standard. Therefore, it has to be assured that the management is informed on the requirements of ISO 9001 and that they must play an active role before attempting to implement the requirements of this element.

4.1.1. Management commitment

Management must define their QMS so it meets the needs of their business. The first step is to secure management commitment to develop and implement an effective QMS. Management must adopt a Quality philosophy which focuses on understanding and meeting customer requirements through preventing errors, not merely fixing them once they have arisen. The commitment required from management to a QMS is absolute if it is to succeed. If management commitment is not absolute then the system will fail. Management must demonstrate their commitment in actions and words. Management are responsible for ensuring that the QMS:

- defines the Quality Policy for the business. Management should ensure that their commitment to Quality is understood and followed throughout the organization
- complies with the requirements of ISO 9001
- is operated by all staff
- is fully documented and controlled.
4.1.2. Employee commitment

A successful QMS will involve all the employees. Everyone must take ownership for the quality of their work. This will only be achieved if they are involved in developing the system to ensure it meets the objectives of the Quality Policy. This means that:

- all employees need to understand their customers' requirements and the internal processes which enable to meet those requirements;
- it will no longer be acceptable to rely on finding and fixing errors. Employees will have to focus on preventing errors;
- individuals should be encouraged to take actions to improve the quality of their output.

To achieve these objectives will require the commitment of all the employees. It may also require some changes in existing management methods and systems. This may rise difficult questions but these need to be resolved. The required level of commitment from the employees is only achieved if everyone understands the aims and benefits of the QMS and the role they can play. The employees must:

- believe the management wants them to become involved. The attitudes and actions of employees are generally determined by what they believe management wants from them. It is essential to define clearly and unambiguously what involvement is required from the employees.
- understand what they can contribute. Individuals are generally reluctant to become involved in an activity unless they have been given permission to do so. They need to know their responsibilities, authority to act and the boundaries of their role. This can be achieved by providing them with a well written job specification. It should not just be a description of the tasks which the employee will be expected to undertake. A properly written job specification can provide the management authority for individual involvement, and specify the resources they have to meet those responsibilities;
- be provided with the necessary education and training. To achieve the involvement of every employee requires their commitment. Commitment requires understanding.
Understanding requires training. Training requires management commitment, planning and time.

Every individual needs to understand the reasons for the QMS, what it means to them and how they are equipped to contribute. The training must be relevant, interesting and enable people to understand and participate.

It is important that the whole workforce is included in the training program. Everyone has their part to play. For example; production line staff are likely to know more about the things that are wrong where they work than their managers and supervisors. They have probably been living with the problems and fixing errors for a number of years.

4.1.3. Ensuring ownership of the Quality Management System

One difficulty organizations sometimes find when establishing a QMS lies in the unresponsiveness of some employees and managers. In most cases this stems from a belief that they are being told how to do their job by people who have no great claim to excellence themselves.

Imposing new working practices and systems without consultation is a recipe for disaster at any time. Imposing a QMS without reference to those whose job is affected is worse because they will resent it. This may well ultimately lead to failure of the QMS, higher costs, dissatisfied customers, and disgruntled employees.

The best results will be obtained if employees are involved at all stages in the process. Analyzing the business as a series of processes will enable to determine what goes on, and to identify and manage the control elements that govern the success of the business. Having identified all the processes of the business, their owners should be involved in documenting them. The first step is to define the technical content, the "how" and "what" of
each process. These should be defined by people who know what actually happens. In order to ensure consistency a standard for preparing documentation could be established. Once the initial data has been recorded, the documents may be polished by a central team. The owners of the processes should continue to be involved at each stage. They should be closely involved in any discussion about process improvements and changes.

This involvement will establish ownership of each process by those who operate it. It will also ensure that details of each process are recorded faithfully. This will establish a baseline for improvement throughout the business. This will ensure the system is accepted and operated by all because everyone was involved from the beginning. This is critical to having a cost-effective system for the management of Quality.

4.1.4. The role of the management representative

One commitment that is essential to meet the requirements of ISO 9000 is the nomination of a senior manager (often called the Quality Manager) to be responsible for the continued integrity of the QMS. This role can be combined with other responsibilities. This individual must have the necessary authority to resolve any issues involving the QMS. It is generally sensible to appoint this individual before starting to implement a QMS. They can develop their understanding of the application of ISO 9000 to the business and manage the implementation process on behalf of the management team.

A mistake made by many organizations is to ask this individual or their team to document and implement the QMS. This may seem an attractive route to follow, but it may encourage the organization to focus on the Standard and not on its business needs. This may force the QMS onto a mould created by ISO 9000. A QMS structured in this way may fail to meet the needs of the business at the moment. It will also probably be difficult to adapt to changing circumstances. Involving everyone in identifying and defining processes might seem time consuming at the outset. However the real commitment could only be achieved if the staff
believes the QMS meets their needs. The most effective way of achieving this is to involve all
the staff in developing the documentation and ensuring they are all collectively responsible for
their QMS.

The management representative should monitor the health of the QMS. They may also be the
internal expert on the requirements of ISO 9000. They may have a responsibility to manage
and guide the implementation process. They are not solely responsible for the QMS. Everyone
must take ownership for the elements under their control.

4.1.5. The necessary documentation

A QMS will only be effective if it is documented, understood and followed by all employees.
This will only be achieved if it:
- defines procedures for all processes
- is documented and available to all users
- is readily used and understood by all users so everyone knows what is required of them.

The first step is to identify and generate the documents required to fully define the QMS. It is
then necessary to control the issuing, changing and withdrawal of these documents so that only
properly authorized, current versions are in use.

There are generally three levels of documentation within a Quality Management System. Each
level becomes more detailed, more specific and generally applies to fewer people within the
organization.

4.1.5.1. The Quality Manual

This is the statement of management policy and objectives for each of the requirements of ISO
9000. It usually begins with a brief description of the business, activities and the scope of the
operation to which the QMS applies. The rest of the manual then defines how each of the ISO 9000 requirements is addressed by the Quality Management System.

The Quality Manual is the policy statement of the company. The remaining documentation within the QMS describes how these objectives are actually met in practice. The Quality Manual is useful for a number of purposes:

-it ensures management understand what commitments the QMS is making on their behalf;
-it ensures employees understand management policy and use it to guide their activities;
-the assessing bodies use it as a starting point for assessing the company's QMS. This provides assurance that each element of ISO 9000 has been addressed by the QMS, and guides them to areas where further information is required;
-it provides a basis for assuring customers that a QMS exists. This can be met by supplying a copy of the Quality Manual.
-as a marketing tool to demonstrate the existence of a QMS and the management commitment to Quality.

4.1.5.2. Procedures

These documents form the bulk of a QMS. They describe how the policy objectives of the Quality Manual are met in practice and how the business processes are controlled.

Procedures describe the controls which exist to ensure all processes operate in such a way that both customer requirements and the requirements of ISO 9000 are understood and met. These procedures should describe how the processes work and how they satisfy the requirements of ISO 9000. Procedures generally describe the purpose of the process, how it operates, and the controls which reduce variability and ensure conforming output.
4.1.5.3. Work Instructions

These describe how to perform specific activities. For example, a procedure might describe a production testing process. A work instruction might describe how to operate a piece of test equipment.

ISO 9000 only requires work instructions where the absence of such a document would present a hazard to Quality. The number of work instructions required in an organization depends on the complexity of the operation and the skill, training and experience of the personnel employed.

4.2. Contract Review

In organizations like Işık Makina, which manufactures to orders, every inquiry requires a comprehensive planning and a quotation. The product is not the result of a mass production. It has its unique specifications and is a completely different design everytime.

The organization waits until a customer inquiry arrives before it begins to rush around in an attempt to respond before the deadline. The planning should follow the steps below:

-receive details of customer requirements

-internal estimates of costs/times/resources put together

-planning undertaken on how to fulfill the terms of the contract

-assessment of customer expectations of cost/delivery

-discussion of possible difficulties in meeting defined customer requirements

-production of a costed quotation for submission to customer addressing each of the contract requirements.

This kind of organizations are always under pressure to respond because deadlines are usually short. Their cost estimates are often inaccurate because they have little quantitative data. Their
time is purely spent responding to the contract, not anticipating alternatives which might better meet the customer requirements.

The difficulties that are frequently experienced within these organizations while putting together an estimate for a new contract are:

- each function will establish what is required from them
- they will then estimate the cost in time and materials to achieve the contract requirements
- most will refer to previous estimates
- most will agree that these estimates are unreliable and make an allowance for contingencies. These will rarely be supported by real data, and frequently will not be declared
- as the estimate goes around the organization different managers add their own view to the estimate
- the final management review almost always reduces the bid to increase the possibility of getting the order.

