QUALITY SYSTEMS

Introduction

The International Organization for standardization (ISO) ISO is composed of more than 90 member countries.

- The ISO Technical Committee (TC) developed A series of Five International standards for quality.

(**ISO 9000, 9001, 9002, 9003, 9004**) were intended to be advisory and were developed for use in two party contractual situation and internal auditing.

- Most organization have found that the system has led to:

- Fewer on site audit by customers.
- Increased market share.
- Improved quality, both internally and externally.
- Improved product and service quality levels from suppliers.
- Greater awareness of quality by employees.
- A documented formal system.
- Reduced operating cost.

ISO 9000 SERIES OF STANDARDS

The ISO 9000 series of standards is generic in scope. By design the series can be lored to fit any organization's needs.

It can be applied to construction, engineering, etc.

Its purpose is to unify quality terms and definitions and use those terms to demonstrate a supplier's capability

The five standards of the series:

1- **ISO 9000** "Quality Management and Quality Assurance Standards Guidelines for selection and use"

Explains fundamental quality concepts, defines key terms, and provide guideline for selecting.

2- **ISO 9001**, "quality systems- model for quality Assurance in design, development,

Production, installation, and servicing," is most comprehensive in the series.

3- **ISO 9002**," quality systems- model for quality Assurance in production, installation, and servicing," addresses the prevention, detection, and correction of problems during production and installation.

4- **ISO 9003**," quality systems- model for quality Assurance in final inspection and test" is the least comprehensive of the standards.

5- **ISO 9004**," quality management and quality system elements guideline" provides guidance for supplier.

Other Quality Systems

There are currently three other systems (QS-9000, TE-9000 and AS9000).

QS-9000

Uses the ISO 9001 as its foundation, but its requirements are much broader.

There are three sections in this standard.

I- common requirements, which include the exact text of ISO 9001.

II- Additional requirements covering production part approval process.

III- Customer specific requirements.

TE-9000

The tooling and equipment supplement (TE-9000).

Provide an interpretation of QS-9000 requirements as they apply to tooling and equipment.

Communizes quality system requirements.

Promote the effective use of reliability and maintainability.

AS-9000

The document is identical to ISO-9000 in most aspect, there are no industry specific element such as those occur in QS-9000.

AS-9000 builds on the simplicity of ISO-9000, adding insight and addressing the distinctive needs of the aerospace industry.

IMPLEMENTATION

There are number of steps that are necessary to implement quality management system.

1- Senior Management Commitment

The most important step that will meet or exceed an ISO-9000 standard is to acquire the full support of upper management. The chief executive officer (CEO) must be willing to commit the resource necessary to achieve certification. This is the critical to the success of the project. Without CEO's support, the process may continuously run into unnecessary road backs or even be doomed to failure.

2- Appoint the Management Representative

The step is the appointment of a management representative. The person is responsible for all parties involved in the process, both internal and external .It is important to note that the quality manager does not have to be the representative. The implementation of the quality system should involve everyone in the organization .The standard requires the management representative be a person who is able to ensure that the quality system is effectively implemented and maintained irrespective *of other responsibilities.*

3-Awareness

This step requires an awareness program. Because the process is going to affect members of the organization as well as require their input, it stands to reason that everyone should understand the quality system. They should know how it would affect day-today operations

and the potential benefits. This information can be relayed through short, one-hour awareness training sessions.

4-Appoint An Implementation Team

An implementation team should be assembled. This team should be draw from the all levels and areas of the organization.

5-Training

The implementation team, supervisors, and internal audit team should be trained. The activity can be accomplished by sending team leaders for training and having them training, the other team members or by bringing the training in-house for all team members through a one-or two-day seminar.

6-Time Schedule

This activity develops a time schedule for the implementation and registration of the system. This time frame will vary, depending on the size and the type of organization and the extent of the existing quality system. Most organizations can complete the entire process in less than 1.5 years.

7-Select Element Owners

The implementation team selects owners for each of the system elements. Many of the owners will be members of the implementation team. Owners may be assigned more than one element. Each owner has the option of selecting a team to assist in the process.