Very few of the above decisions will have been based on real data.

Clear planning is the cornerstone to achieving satisfactory business performance and the business requires certain key information to enable it to understand and plan to meet customer requirements:

- the skills, facilities and capabilities of the organization should be determined. The business may know what it is capable of, but it shall assess and document this in a structured way. If the capabilities are documented and regularly updated, a speedy and accurate response to requests from customers could be provided. This also enables management to picture where it is at present and to make plans to control future developments;
- the likely cost of providing a product could only be assessed if there exists an effective system for costing the inputs that are used;
- a mechanism for identifying statutory (health and safety) requirements which have an impact on the business should be ensured. This minimizes the time it takes to produce a meaningful response to a contract when this is required.

Too many organizations take on a contract and worry about how they will meet the requirements later. An effective QMS enables to understand and plan to fulfill every contract before acceptance.

4.3. Design Control

As mentioned in the Contract Review, in companies like Işık Makina, products require different designs everytime according to the specifications of the customer. Therefore, the key to a successful product is a good design and hence good understanding and documentation of the customer requirements. Poor production can devastate a good design but the production process can do little to improve a design that is inadequate.

The design process translates specified or implied requirements into instructions that will define the new product. There is the need to operate procedures to control and verify the design activities so that all specified requirements are met. Control of the design process is critical to the successful production of conforming goods. The design procedures and codes of practice should be documented and form part of the controlled Quality System.

4.3.1. Design Control

The objective of design control is to produce:
- a structured design
- that meets the requirements of the customers
-which can be manufactured
-within the cost/time constraints allowed.

The following key elements affect the quality of the design process. The QMS should define and document the procedures to control each of these elements:

-organization of the design function. It is essential that everyone understands their role in the design process;
-planning the design process;
-defining design inputs to ensure customer requirements are identified;
-defining design outputs to ensure they fully define the product;
-verification procedures to ensure the design output meets the input requirements. The designed product should meet the requirements of the customers and employees who have to produce and support the product;
-controlling design changes to ensure their impact on the design is assessed before implementation.

4.3.1.1. Organization of the design function

In order to create a successful design team it has to be ensured that the individuals involved are competent and understand their roles and responsibilities. The following issues should be addressed in the QMS:

-Structure: Organization charts, team descriptions and job descriptions should be used to help individuals understand their role within their team and to help teams understand their role within the design function.
-Competencies: A design group should have the technical and communication skills to enable it to:

- understand customer requirements
- extract further details of customer requirements if necessary
- understand how the product is to function
which can be manufactured
within the cost/time constraints allowed.

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- Competencies: A design group should have the technical and communication skills to enable it to:

  - understand customer requirements
  - extract further details of customer requirements if necessary
  - understand how the product is to function
-understand how it is to be produced
-translate the design inputs into design outputs
-document the design activities and decisions accurately.

It is not uncommon to find designs that cannot be produced at all, or can only be produced by incurring excessive costs. For example, specifying materials of non-standard sizes or defining processes with a high manual input will lead to a failure to design for lowest cost production.

-Responsibilities: The structure defines the roles and responsibilities of individuals and teams within the design function. Responsibilities are, however, meaningless without the associated authority and resources to perform those tasks. The design activity requires resources to operate effectively. The requirements include equipment, access to up-to-date information, and the opportunity to update skills and experience when required.

-Interfaces: The organization will mostly use a number of small teams each working on a small part of the overall design. When individuals or groups work on part of an overall task, the most important and difficult area to control is the interface between the groups. The QMS should document how interfaces between teams are defined and how information is communicated across these interfaces in a controlled way.

4.3.1.2. Planning

Planning is critical to the control of the design process. If an activity is not planned then it cannot be managed. The purpose of design planning is to ensure that all the activities are understood, planned for and monitored throughout the design process, the aim being to reduce the risk of producing non-conforming outputs at any stage in the process.

Design planning should enable to:

- break complex design projects down into individual modules which can be designed as stand alone elements and then integrated to produce a complete system design;
- define discrete design activities and establish responsibilities for their execution;
assign appropriate technical resources to the total design task;
-define design teams and how they should interact;
-verify that the design output satisfies the input requirements before the design is released for production;
-document the design processes for each product or project.

No matter where or by whom the design process is conducted, it is a requirement of the Standard, and good management practice, to ensure that every activity is planned, documented and recorded. It is important to keep adequate records so that:

-a record of design activities carried out is maintained;
-it could be demonstrated that the work was actually carried out as planned;
-a record of the total design and the basis on which decisions were made about changes to the design is maintained;
-data on which to base future decisions is obtained. Any lessons learned from this design can be used to guide future designs;
-a basis could be formed which would enable to build on existing designs in the future.

The QMS should define the record-keeping requirements for the design activities. All design records should be retained. They should not be edited. Iteration is a common feature of design activities. Records of past decisions and tests may be used as a basis for developing new designs. Design calculations, projects, operational plans, design reviews, etc. all form a part of the history of the design and will enable to trace decisions and assess data long after the design phase is over.

4.3.1.3. Design input

A completed design can only conform to the requirements if the requirements are fully understood at the beginning of the design process. It is, therefore, essential to control and document the design inputs, including:
- customer specifications and requirements;
- statutory requirements for the product and business sector;
- the requirements of production and support departments;
- standards for both the design output and the product which will be produced from the design.

Design input is the process of identifying the requirements of the customers from contract review and the requirements of the production and support departments from the capability statement.

One of the principal reasons for not documenting design inputs is that the requirements may change as the design progresses, so it does not mean much to document the requirements at the beginning.

In the absence of an adequate specification of input requirements, individuals within the design team may define the key parameters for themselves. These may not match the requirements of the customers. In that case, dialogue with customers ensures they are aware both of progress made and difficulties encountered, in achieving the original design objectives. Changes to the design documents, or to the design requirements should be agreed and fully documented. For a typical Overhead Traveling Crane, some of the design inputs are as following:

- hoisting capacity
- span
- traveling and hoisting speeds
- maximum hoisting height
- working class
- intensity of usage
- legal, health and safety requirements.

Where requirements cannot be understood or are ambiguous they must be resolved with the customer.
4.3.1.4. Design output

The design output is not the delivered product. It is the information from which the delivered product is produced. It is important to define the output required from the design process. Design output should be sufficient to enable the design to be produced. It should also be ensured that the design output meets the design requirements and that objective evidence is available to demonstrate it.

The design output should define or refer to acceptance criteria for the product. These criteria should ensure the design meets the requirements of the customers and the production department. There are two principal types of acceptance criteria. Design acceptance criteria define the customer and production requirements which must be met before the design can be released for production. Production acceptance criteria are the criteria the production department uses to assess whether the product has been produced as designed.

The design output should be fully documented. This should include the specifications, calculations and the projects (drawings) depending on the product. This information should be capable of being understood and used by technical or commercial personnel. It should therefore be clear, easy to understand and unambiguous. The QMS should define the format for the design output.

The design output documentation should identify the project or product to which it relates, and record the identity of the designer. It should also define:

- the characteristics of the product
- production methods
- design acceptance criteria
- test or verification methods applied in production that are proving the design integrity
- appropriate regulatory requirements for the product, regardless of whether these have been explicitly stated in the contract
-the characteristics of the design/product that affect safety and correct functioning.

4.3.2. Design verification

Having designed the product it is important to verify that the design output meets the input requirements. Design verification procedures should ensure adequate evidence is produced to prove that the input requirements have been satisfied.

It is important that the design verification activity is planned at the start of the design project. The plan should specify when in the design process verification will take place, and also the methods which will be used. When the design is broken down into modules, it is generally more effective to verify that each module conforms with its requirements before integrating them. It is then necessary to verify that the whole system conforms to requirements.

Some of the appropriate methods to verify designs are as following:

- design reviews
- carrying out alternative calculations
- comparison of new design with similar proven designs.

4.4. Document Control

Control of documents is required to ensure everyone operates a process in same way following the same instructions, and to ensure that procedures are defined, approved and understood. Any document which has an impact on the Quality of the products must be controlled. These may include the Quality Manual, procedures, work instructions, specifications and drawings.

4.4.1. Authorization

Before a document can be released it must be authorized. This should be undertaken by
designated individuals with the required skills to make the final decision as to how a process should operate. Different individuals will be responsible for authorizing changes to different documents. The most appropriate place to define who has authority to release documents is within each procedure. The overall document control procedure should define how the authorizing individuals or functions are selected.