8-Review The Present System

Perform a review of present quality system. Copies of all the quality manuals, procedures, work instructions, and forms presently in use are obtained. These documents are sorted into the system elements to determine what is available and what is needed to complete the system. This activity is a gab analysis and can be performed by the element owners and their teams or by an external consultant.

9-Write The Documents

Prepare written quality policy and procedure manuals –they can be combined into document. Write appropriate work instructions to maintain the quality of the specific function.

10-Install the New System

Integrate the policies, procedures, and work instructions into day –to day workings of the organization and documents what is being done .It is not necessary for all elements to be implemented at the same time.

11-Internal Audit

Conduct an internal audit of the quality system. This step is necessary to ensure that the system is working effectively and to provide management with information for the comprehensive management review.

12-Management Review

Conduct a management review .The management review is used to determine the effectiveness of the system in achieving the stated quality goals.

13-Preassessment

This step is optional .If a good job has been done on the previous step, Preassessment is not necessary.

14-Registration

This step requires three parts: choosing a registrar, submitting an application, and conducting the registrar's system audit. Considerations in choosing a registrar include cost, and lead-time. The application for registration should also include supplying the registrar with the policy and procedure manuals for their review.

DOCUMENTATION

A quality system is a method used to ensure that the quality level of a product of service is maintained. The system documentation can be viewed as a hierarchy containing four tiers as shown in Figure. All documentation moves from one level to the other in a descending order .If the system is properly structured, changes at one level will dom affect the levels above it but may affect those below.

1-Policy

This is the document that define what will be done and why. A quality policy manual should be written so it is clear, precise, practical, and easy to under strand. The why can be stated juste once as a quality policy statement. Each element of the standard is addressed individual and usually requires one page or less.

2-Procedure

These procedures describe the methods that will be used to implement and perform the stated policies. The procedures define who should perform specific tasks. They dictate the strategies that will be used to the quality of the system. Procedures are more detailed than the policies; however, they too should be written in a manner that will allow for easy understanding. Many organizations combine the policy and procedures into one document.

3-Work Instructions

Work instructions are usually department, machine, task, or products oriented and spell out how a job will be done. These instructions are the most detailed of the documentation hierarchy. A work instruction may be in the form of detailed drawing, recipe, routing sheet, or specific job function.

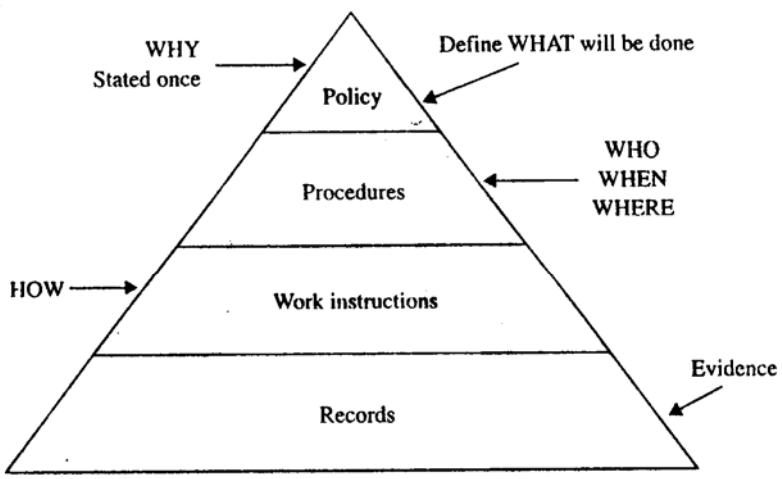

Figure **The Documentation Pyramid**

4-Records

The previous procedures may be forms that are filled out, a stamp of approval on a product, or a signature and date of some type of document. They provide data for corrective action and a way of recalling products, if necessary.

DOCUMENT DEVELOPMENT

To begin creating the documentation system, the implementation team should gather all the existing policies, procedures, work instructions, and forms that are presently in use. Each document should be reviewed and an attempt should be made to fit into of the elements. If a document does not appear to pertain to any element, it show set aside. Where it belongs may become evident at a later time. In addition they should decide if the document is currently accurate and up to date .If it is not, is so be updated or discarded.

As the documents are produced, the implementation team becomes the review committee .If changes appear necessary, suggestions are made and reviewed. The initiating team then either clarifies what they have written or revises the documents as required. When the documents have been completed, they should formatted in a manner that will allow for simple and effective document control.

ISO/ QS 9000 ELEMENTS

We will refer to the numbering system used in the **ISO 9001** standard. Additional information prescribed by QS-**9000**.

1-Management Responsibility

Three major topics are addressed here –the quality policy, responsibility and authority and management review. The quality policy statement should be a short statement that defines the organization objectives for, and commitment to, quality.

Responsibility and authority must be defined for all personnel affecting quality. The senior managers must be the ultimate manager of quality .the use of an organizational chart is one method of showing the flow of authority in an easy –to- understands format. A management representative must be appointed and given the authority to implement and maintain the quality system.

Management review is required to ensure that the system remains effective. Reviews should make use of information from customer's feedback and internal audits, as well as process and product performance.

2-The Quality System

This element requires the establishment and maintenance of document quality system .It describes the levels of documentation, such as the policies, procedures, and work instructions. Emphasis is placed on problem prevention, rather than detection, in all activities from sales through installation and servicing after delivery.

3-Contract Review

This review should answer questions. First, are the requirements of the contact clearly defined? Supplier must be sure that the requirements of the customer are understood before quality product

Or service can be supplied Second, are there any unused quality requirements? A deviation from a standard product or service may require especial processing these requirements will have to be passed on to the proper area to ensure meeting the specification. Finally, dose the organization have the capability to meet the requirements? Capability to meet the requirements means not only having material and equipment to perform the necessary operations, but also the technology qualified employees, and the ability to deliver on time.

4- Design Control

The general requirement of design control is the establishment and maintenance of procedures to control the verity that the product design meets specified requirement and aligned with the contract review. The procedure should take into account the sequential parallel activities involved in the design and provide the method to verify that the activities are being performed. Evaluations of safety, dependability, and performance. Documentation is required to ensure that the design output meets the input requirements. Outputs include some things as drawings, instructions, specifications and serving procedures. The comparison of output to input should be carried out through regular reviews during the design process. All design changes are reviewed and evaluated for the effect that will take on the overall product or service.

5-Document and Data Control

This element requires that procedures and a master list be established and maintained to control all documents and data that affect the quality of product or service. Methods must be in place to provide for the review and approval of documents for adequacy before they are issued.

6-Purchasing

The general requirement of this element is to established and maintain documented procedures to ensure that purchased material or products will conform to specified requirements .To meet this requirements, the procurement specifications must clearly describe the material, product, or service being ordered. This element also require procedures for evaluation, approval and monitoring of subcontractors. This evaluation can be accomplished through (1) a review of subcontractors' s past performance, either to the organization involved or through a check of references, or (2) by conducting a survey of the subcontractors' s quality system and facilities.

7-Control of Customer-Supplied Product

There are times when the customer may also supply the raw materials used in the production of a product. Because the organization dose not own items, it must take precaution to ensure the identification and segregation of them any similar organization –owned items. Customer – supplied products are treated the same as other purchased item respect to inspection and test procedures.

8-Product Identification and Traceability

This identification can be accomplished through the use of lot or batch members on smaller. The most important reason for establishing procedures to identify products or services the ability to track material through the production process and facilitate the recall of nonconforming items.

9-Process Control

Controlling the processes used to produced a product or provide a service is the best way of preventing problems and nonconformity. The first step in control is identify and plan the steps necessary to produce the product or service. Document instructions should then be provided to ensure that the plans are carried out. A monitoring system needs to be in place to verify that the instructions are being carried out. The processes must conform to existing codes, standards, and procedures. Finally controls should exist to ensure that the proper equipment is maintained and environmental conditions are adequate. This type of process may requires destructive testing – for example, the testing of a weld for tensile strength. It would be subjected to increasing pressure until it separates from the parent metal.