4.4.2. Issuing documents

In order to ensure its products meet the requirements of the customers, the company has to ensure everyone operates the procedures as planned. This can only be achieved if the operating requirements have been documented, and the same version of these documents is available to everyone who needs to use them. The QMS should define:

- who should receive a copy of each document. There should be a balance between restricting the number of documents issued to reduce the risk of errors in the issuing mechanism and the need to ensure everyone has access to the documents they need to operate their process with minimum error. This could be achieved by issuing a set of documents to a given work area and then ensuring everyone is aware of the documents, what is in them, where they are and the importance of understanding their contents.
- how new documents are issued and obsolete documents withdrawn. It is important to avoid the risk of obsolete documents being available. The return of withdrawn documents when issuing new ones is an effective control.
- a mechanism for identifying which issue of a document is current at any given time. A master list of all documents and their revision status at any given time is essential. This document should be available to individuals so they are able to ensure their documentation is current before use.

4.4.3. Controlling changes to documents

Once a document has been generated and issued it will define the procedure the employees will
be expected to follow. If an improvement is identified the procedure should be amended and reissued. It is essential to establish a system to ensure changes are implemented in a controlled way, so they are properly assessed and are implemented effectively. The key features of a system to control document changes are:

- details of the proposed change must be fully documented. This is the basis on which the assessment will be made;
- the change must be reviewed thoroughly before acceptance;
- all changes must be authorized. This should be the responsibility of the department, or individual responsible for the original document. This ensures continuity of approach and a greater understanding of the implications of the proposed change;
- once a change has been incorporated within a document, it should be possible to identify details of the change. These details should also be recorded in the document itself;
- it is important to keep a master list recording the current status and history of the documentation.

4.4.4. Keeping records

In order to enable the control of the business, it has to be ensured that the defined procedures are, in fact, operated. It has to be ensured, for example, that the contracts are reviewed, tests are carried out and Quality Audits have been completed. Therefore the records has to be kept to demonstrate achievement of the Quality objectives. It is a must to keep the following types of records:

- contract review records
- design control records
- inspection and test records
- calibration records
- records of non-conforming products, including customer complaints
- corrective action records
- audit reports
The format of these records is important. If they are defined user friendly, for example, a checklist against which to record a contract review or a standard audit report format, they are going to be used with some enthusiasm. It is important to involve each process operator in defining what needs to be recorded for their process and the format of the record.

ISO 9000 requires that evidence is kept to demonstrate that all the requirements have been met. The QMS should therefore ensure each procedure defines the records required to demonstrate it has been followed. These records may need to be referred to long after they were generated. When defining the record system it has to be ensured that the records:

- identify key details
- are legible and incorruptible
- are retrievable
- are disposed of in a controlled way

4.4.4.1. Identification

It should be possible to identify the product or event to which each record applies, and answer the following key questions:

- who was involved in the process?
- what was the subject of the record? What happened? What decision was taken?
- when did the event occur?
- where did the event occurred?
- what was the basis for the decision? This may refer to a specific inspection procedure, or other documents if necessary.
4.4.4.2. Legible and incorruptible

It must be possible for anyone else to be able to read the record in a meaningful way long after the recorded event. The record should remain readable throughout its storage period. It is important to consider storage conditions and storage media to ensure this. The records should be incorruptible and should not be subject to amendment. This could be achieved by restricting access to records.

4.4.4.3. Retrievable

Records should be accessible during the storage period. Where and how the records are stored is important. They may need to be accessed in a different order to that in which they were stored. Storing the records in date order and according to the Work Order Numbers is a good application. A catalogue summarizing the nature of the records and where they are stored should be maintained.

4.4.4.4. Disposal

It is important that records are disposed of in a controlled way at the end of the storage period. An overall document should be generated defining the record keeping requirements common to all records, including retention time, storage media, storage responsibilities, disposal authorization.

4.5. Purchasing

Işık Makina is responsible for ensuring that the products it supplies conform to the requirements of its customers at minimum cost.

The company purchases great amount of goods from external suppliers. These are mainly used
as part of the product delivered to the customer, or to support the internal processes. The company's ability to meet the needs of its external customers mostly depends on goods (raw materials, sub-assembly parts, etc.) it receives from external suppliers. Therefore controlling the procurement activity is an essential part of the company's QMS.

Most businesses like Işık Makina suffer because they accept the supply of goods that do not conform to their requirements. It is often easier to attempt to compensate for poor suppliers rather than take steps to improve their performance. However, the use of poor suppliers has a significant effect on the company's ability to meet its customer's requirements at minimum overall cost. Holding excess inventory, living with excessive lead times, using equipment that is less than satisfactory or engaging in expensive on-receipt inspection activities. All these have a significant impact on the costs the company bears and hence the efficiency of its business.

The company has to ensure that it manages its suppliers so it only receives goods that conform to the requirements. The following key elements need to be managed:

- controlling the purchasing activity;
- selecting suppliers carefully;
- monitoring supplier performance in order to ensure receiving conforming goods.

4.5.1. Controlling the purchasing activity

It is only possible to receive conforming products from the suppliers if the requirements are fully, clearly and unambiguously defined. Most of the purchasing errors are due to an inadequate specification of requirements by the purchaser.

It is, therefore, essential that the QMS ensures all orders are placed in a consistent manner and specify the data required to fully define the wanted product. The following specific types of data are required in any purchase order:

- technical specification
-quality requirements
-delivery, cost and commercial terms.

4.5.1.1. Technical specification

A detailed description of the product should cover the essential performance parameters. Wherever possible, the purchase order should refer to specific part numbers, drawings, specifications, proposals or reports to describe the items required in such a manner that the requirements cannot be misinterpreted.

4.5.1.2. Quality requirements

The company might want the supplier to conform to specific quality requirements. These must be detailed on the purchase order such as:

-the supplier must conform to a specific quality standard (such as ISO 9001)
-specific inspection or test procedures must be carried out
-specific records are to be kept to demonstrate compliance with defined procedures
-for large contracts the supplier should provide details of specific processes, controls, inspection and test procedures, their principal suppliers and records. These should be detailed in a specific Quality Plan for the contract or order.
-some of the external customers may specify requirements which apply to the company’s suppliers. For example, a customer may specify that all suppliers should hold a recognized quality system approval, or they may reserve the right to carry out inspection activities at the company’s supplier. The QMS should recognize specific customer requirements and ensure they are included on purchase orders.
-acceptance criteria defining the way in which conformance to requirements should be measured. This ensures that both the purchaser and the supplier determine acceptance against the same criteria. This avoids problems which could arise if different methods were used by the supplier and purchaser.
The costs associated with an inadequate description of technical and quality requirements are usually hidden but are important since they are likely to be high and they may have an important impact on the company's ability to meet customer requirements.

4.5.1.3. Delivery, cost and commercial terms

It is necessary to include details of quantities, delivery times, pricing required and a definition of the terms of trade between two organizations. The QMS should ensure that an adequate description of the total requirement is specified when an order is placed.

4.5.2. Selection of suppliers

Having determined exactly what is needed to purchase it is time to select a supplier. The company's ability to meet its customers' requirements also depends on the ability of the suppliers to meet the company's requirements. An effective QMS requires a robust and effective system to control the selection of suppliers.

The method used to select suppliers should be carefully considered and documented as part of the QMS. The selection process may involve a number of functions within the business:

- **finance**: to gauge the financial soundness of the supplier
- **purchasing**: to negotiate the terms of the agreement
- **design**: to ensure the supplier has the capability to meet the technical requirements
- **production**: to assess the supplier's ability to produce the product in accordance with the requirements
- **quality**: to assess the supplier's Quality System to ensure conforming products are consistently produced.

There are a number of different criteria which can be used as the basis for selecting suppliers:

- **past performance**
Different criteria may be used in different circumstances. Whatever combination is used, it must be capable of assessing the supplier's ability to meet the company's requirements; technical, quality, delivery, cost and commercial.

4.5.2.1. Past performance

The company should collect data on the performance of its suppliers. This data may exist informally in the minds of the related personnel, however, recording it is always better and will provide an ease in accessibility. This information can be very valuable as it can help the company assess the likely performance of individual suppliers in the future. Three factors are important when considering past performance as part of the decision making process:

- the data on which the decision is made should be factual and recorded data. The decisions should not be based merely on opinion;
- the product required should be similar to that previously supplied;
- the supplier should not have been subject to significant changes in the period since the data was measured.

Past performance may include the company's own experience, or that of other users. It may be useful to call on the experience of others, such as trade organizations or other companies.

4.5.2.2. Assessment of quality system

An assessment of a supplier's Quality System can be useful in determining their potential ability to understand and meet the company's requirements. It is possible to use the TSE register of quality assessed companies or companies holding a Production Sufficiency Certificate. It is
important to check that the registration is current and that the scope of the approval covers the products which are required.

The supplier's premises could also be visited in order to review their technical, commercial and quality procedures in practice. During assessment, it is important that the basis for the decision, and the standard against which the system was assessed are recorded. Assessment of the supplier's QMS does, however, only provide a general view of their potential ability to consistently supply the type of product that is going to be purchased. It does not assess their actual ability to meet the company's specific technical requirements.

4.5.2.3. Product assessment

The company may ask its potential suppliers to produce samples that conform to their requirements. This method is useful since it determines the supplier's ability to meet the company's actual requirements. It may also reveal weaknesses in the requirement itself. It should not, however, be used as the sole means of assessment, since it only assesses the ability of the supplier to meet some of the requirements (usually only the technical) at the specific time when the samples were made. This method does not test the supplier's ability to meet all the requirements consistently over a period of time.

Each of these selection criteria may be appropriate in different circumstances. Rarely is one criterion sufficient as the basis for a decision. The QMS should define:

- the criteria to use in different circumstances
- who decides which criteria to use
- who is involved in specific supplier assessments
- records to be kept describing the basis for decisions, who was involved, and the data on which the decision was made.
4.5.3. Approved suppliers

It is important to ensure that individuals who place purchase orders know which suppliers have been approved to supply specific products. This information should be recorded in an Approved Suppliers list which typically includes the following information:

- name and address of the supplier
- basis on which approval has been given including details of national approvals, on-site assessment and historical data
- data on which approval given and the duration of approval
- scope of products for which approval given.

The QMS should specify the information to include in this list and who is responsible for maintaining and issuing it. Supplier approvals should be subject to regular reviews based on performance and changes in business circumstances. The QMS should describe how the Approved Supplier List is reviewed, by whom, how often and on what basis.

4.5.4. Monitoring supplier performance

The proof that the goods or services have been supplied in accordance with the requirements comes when this has been verified. There are three key points at which verification can take place:

- at source inspection
- on-receipt inspection
- in-use verification

4.5.4.1. At source inspection

The company sends his personnel to the supplier's site to test or inspect the products before release for despatch. This approach is very costly as the company has to attend the supplier's
premises. It may also, if continued for any length of time, reduce the supplier's ownership of the product, perhaps because they feel they lose responsibility for ensuring the product conforms to the requirements. There is a real danger that this involvement will be seen as an extension of their Quality System.

This type of inspection can, however, have a limited role at the beginning of a large project or when a supplier has been selected, perhaps because of lack of choice, which does not totally meet the selection criteria.

For inspection at source to be effective it should be seen as a short term expedient. The objective is to ensure the supplier is able to consistently produce products that meet the requirements. It may also be used as a means of improving supplier performance. By detecting deficiencies early corrective actions could be implemented rapidly. This minimizes the impact of defects on the company's business.

This type of inspection shortens the lines of communication between the supplier and the company.

4.5.4.2. On-receipt inspection

Here products are verified on receipt, before being accepted for use by the purchasing organization. This is another expensive activity which is only required because the supplier does not meet the requirements for which he has been paid.

On receipt inspection can be a useful means of gathering data to enable the company to improve the performance of its supplier. It should only be used until supplier performance has improved to a point where the on-receipt verification is no longer required. This may be the result of improvements by the supplier, or it may result from improvements in the specification of purchasing requirements.
4.5.4.3. In-use verification

If you adequately define the requirements for goods and only select suppliers who will consistently meet those requirements, then there will be no need for pre-use verification. Here, verification will only need to take place at the point of use and the system will be operating at minimum overall cost. This method has the advantage that responsibility for meeting requirements rests where it most certainly belongs, with the suppliers.

However, this method does mean that if the system breaks down, then errors will not be found until the product is in use. This may have serious implications in terms of failing to meet the customers' requirements. This method can, therefore, only be used if the company have the confidence in the effectiveness of its prevention system. This confidence should be based on factual data.

4.6. Controlling The Production Process

After designing the product to meet the requirements of the customers, the company must ensure its production as intended. Therefore, the production process which turn the initial specification into a product should be defined documented and controlled. The effective QMS should incorporate the following key elements:

- plan and define the production processes which translate the specification into a delivered product;
- ensure that the product is identified throughout the production process to prevent the risk of error;
- plan how to verify that the product meets the requirements of the customers. Any suitable means including test, inspection and process monitoring throughout the production process could be utilized. The methods selected must be defined, controlled and capable;
- plan how to protect the product from damage, deterioration or loss;
- If the customer supplies any items to be incorporated in the delivered product then plan how to prevent loss, damage or incorrect use.

### 4.6.1. Planning and controlling the production process

Production is the series of processes which converts the initial specification into a delivered product which meets the customer requirements. If it is to be successful then it must be planned and controlled. When defining the production process two key elements need to be addressed:

- Define the series of processes through which the product must pass to convert the input into a delivered product which conforms to the customer's requirements.
- Devise a system for recording that any given product has passed through the predetermined series of processes.

Strict use of route cards in the manufacturing operations should be maintained in order to define the sequence of production stages. Each card should specify the process which must be completed, referring to relevant work instructions defining the activities at each stage in the production process. Marking off the route card as each stage is completed establishes a system to identify what stage the job has reached. At the end of the production activity this card provides a record of the total production process.

Checklists could also be used in order to control the work. Individuals sign the checklist once they have completed a specified step. The list then provides evidence that procedures have been followed. This enables the product to be released at the end of the production process.

Planning and recording progress through production ensures products follow the predetermined route designed to ensure they conform to customer requirements. It also enables anyone else who becomes involved in the assignment to quickly assess what has been done and what remains to complete the production task.
It is important to identify specific products in order to enable the personnel to:

- ensure they supply the correct product to each customer
- ensure they can uniquely identify any product to ensure they are working on the right one
- ensure they know what stage in the production process the product has reached.

The purpose of identification is to minimize the potential for error and hence reduce the risk of non-conformance. The QMS should define the methods the company uses to identify products. The means that are used should ensure the identification of any product and its current status. In order to physically relate the identification to an item, tags, labels, stamping and branding could be used where appropriate.

4.6.3. Traceability

The purpose of traceability is to provide a history of the product which can be used to make it easier to solve problems that arise later. This reduces the cost of finding a solution if things subsequently go wrong. Therefore it is essential to keep detailed records to establish an effective system for traceability. By this way, it will be possible to relate products to particular production processes and this will enable to investigate the causes of failure and implement corrective actions if defects arise.

4.6.4. Inspection and testing

The company is responsible for ensuring that the products it supplies to the customers conform to their requirements. A system should be implemented to provide confidence that processes work as defined: that is right first time, everytime. There are two basic approaches to ensuring that products conform to requirements:
-inspecting, measuring and test output. This is costly, delays the production process, can introduce errors and does not improve the production process.
-ensuring that the process which are employed are fully understood and the process parameters are controlled so they produce conforming output. This eliminates the cost of inspection and test.

The most effective way to minimize operating costs is to control processes so they are reliable and error-free. This minimizes the need to inspect and test their output. There is, however, a risk that if the process control breaks down, non-conforming products will carry on through the production process. Therefore, at some point there would be a need to do some testing or inspection. There are three principal stages for inspection and test procedures:
- receiving inspection is carried out before products are accepted for use;
- in-process inspection is carried out between production processes. Its purpose is to ensure processes are under control and to prevent the movement of non-conforming product between processes;
- final inspection is carried out before the product is released for delivery. As a minimum, this should ensure that any inspection or tests required earlier in the production process have been carried out.

The company's QMS should document its system for controlling output from the production process. It should define how to:
- plan and schedule the tests and inspections required
- define the purpose of each test and the method and equipment to be used
- identify who is responsible for carrying out the tests
- decide the criteria for passing or failing the test
- decide the actions to be taken once the inspection has been carried out
- specify the records that are to be kept
- identify passed and failed items.
Tests and inspections should be planned and scheduled. They should be conducted by staff of adequate competence and integrity. They also require clear leadership from management. Management should demonstrate their commitment to the test and inspection procedures. Employees should know that test results will not be compromised by the need to achieve a particular result on a given day. Product should not be despatched if it fails a test.