10-Inspection and Testing

This element addresses three areas –receiving, in-process, and final inspection. Receiving inspection is used to verify that purchased items comply with require standards and to ensure that they are not used prior to such verification .In –process inspection and testing procedures should be designed for early determination of nonconformity. Statistical process control **(SPC)** techniques are the most commonly used techniques for in –process inspection. Final inspection and testing verifies that completed product meets the required specifications. Verification can be accomplished in two ways: acceptance inspection or product quality auditing.

11-Control of Inspection, Measuring, and Test Equipment

This element requires the control calibration, and maintenance of all equipment used to ensure product quality, whether equipment belongs to the organization, is on loan from a customer, or is owned by employee. Calibration must be performed on a regular schedule basis and documented. Procedures must provided for reporting and segregating any equipment that has been damaged.

12-Inspection and Test Status

It also must relate to the written control plan. The status should indicate whether the product has been (1) inspected and accepted, (2) inspected and rejected, and (3) inspected and on hold for a decision as to accept or reject, or (4) not yet inspected. The inspected authority should also be identified through a signature, stamp, or some other identifying mark.

13-Control of Nonconforming Product

When nonconforming product is identified, it must be removed immediately from further processing, clearly marked, and segregated in a manner to produce any possible use until its disposition is decided. There are four ways in which nonconforming material can be handled. It may be reworked to meet the specified requirements, accept without repair by agreement of the customer, regarded for alternative use, or scrapped .All that is repaired or reworked must be re -inspected in accordance with documented procedures before it is released.

14-Corrective and Preventive Action

Corrective action begins with the detection for any suspected nonconformance and ends in talking the appropriate action to correct the deficiency and prevent its recurrence. Preventive actions include the effective analysis of data to eliminate potential causes of nonconformity and the use of control to ensure that it is effective.

15-Handling, Storage, Packaging, Preservation, and Delivery

These activities take place throughout the manufacturing process. . Material and product in storage must be easily identified, and the storage areas should provide for physical security, environmental controls, and rotation of stock. Packaging must provide protection against damage, deterioration, or contamination for as long as the product remains. Preservation of the product is required when under the supplier's control. Delivery product must be designed to protect the product during the transportation to its destination.

16-Control of Quality Records

Quality records are used to demonstrate the achievement of required quality and verify the effective and economical operation of the quality system. This element requires that the records be maintained for the establish retention period or as prescribed by contractual requirements.

17-Internal Quality Audits

The purpose of this element is to ensure that the quality system is working according to plan and to provide opportunities for improvement .It is an important tool for the management review process. Internal audits must be performed for all organization activities.

18-Training

Most programs include training in plant safety, the quality system, basic statistical concepts, and technical skills. Records must be maintained to document that the training requirements have been fulfilled. This element should be viewed as a strategic issue affecting all employees and should be periodically evaluated.

19-Servicing

After - delivery service on product and verifying, through documentation, that the servicing meet the contract's specified requirements. Procedures must be established to provide feedback on service information to manufacturing, design, and other appropriate activities.

20- Statistical Techniques

The selection of the appropriate statistical tools is determined during advanced quality planning. Knowledge of basic statistical concepts such as variation, stability, capability, and over adjustment should be evident throughout the supplier's organization.

SECTOR-SPECIFIC REQUIREMENTS

There are three sector –specific requirements: Production Part Approval Process **(PPAP)**, Continuous Improvement, and Manufacturing Capabilities. Production part approval is required for any change in part numbers, engine changes, manufacturing locations, and material. Suppliers must continuously improve their quality, service, and price. Specific plans provide process stability and acceptable capability.

WRITING THE DOCUMENT

When writing the documents is to create simplicity of complicity. To accomplish this objective, the documents must be simple and condense. The first step in writing the documents is to create a format that can be used throughout the documentation hierarchy, although it is required by three ISO. Each document should have a title, a number that is unique to only one document, a date, revision number or letter for control purposes, and number of pages it contains.

INTERNAL AUDITS

All the elements should be audited at least once per year and some more frequency, depending on need

1-Objective

There are five objectives of the internal audit. They are to:

- Determine that the actual performance conforms to the document quality system.
- Initiate corrective action activities in response to deficiencies.
- Follow up on noncompliance items of previous audits.
- Provide continued improvement in the system through feedback to management.
- Cause the auditee to think about the process, thereby creating possible improvements.