Every test and inspection should be conducted in accordance with the planned schedule, and the results recorded. These records have two purposes:

- they provide evidence that the test or inspection has been carried out. They also enable the recorded results to be checked if there is reason to doubt the information or the validity of the test
- the data can be used to measure trends in performance. This analysis can be useful for corrective action purposes. For this reason the practice of recording a simple pass or fail should be avoided. Empirical results of measurements should be recorded. This information will enable to detect if a process is moving towards its control limits and is about to produce non-conforming output. This sort of empirical data is an important basis for investigating the root cause of problems.

4.6.5. Inspection and test status

It is important to ensure that non-conforming products are not allowed to mix with conforming products. If they are allowed to mix then the whole purpose of performing the test will be lost.

It is therefore necessary to distinguish items which have passed from those that have failed. This is the test status of the product. There are a number of ways indicating the test/inspection status. The following methods should be used as appropriate:

- applying a stamp or label
- signing a checklist or a route card
- use of inspection locations.
The key requirement is that any individual involved in the process should be able to determine unambiguously whether the product has passed, failed, or has not yet been subject to the required test or inspection. It should not be possible to move an item to another process if either the required test/inspection has not been carried out, or if the result was unsatisfactory.

Inspection and test requirements should be included in the records used for defining the production part. Manufacturing route cards may include details of any inspection or test procedures required. Including a space on the card to record the results of the test fulfills the requirement to record the inspection status of the product.

4.6.6. Inspection, measuring and test equipment

It has to be ensured that inspection, measuring and test equipment is capable of performing the job demanded of it. The purpose of calibration is to provide confidence in any decisions that are based on measurement data. There are two requirements to fulfill: using the right equipment and ensuring the equipment is properly calibrated so its results could be relied on. Equipment should be regularly checked against appropriate standard and adjusted if necessary. These calibrations should be certified by competent organizations which are able to trace the validity of their standards to the absolute measurement defined by national and international standards. TSE and some private organizations perform such work.

If measurement systems are inaccurate then measurements will be inaccurate. The conclusions and decisions resulting from these measurements may well be wrong. Then it will not be possible to ensure that customer requirements are met. To control the measurement activity to achieve confident results requires the following:

- defining what measurements are required. Measurements may be required throughout the business: in procurement, in the production process, or during the design verification process;
- defining the methods and equipment to be used for each measurement;
-defining the accuracy required for each measuring instrument. All equipment used for
the assessment and checking of deliverable products must be subject to a documented
and audited calibration system.

After identifying the equipment measurement requirements, the calibration system should be
documented to address the following:

-identifying equipment, its accuracy, its calibration status and the date it requires re-
calibration

-ensuring that once calibrated, adjustments cannot be made locally which will affect its
accuracy

-recalling equipment which is due for calibration

-adjusting the periodicity of equipment re calibration

-the records which should be maintained.

4.6.7. Handling, storage, packaging and delivery

The company is responsible for ensuring that the products delivered to its customers meet their
requirements. Therefore, there has to be some effective means of protecting the products from
damage, deterioration or loss. These are:

-protection from physical damage

-security against theft

-minimizing deterioration and contamination during storage by adequate stock checking
and stock control procedures

-enabling adequate protection of the product within the company and during its delivery
to the customer by using the appropriate packaging

-making adequate arrangements to ensure safe, accurate delivery of products.

The methods adopted to control the handling, packaging, storage and delivery of the products
should be documented in the QMS.
4.6.8. Customer supplied product

The customers may supply the company with products or equipment to use in the production. There should be a system to prevent loss, damage or incorrect use of any items supplied by the customers for incorporation into their product. Normal practices and procedures should be applied considering the product as an incoming good for a specific work order.

4.7. Control of Non-conforming Products

It should be ensured that non-conforming products are not inadvertently used, installed or delivered. An effective QMS should address the following key points:

- identification of suspect product
- documentation
- review and disposal
- notification of actions required.

4.7.1. Identification

Suspect products should be labeled in such a way that their status is identifiable to any individual who might otherwise carry out further work on them, or deliver them to a customer. The system should also ensure that when a non-conformance is found, other products which may have followed the same process are identified as suspect. The means used to identify non-conforming material may vary greatly. The only requirement is that the means of identification should be clear and should stay in place until a decision is made about disposal. Where possible, the non-conforming product should be physically segregated from conforming products.

The QMS should define the appropriate means of identifying non-conforming product and specify who is responsible for carrying out this identification.
4.7.2. Documentation

When an instance of non-conformance is identified, a full record should be generated for three reasons:

- to enable an informed decision to be made on disposal;
- to enable the root cause of the non-conformance to be investigated and effective corrective actions introduced;
- to provide evidence that the QMS has been followed.

The documents should record the following details about the non-conforming material:

- the identity of the non-conforming product. This may be by referring to, for example, the work order number, part number, the stage of work or the process and time of incident;
- at what stage in the process the non-conformance was identified, and by whom. This helps identify other potentially non-conforming products and also helps when investigating the root cause of the problem;
- the number of items affected and the extent of the non-conformance. This determines the size of the problem;
- full description of the non-conformance to enable sound decisions to be taken on the actions required, and to assist the investigation of root causes.

Having fully documented the non-conformance the same record should also be used to record:

- the immediate decision taken on disposal and the basis for that decision;
- the results of the investigation to identify the root cause of the problem, together with the corrective action implemented to eliminate it.

The QMS should define the nature of these records and specify:

- what information should be recorded
- who is responsible for recording the information
-how the records should be stored.

4.7.3. Review and disposal

All instances of non-conformance should be reviewed and a decision taken about what to do with the non-conforming products. The review should identify the impact of the non-conformance on safety, function, customer satisfaction, reliability and cost. This information can be used as a basis for reviewing alternative courses of action:

- rework the product so it meets the requirements. In this case the method of rework and acceptance criteria should be documented;
- accept the product as it is. This may mean accepting the deviation. However, the deviation would need to be authorized by a concession, or by officially changing the requirement;
- regrade the product for an alternative use. If the requirement has little impact on customer satisfaction and none on safety and reliability then the product could be regraded as seconds;
- reject or scrap as unusable and un-reworkable. A non-conformance which has a major impact on safety may mean that the product must be tested to identify defects. All non-conforming products would have to be reworked or scrapped.

It is important that the decisions are soundly based on factual data, and made by individuals with the skills and experience necessary to equip them to make such decisions. It is for sure that customer requirements are the basis during this decision making process and even they may be required to involve in the process.

The QMS should define:

- who is involved in the review process
- what criteria are to be used as the basis for decisions
- what data is required to make a decision
- how is the decision recorded
- how is the customer involved in the decision where this is a requirement.

4.7.4. Notification

The responsible personnel should be informed of any instance of non-conformance either during the production process or after delivery to enable effective actions to be taken. Any errors may indicate a failure in the QMS and need to be investigated. The system for notification should define who is required to be notified, how notification takes place, and who is responsible for notification.

4.8. Corrective Action

In İşık Makina and in many organizations, a great amount of time is wasted finding and fixing errors because the conforming output is not produced first time round. There are three key reasons why a process may not produce conforming output:

- the output requirements are not understood, defined and agreed;
- the process is not capable of meeting the requirements;
- the process is not being controlled to ensure it produces only conforming output.

As a result the following inefficiencies arise:

- It will not be possible to identify every non-conforming product. Therefore customer requirements sometimes may not be met;
- it is very costly to test, inspect and rework products;
- it is time consuming. Test, inspection and rework will introduce delays into the production process;
- there is the risk of removing ownership for conformance from those responsible for the process. They may be encouraged to believe it does not matter what they do. Any errors will be picked up and corrected.
This is not the route to success. An effective QMS is based on the concept of controlling the process and preventing errors arising. The steps in operating an effective prevention system are:

- ensure the process within the business is well understood;
- set up each process so it is in control. This requires management of the parameters that control the process to ensure output conforms to requirements;
- ensure the process owners monitor the key characteristics of the process. The purpose is to monitor trends and introduce corrective actions before the process drifts out of control and produces non-conforming output;
- if non-conformances are identified the following steps should be taken immediately:
  - ensure the non-conforming products are not inadvertently used, installed or delivered
  - ensure the causes of non-conformance are fully investigated and removed. The objective is to ensure the error will not recur. This is known as Corrective Action.

4.8.1. Building an effective corrective action system

Investigating the root causes of errors and implementing effective corrective actions is the cornerstone of an effective QMS. Merely fixing errors is not adequate. A system must be established which ensures they are eliminated, not just for today, but for ever. There should be three stages in an effective corrective action system:

- short-term fix: this is the immediate fix for an identified error;
- the cure: investigate the root cause of the errors and eliminate them;
- prevention of errors: identify potential causes of error by analyzing data to detect trends which, if allowed to continue without intervention, would result in errors. Data sources can include customer complaints, warranty reports and system audits.

The objective of all corrective action is prevent errors occurring. This improves the company's
ability to meet its customers' requirements and minimizes the cost of non-conformance. An effective corrective action system requires a logical and systematic approach:

- analyzing the process to understand how they operate. This could be achieved by flowcharting the process and defining process inputs, controls and outputs;
- monitoring processes to detect errors and identify trends which might give rise to errors;
- investigating all potential causes of the problem. A number of problem solving techniques may be applied including brainstorming, cause and effect diagrams and experimentation. The objective is to identify the most likely root cause of the problem;
- taking actions to eliminate the root cause of the problem;
- monitoring the effectiveness of the corrective action to ensure it really does eliminate the problem;
- recording the actions taken.

The procedures that are used to identify the root cause of problems, and implementing, monitoring and recording corrective actions should be documented. This system should cover corrective actions taken when non-conformances are identified as well as the analysis of trends and consequent intervention to prevent errors occurring.

The company already operates a corrective action system but it is often ineffective for a number of reasons. The actions taken when problems have been identified are often not really preventive actions. They may fix today's problem but often do not introduce the long-term improvements necessary to prevent the problem recurring in the future. The approach to resolving problems is to form a team of managers and supervisors. However, it is important to involve people in these teams who do the job on a day-to-day basis. They will understand their processes in detail and will understand the impact of different courses of action on those processes.
4.8.1.1. Features of an effective corrective action system

To be effective it is important that corrective actions are properly planned and implemented. They will then be able to eliminate the problems once and for all. The following features typically need to be present in order for a corrective action system to be effective:

- an effective mechanism should exist to identify errors or adverse trends as they arise;
- once a problem has been identified it is important to involve all the people concerned with the problem in investigating the causes of error and developing corrective actions;
- someone within the group should have some knowledge of problem solving methods;
- the team chairman should have some understanding of team dynamics to ensure effective team working. Teams should bring together representatives from all the functions affected by the problem. This helps to ensure effective corrective actions are identified and improve the interfaces between departments;
- corrective actions should be carefully assessed to ensure they are the most effective means of eliminating the problem once and for all. The results of corrective actions should be monitored to ensure they achieve the objectives set for them;
- management must demonstrate their commitment by taking an active interest in the progress made by problem solving teams.

4.9. Internal Quality Audits

Internal Quality System audits verify that activities are carried out in accordance with the QMS, and that the QMS continues to meet the needs of the business and the requirements of ISO 9000. Effective audits by competent auditors which are taken seriously by management are the key to ensuring that the QMS remains alive and delivers the full benefits for the business.

There are two principal objectives of a Quality System audit:

- to ensure the QMS meets the requirements of ISO 9000
Audits provide one of the best opportunities for analyzing the QMS to identify ways in which it can be improved. It will be possible to identify procedures that will enable a better control over the business. Also, existing inspection and test activities which could be replaced by improved control of underlying processes might be identified.

The effectiveness of the internal auditing system provides signs of how committed the organization is to its QMS. Well-performed audits with a rapid response to deficiencies indicate an effective and widely respected QMS which is actively working to improve business performance. An ineffective QMS results in quality system audits which are poorly carried out and whose results are largely ignored by the organization.

The QMS should define the procedures that are used for carrying out quality system audits. This documented system should cover the following points:

- responsibility
- scheduling
- planning
- execution
- reporting
- corrective actions.

4.9.1. Responsibility

The QMS should define who is responsible for carrying out audits. Although the Standard does not define who should be responsible for audits, it states that they need to be qualified, competent and independent of the area being audited. The QMS must document how to fulfill this requirement. Auditors require a number of important skills:
-a through understanding of the requirements of ISO 9000 and the ability to determine whether an activity, as presented, meets those requirements;

-an understanding of how to plan an audit, how to follow an audit trail and how to gather objective evidence;

-the ability to think creatively to identify potential problems in the existing system, or to identify possible improvements to the existing system;

-the ability to communicate sensitively with a wide range of individuals. The audit can give rise to stress in some people. The auditor should work to minimize this;

-the ability to record events clearly and unambiguously;

-the ability to distinguish important issues and focus on them.

4.9.2. Scheduling

Audits should be systematic and carried out in accordance with a pre-planned schedule. They should not just be carried out in response to problems. The QMS should therefore define how the audit schedule is put together: who is responsible for defining it, the criteria for determining the areas/activities for audit and how the schedule is recorded.

The schedule should ensure that all the applicable requirements of ISO 9000 are thoroughly audited over a suitable time frame. The frequency of auditing depends on how critical the process is and whether any problems are known to exist.

Audits could be carried out in one of two ways:

-functional audit: each department is scheduled for audit and then all the ISO 9000 requirements which apply to that department are audited;

-requirements audit: all the ISO 9000 requirements are scheduled for audit and then all the departments to which that requirement applies are audited.

Functional audits are generally easier to schedule and carry out since only one department is
audited at a time and boundaries are clear cut. Requirements auditing enables system
deficiencies to be identified more easily. However it is generally more difficult to plan and carry
out requirements audits since a number of departments are involved and because many of the
requirements interlink.

It is a better choice to implement requirements audits in companies like İşık Makina which has
strong interdependence between its departments. Since it will not be possible to restrict an
audit trail to just one requirement it is also possible to link closely related requirements and
audit them at the same time.

When constructing the audit schedule the following headings should be used:

- the functions to be audited
- the ISO 9000 requirements covered
- the planned date for the audit
- when the audit was carried out
- the number of deficiencies raised
- the date corrective actions were implemented
- the date the audit was closed.

In this way it is possible to ensure that all functions and requirements have been audited during
the specified time frame. It is important to have a system which tracks open audits until all
corrective actions have been implemented and the audit can be closed off.

In addition to the scheduled audits, additional unplanned audits could be carried out in
response to particular problems. They are supplementary audits which contribute additional
information on the general health of the QMS. The same system should be followed for these
audits as for scheduled audits.
4.9.3. Planning

It is important that audits are carried out systematically, consistently and comprehensively. Effective planning is the cornerstone of a good audit. This planning starts when the audit schedule is put together as this determines the overall scope of each audit. The plans for individual audits determine how the audit will be carried out within that scope. A competent, professional auditor should define a tailored plan for each audit. Each plan would be based on the results of past audits, the ISO 9001 Standard, the procedures under review and details of any known problem areas. This ensures each audit takes a different slant rather than being a rerun of the previous audit. This approach enables the auditor to:

- identify problem areas which might be missed by a less well planned audit
- identify opportunities for improving control of business process.

Audit checklists could be used to provide a baseline to guide the auditor. However, they should not be used as a ticklist that will lead to routine audits which focus on trivial issues and fail to recognize more serious system deficiencies.

The QMS should document the procedures used for audit planning.

4.9.4. Execution

The purpose of the audit is to seek objective evidence that the QMS is adequate, documented, understood and followed. Objective evidence is provided by documents, records and testing the understanding of individual process operators. An auditor has two main sources from which to gather evidence. Talking to individuals provides evidence they understand and follow the QMS. Examining records provides evidence that the QMS has been followed.

The audits should make use of evidence from both these sources to provide an overall picture of the effectiveness of the QMS. The skill and experience of the auditor should ensure that:

- the plan is followed during the audit
open-ended questions are asked to check operator understanding of the system
-an audit trail is followed to determine the full extent of any problem identified
-the audit focuses on important issues as these become evident during the course of audit
-if a deficiency is found, the auditor can assess if this is actually an opportunity to improve the QMS.

4.9.5. Reporting

A report should be issued following each audit. This should be an accurate summary of the audit events and findings. It is useful to give a unique reference number to each audit. To ensure consistency in reporting, the audit procedure should define the information required within the audit report. The audit report should cover the following:

-auditor: who carried out the audit and when
-scope: what was audited, the areas and the requirements
-summary: how the audit was carried out, what was audited (may refer to the audit plan), summary of events
-deficiencies: details of instances when the requirements were not met
-conclusions: conclusions on the overall audit. This also provides an opportunity for the auditor to identify potential improvements to the QMS.