2-Auditor

Audits should be performed by qualified individuals who have received training auditing principles and procedures. To be able to audit efficiency, an individual should passes good written and oral communication skills, be good listener, and be good taking notes.

3-Techniques

There are a number of techniques that the auditor should employ. The objective is to collect evidence, and there are three methods: examination of the documents, observation of activities, interview .The easiest method is to examine the documents. For example, the auditor check the purchase orders to determine whether they were accurate and followed procedures, all appropriate attachments were present. Observation of activities is also an easy method that requires an aptitude for detail. For example to evaluate the process control

element for suitable working conditions, the auditor observe the processing stations for safety, cleanliness, clear aisles, and so forth. The most difficult method of collecting evidence is by interviewing the employee or auditee. However, there are ways to make the process easier. First, place the auditee in a non-threatening environment by starting with introduction and an explanation of the purpose of the audit.

Examples of open questions:

"When are supplier reviews performed?"

"How is the inspection status identified on this item?"

Examples of closed questions are:

"Do you have a work instruction for this operation?"

"Does this instrument require calibration?"

Examples of clarifying questions are:

"Tell me more about this operation?"

"Please give me more examples?"

An example of a leading question is:

" Do not you agree that the nonconformity was caused by not understanding the purchasing Order?"

4-Procedure

Before the audit takes place, an audit plan and check list should be prepared. The contents of an audit plan should identify the activity or department; list the procedures, documents, and regulatory requirements involved, the audit team; and list who is to be notified of the audit and who will receive audit reports .The plan also contain a schedule similar to Figure. In addition an audit matrix can be very helpful. It determine the most affected areas and elements .The audit itself has three parts, the preaudit meeting, performing the audit, and closing meeting. During the preaudit, the audit process and timetable are discussed and prior audits are reviewed. Minutes of the meeting should be recorded and included with the audit documentation. A list of this attending the meeting is recorded in the minutes. The object of the auditing process is to provide for continuous improvement and increased customer specification. The audit findings should be written out in detail from auditors' notes should include the conforming as well as the nonconforming items. Separate reports prepared for each nonconformance and should include:

1. The element title and a unique identification number such as NC-4.3.2.2.1, which the NC stands for nonconformance and the other numbers give the clause number.
2. Where the nonconformance was observed.
3. Objective evidence used as a basis for the nonconformance.
4. The nonconformance worded as a closely as possible to the language of requirement.

At the closing meeting, the lead auditor presents a summary of the audit finding along with the evidence that supports them. An estimate is made of when the final report will be issued .The audit report will:

1. Have a cover sheet that includes the audit date, names of the audit team, and a statement that the audit is only a sample, and it will be signed by the lead auditor.
2. List the non-conformances and copies of all nonconformance reports.
3. Outline procedures for corrective action and subsequent follow –up.

Registration

Quality system registration is the assessment and audit of a quality system by a third party, known as a registrar. There are tow parts: selecting a registrar and the registration process.

A-selecting a registrar

A registrar accreditation Board (RAB) was established in 1989 as an affiliate of the American society of quality (ASQ) to develop a program to evaluate the quality of the services offered by the registrars .The **RAB** maintains the list of approved registrars. Registrar selection can be based on four general criteria:

1-Qualifications and Experience

Of particular importance is the number of companies that have been registered, their experience in particular industry sectors, and their customer's structure such as size and location. Also important are their auditor qualification and continued training of auditors.

2-Certificate recognition

The registrar must be approved by a regulatory agency such as **RAB** .It must be recognized by existing and potential customers.

3-The Registration Process

The registrar should have a structured registration procedure that is tailored to your needs. They should be responsive to requests. The registrar should not only evaluate the system but also identify opportunities for more efficient practices. Of future importance is the ability of registrar to perform audit combination environmental, quality, and workplace safety.

4-Time and Cost Constraints

The evaluation should include the lead-time necessary prior to the audit. In addition you will want to know the time and cost required for the initial audit.

Registration Process

The registration process has six basic steps:

1. application for registration,
2. document review,

3. preassessment,
4. assessment,
5. registration, and
6. follow –up surveillance.