4.9.6. Corrective action

For audits to be effective it is important that any deficiencies found are brought to management attention and acted upon rapidly. The reporting of audit deficiencies, implementation of corrective actions and follow up must therefore be documented as part of the audit procedure. In addition to the audit report, deficiencies can be documented and referenced individually so they can be circulated as required and used to stimulate corrective action. A well designed audit deficiency report can detail the deficiency found and can also be used to record details of
the corrective action implemented and the follow up to ensure the corrective action was effective. The audit deficiency report should detail the following:

- report number
- auditor
- date of audit
- function and requirement audited
- deficiency found
- person responsible for corrective action
- proposed corrective action
- date for completion of corrective action
- verification by auditor of the effectiveness of the corrective action.

The procedure should describe how deficiencies are documented, how they are brought to the attention of management in the area where the deficiency occurred, how the corrective action taken is recorded and how its effectiveness is verified. It is the responsibility of the auditor to bring deficiencies to the attention of management. It is then the responsibility of the appropriate manager to implement the necessary corrective action.

4.10. Training

The QMS defines how business processes are to be operated. These processes can only be operated as described if the individuals have sufficient skill, knowledge and experience. An important element in the QMS is therefore the analysis and fulfillment of training needs. ISO 9000 requires that a system exists to monitor regularly the skills required to operate the business and ensure these skills exist within the workforce. The system should include:

- a means of assessing the skills required by the business. This should be achieved by using job specifications to define the skills required for a particular job;
- a means of assessing the skills base of the workforce. This should be achieved by using an appraisal system to identify training needs;
-a means of demonstrating that training needs have been met. This should be achieved by training records.

Training can be provided in any form suitable to fulfill the need and may include:
- external training courses
- internal training courses
- correspondence courses
- on the job training.

The form of training is not important. What is important is that it adequately fulfills an identified need, and a record is kept of the training carried out.

4.11. Statistical Techniques

In companies like Işık Makina which produces specially designed heavy industry equipment, the production quantity of both the equipment and its components are low. Therefore, it is not convenient to use tools of statistical techniques like Control Charts and etc. during production. Hundred Percent inspection would be proper and costless. However, in other areas like incoming inspection of high quantity purchases like bolts, nuts, etc. Sampling Techniques could be used. In departments other than Production and Inspection statistical techniques could also be used for different purposes.

ISO 9000 states that if statistical methods are used then they should be understood, controlled and soundly based. When documenting the system for controlling statistical techniques the following should be covered:
- identification of appropriate techniques
- documentation of when and how these techniques should be used
- ensuring that the techniques are used by competent trained personnel.
CHAPTER 5
ACTION PLAN: THE INITIAL STEPS

5.1. Organizational Structure

As mentioned previously, Işık diverted all of its resources to hoisting and handling machinery production because of the instability in hydro-mechanical equipment need. If the company had not this kind of a flexibility it would not be able to survive in an uncertain environment.

The company’s resources are not rich enough to provide separate facilities and personnel to each product or project. However, it should still deal with several projects at the same time. In case of a lack of capacity, the things that can be done are increasing the number of employees and shifts. It is not possible to increase the number of milling machines or lathes or the square meters of production area in the short run.

At this point, the planning job that is carried out by the engineering (for the design work) and manufacturing departments gains greater importance.

Işık Makina usually carries out several big projects at the same time. For example, production of Overhead Traveling Cranes of ERDEMIR Continuous Casting Facilities may have to be carried out at the same time with the production of a Slab Handling Gantry Crane that is going to be used in EKINCILER Steel Mill.

All of these big projects needs a project manager who will coordinate the functions and do the necessary allocation of resources. He has to continuously work in coordination with manufacturing and engineering departments to follow up the things that are going wrong in
order to take the necessary actions.

In middle-size companies like Işık Makina, which manufactures to orders, Matrix Organization is the most suitable structure. The unique aspect of a Matrix Structure is that both product and functional structures are implemented simultaneously.

The organization has to pursue more than one goal, such as emphasis on both products/projects and function in order to be more effective. A high-technology manufacturing organization may have to have strong scientific and technical expertise, and at the same time it must quickly respond to customer needs.

The need to process large amounts of information usually means that the organization is experiencing high uncertainty in several environmental sectors. Things change quickly, requiring enormous amounts of information processing and coordination within the organization. The pressure for shared resources indicates that the organization is not large enough nor rich enough to provide separate facilities and personnel to each product or project, and so facilities must be shared by several product/project lines.

The managers of each project have authority over functional personnel assigned to that project. This system enables project managers to achieve coordination necessary to complete project requirements on time. On the other hand, managers of the respective function such as engineering and manufacturing also have authority over personnel. This authority ensures that personnel are up to date with recent technological developments and company specifications, and it provides a home base for training and reassignment to other projects. The flexible and shared use of organizational resources is accomplished (Figure 1).

5.2. Management Commitment

Although the management of Işık Makina accepts the benefits of and the need for an ISO
Figure 1: Matrix Structure for İşik Makina.
9000 Quality System, it is not successful in demonstrating a commitment to it. The system is seen as another fad among the office personnel and the workers.

The thing to do for the management is to show its commitment and gain their commitment. The employees are not aware of the requirements of an ISO 9000 System. In order to accept the new quality system they first have to believe in its benefits.

The senior management team could do the following to further the cause of quality:

5.2.1. Quality Meeting

A meeting could be held where the senior management take the opportunity to stress the top-to-bottom commitment to the scheme. They could, at this time introduce the Quality Manager, who could run through a short presentation of how the organization intend to work within the conditions of the Standard. This is a good chance to promote Quality and hence it should be done with style. Best speakers should be used with visual aids and etc. The management must not forget that they are selling Quality and so this to be the one business meeting which must have class and not fade away from the minds of the employees.

5.2.2. Quality Video

Since it may not be practical to bring everyone in for this launch presentation, a well made video may be the solution which can have a powerful and lasting impact. One further advantage of the video is that it could be used over and over again to introduce new members of the company to its commitment to Quality. Also the video could be the first item of the program at the launch presentation, as a hook to capture the attention from the start.

5.2.3. Quality Statement

A Statement of Quality Policy from the head of the company is required (as mentioned above)
and that a letter spelling this out is virtually mandatory. However, sending it out, getting it read, and more importantly getting it etched in the mind is a hard job to expect from one sheet of paper. A more durable method of placing the message before the staff is to provide each manager with a simple but neatly framed copy of the Statement, which could be hung in some prominent position in the department.

5.2.4. Quality Awards

An Awards scheme which would incorporate the formal recognition of the contribution of some member of staff, on a monthly basis could be initiated. It is not difficult for the Quality Department, who see right across the various departments, to spot someone who has demonstrated the principle of Quality in some special and individualistic way.

5.2.5. Conveying Quality to Newcomers

The commitment of the company to Quality should be conveyed to all newcomers. The best time to start doing this is the second they walk through the door on the day they join. The section of their initial training where they get to know all those important things, like the size and diversity of the organization and how the senior management is structured, is a perfect time to introduce them to the Quality Policy. All the senior managers, if possible, should be ready during this presentation to the new people so that they know from the start of their careers with the company that Quality is a top-management-driven discipline.

5.2.6. Quality Bulletin

Something exclusively focused on the company's drive on Quality may serve as a reminder periodically that Quality was not just the flavour of the month when it was introduced. It would serve to demonstrate that it is an ongoing campaign. There are generally plenty of substantial topics which can be quoted to demonstrate improving Quality, such as simple statistical
diagrams showing items like reducing customer complaints, customer satisfaction survey results, improving response time to customer requests for service. Just as they might take pride in the parameters which show a constant line of improvement, the employees need to know when the charts are going the other way. To broadcast to the staff that there is a disturbing trend downwards in some parameter or another is all that is needed to effect the desired reverse trend.

5.2.7. Quality Notice-Board

An alternative to the bulletin idea may be an attractive dedicated notice-board in some prominent position which will catch the eye and attention of everyone including visitors. This could be used to show off a few key top-level statistics and perhaps photographs and citations of award winners.

5.3. Contract Review

There are three main requirements in preparing a quotation. These are; current capacity reports, material and workmanship need of the potential project and customer specifications.

At Işık Makina the capabilities are documented however are not regularly updated. To ensure this, the production planning department has to revise its capacity report every week and send one copy to the project manager who needs it in preparing a quotation. Another item that is required is a regularly updated material and component price lists. At an inflationary environment the prices of the domestic supplies change continuously. An old list may lead to a wrong cost estimation. Therefore, the purchasing department has to inform the project manager about the price changes every month.

In preparing a quotation, customer requirements and specifications have to be considered with great care. Some of these requirements may be beyond the scope of supply or the capability of
the company. One big problem of Işık Makina is realizing these kinds of requirements after getting the order and being unable to meet them within the estimated schedule and budget.

The contract review committee consisting of the representatives from the engineering and production planning departments and the project manager shall document these kinds of requirements for further investigation. A special kind of material that is difficult to obtain from domestic suppliers or a specific machining operation which is not possible to carry out in the workshop may be among the requirements of a potential project. The extra cost and time need which is born shall be included in the quotation. Otherwise, the company may loose all of its profit and goodwill by not being able to realize its promises.

5.4. Design Control

The key to a successful product is a good design and hence good understanding and documentation of customer requirements. Poor production can devastate a good design but the production process can do little to improve a design that is inadequate.

The first thing that the engineering department has to do is to write the above observation on a paper with big and bold characters and hang it on the notice-board in the design section.

The most important deficiency of the design function at Işık Makina is not properly documenting the revisions that has occurred in the design of an assembly part. At this phase we have to describe the revision request procedure at the company:

As described in Chapter III, the projects are sent to the manufacturing department after the design work is completed. At the production phase the worker that is machining the part or the forman of that section realizes an inadequacy in its drawing. He writes a revision request form describing his observations and sends it to the chief of the manufacturing department. The chief of the manufacturing department discusses the request in the engineering department and if the
request is found to be correct the drawing is revised, the old drawing is canceled and the new
drawing is sent back to the related manufacturing area.

Here, the deficiency in documentation may both occur at the initial and final phase. The
worker or foreman has the authority to correct the mistake in concession with the chief of the
department to quicken the process and inform the engineering department about the revision
later on. However, in some cases this information is forgotten to be conveyed to the
engineering department or the department misses to revise the drawing accordingly. As a result
of this the drawing is documented with its wrong form.

This deficiency causes the past mistakes to be carried to the future when the old designs and
drawings are taken as reference in current projects.

In order to avoid this, the chief of the manufacturing department shall strictly follow the
revision requests and convey them to the engineering department. The engineering department
manager shall be responsible from controlling the documentation of these revisions.

Another deficiency of the engineering department is the missing technical knowledge of its
constructors. Although the constructors are experienced, they are poor at dimensioning the
assembly drawings. The main reason of this is their inability to visualize the product, the
assembly parts, how they are to be produced and how the product is to function.

To overcome this, it has to be ensured that the constructors have the opportunity to observe
the product and its production phases. A tour of constructors in the workshop guided by the
managers of engineering and manufacturing departments could be performed every week.

Finally, an important deficiency occurs on the drawings. For a proper production, every detail
that plays a role in the production process has to be on the drawing. The drawing does not just
show the three-view of the part to be produced. It has to guide the operator informing him
about every requirement for production. On the drawing, the material the part is going to be produced from, specific machining and welding techniques that are required, heat treatment requirements and etc. shall also exist. Therefore, a checklist shall be available for the constructors to control all of these items during and after the drawing work.

5.5. Purchasing

Purchasing is one of the most critical function of İşık Makina since its production totally depends on purchased raw materials and sub-assembly parts. The ability to meet the customer's requirements at minimum overall cost has to be the aim of the purchasing department. However, the required quality level has to be ensured. This quality level is determined by the engineering department and conveyed to the purchasing department. This is done by the national or international codes like DIN, TSE, etc.

One big problem is the result of poor coordination between the engineering and purchasing departments. Engineering department is always quality conscious and purchasing department is totally the opposite, that is cost conscious. As a result of this the engineering department always demands a high quality level where in some cases it is not critical to have that level. This brings an extra cost. On the other hand, the purchasing department tries to minimize the cost and sometimes supply poor quality material where it is not allowed to do so. For example, the steel plates that form the girders bearing high stresses, the steel ropes which carry the load, the forged bars forming the transmission shafts requiring high torque carrying capacity shall never be supplied without their test certificates and from suppliers of unknown origins.

The material need has to be determined with an optimum level and the purchasing activity shall take place accordingly. The commitment to this could be ensured by informing the purchasing department about the adverse effects of poor quality and informing the engineering department about the incurred costs of overstated quality level.
Işık Makina's another problem under the purchasing function is that it does not have a formal approved supplier list. A supplier list consisting of reliable and assessed manufacturers has to be documented and their performance on quality, cost and time of delivery bases should be checked.

Due to the hazardous nature of the product it manufactures, it is not enough for Işık Makina to form the list of suppliers from reputable companies in the market or from companies holding a Production Sufficiency Certificate of TSE. Işık Makina has to, for example, perform at source inspection for the hydraulic buffers which are manufactured outside the company. The production processes of these kinds of sub-assembly parts which are designed at Işık and manufactured outside has to be assessed periodically.

For the raw materials having a critical area of usage (steel plates, forged bars, steel ropes, etc.) hundred percent on receipt inspection has to be performed if the material does not have a reliable test certificate issued by a third party. These activities shall be documented for the companies records (for supplier assessment, etc.) and for submission to the customer later on.

5.6. Production Process

The production process which turn the initial specification into a product should be defined, documented and controlled.

At Işık Makina, the production processes are defined informally. The success of the process totally depends on the experience of the worker and the foreman. There is neither a procedure, nor a work instruction that is operative in the workshop. As a result of this, the controls that are carried out are informal and are not planned.

As described in Chapter III, Işık Makina has eight sections under the manufacturing department. These sections deal with the major processes which translate the specification into
a delivered product and these processes have to be defined, documented and controlled.

For example; standard assembly section needs a procedure which describes the steps in the assembly work of an electrical hoist and the painting section needs a procedure describing the steps from preparing the paint to how to apply the final layer of the paint to the crane. These procedures shall not only be in the Procedures Manual but also exist in the related work area.

All of these sections shall also have their work instructions. Welders shall have a work instruction on how to operate and use different welding machines. Quality control personnel shall have a work instruction on how to adjust and use the hardness testing gauge and etc.

The important point here is gaining the commitment of employees to these requirements of the new quality system. The first objection is expected to come from the foremen i.e. section chiefs since these procedures and instructions are informally dictated to the workers by them. They will see this as a limitation to their authority.

To overcome this, the quality manager with the help of the manufacturing department manager shall design a system of creating procedures and instructions with the involvement of all the workers and foremen. Every week, a meeting for an hour could be launched during which the employees themselves create their own procedures. Everything has to be discussed until everybody is totally convinced.

During these meetings, the quality manager shall strictly emphasize the boundaries of responsibility and authority of the workers. The worker shall know that he has the responsibility of doing the right thing the first time and has the authority to stop the process if he recognizes an inefficiency in the process or a mistake on the drawing. Remember that one of the most important cost item for İşık Makina is revisions and re-works. The involvement of workers will make them more confident and they will assume the ownership of the process.
At Işık Makina, another important deficiency is the improper use of route cards. Due to the nature of the process, the route cards have great importance for an efficient production.

If we consider the manufacturing process of a gear, the first step is cutting the forged bar to the machining dimension. This order comes from the chief of the manufacturing department with the related route card defining the sequence of production stages. After recording the completion time of cutting and signing the card, the worker informs the related department for the next operation. The gear is machined in the chip removal shop, sent to outside companies for heat treatment and grinding and finally brought to mechanical assembly section for gearbox assembly.

All of these steps are recorded on the route cards. The workers who performed the job, the time they used and the stage the job has reached are all determined. By the help of this information the production planning department controls its time schedule, the manufacturing department clearly follows the process and the company ensures its products conform to customer requirements.
CHAPTER 6
CONCLUSION

In today's marketplace, quality becomes an increasingly vital differentiator and the companies adopting themselves to ISO 9000 Quality System will enjoy a clear competitive advantage. The purpose of increasing efficiency is a good reason to adopt the ISO 9000 Standard for non contractual reasons simply as a model for an ideal quality system. Moreover, customers are increasingly making ISO 9000 a condition of their contracts with the facilities. This obligates the facilities to acquire ISO 9000 Certification.

Implementing the system can take many months. Shortening this time period and the proper application of the system elements mostly depends on the Preliminary Audit which the company has to carry out before taking any action. This audit will enable the facility to establish the conformity or non-conformity of the products or processes within the existing system and establishing the degree of success or failure of the existing system in meeting both the customer and regulatory requirements.

The elements of the standard should be tailored to the specific requirements of the facility according to the Preliminary Audit Results. Otherwise, the facility may find itself in a mass of useless paperwork which will further cause inefficiency.

This study has also followed the same route. A Preliminary Audit has been performed, the elements of the standard have been tailored to the specific needs in order to form an effective Quality Management System and an action plan has been suggested for the functions directly effecting the quality of the product and the process. The action plan defines the non-conformances (audit results) and suggests corrective actions.
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