

**QUALITY PROGRAM**  
**OF**  
**THE BISHOP GROUP, INC.**

**REPORT R02-03**

**Revised**  
**June 9, 2003**



**The Bishop Group, Inc.**

**Panama City, Florida 32405**

## **FORWARD**

This document describes the Quality Program to be used in the general conduct of business for The Bishop Group, Inc. (the Company). The program is tailored to grow as the company grows with the expected end result being ISO 9000 certification at some time in the future.

The procedures in this document are mandatory for all officers and employees of The Bishop Group, inc. Employees are encouraged to identify procedures that are inconsistent or appear to require revision.

This document is effective as of June 18, 2002.

Paul C. Bishop  
President

## CHANGES & REVISIONS

<b>DATE</b>	<b>DESCRIPTION</b>
6/18/02	Original
6/19/02	Corrected minor typos and format errors in response to QDR 02.
4/9/03	Retyped document due to lost file.
6/02/03	Corrected typos/reworded paragraph

## TABLE OF CONTENTS

FORWARD .....	<a href="#">i</a>
CHANGES & REVISIONS .....	<a href="#">ii</a>
1. INTRODUCTION .....	<a href="#">1</a>
1.1 General .....	<a href="#">1</a>
1.2 Definitions .....	<a href="#">1</a>
1.2.1 Officers .....	<a href="#">1</a>
1.2.2 Management .....	<a href="#">1</a>
1.2.3. Employees .....	<a href="#">1</a>
1.2.4 Non-Management Employees .....	<a href="#">1</a>
1.2.5 Board of Directors .....	<a href="#">1</a>
2. BACKGROUND .....	<a href="#">3</a>
2.1 ISO 9000 Standards .....	<a href="#">3</a>
2.2 Implementation of ISO 9000 Requirements .....	<a href="#">4</a>
3. QUALITY POLICY .....	<a href="#">5</a>
3.1 High Quality Products .....	<a href="#">5</a>
3.2 On-Time Delivery .....	<a href="#">5</a>
3.3 Fair Price .....	<a href="#">5</a>
3.4 Continuous Improvement .....	<a href="#">5</a>
4. QUALITY MANAGEMENT SYSTEM .....	<a href="#">6</a>
4.1 Business Quality Processes .....	<a href="#">6</a>
4.1.1 Contractual Processes .....	<a href="#">6</a>
4.1.2 Personnel Processes .....	<a href="#">6</a>
4.1.3 Other Business Processes .....	<a href="#">6</a>
4.2 Quality Management Processes .....	<a href="#">6</a>
4.2.1 Management Review .....	<a href="#">7</a>
4.2.2 Peer Review .....	<a href="#">7</a>
4.2.3 24-Hour Rule .....	<a href="#">7</a>
4.2.4 Feedback .....	<a href="#">7</a>
4.2.5 Quality Non-Conformities .....	<a href="#">7</a>
4.2.6 Quality Data Base .....	<a href="#">7</a>
4.3 Documentation Requirements .....	<a href="#">8</a>
4.3.1 Correspondence .....	<a href="#">8</a>
4.3.2 Proposals .....	<a href="#">8</a>

4.3.3	Contracts	8
4.3.4	Working Papers	9
4.3.5	Working Drawings	9
4.3.6	Final Deliverables	9
4.4	Quality System	9
4.4.1	Quality System Documents	9
4.4.2	Quality Manual	9
4.4.3	Control of Documents	10
4.4.4	Control of Quality Records	10
5.	MANAGEMENT RESPONSIBILITY	12
5.1	Management	12
5.1.1	Importance of Quality	12
5.1.2	Quality Management System	12
5.1.3	Quality Implementation	12
5.1.4	Quality Improvement	12
5.2	Customer Focus	13
5.2.1	Customer Satisfaction	13
5.3	Quality Policy	13
5.3.1	High Quality Products	13
5.3.2	On-time Delivery	13
5.3.3	Fair Price	13
5.3.4	Continuous Improvement	13
5.4	Planning	14
5.4.1	Quality Objectives	14
5.4.2	QMS Planning	14
5.5	Responsibility, Authority and Communication	14
5.5.1	Responsibility and Authority	14
5.5.2	Management Representative	15
5.5.3	Internal Communication	15
5.6	Management Review	15
5.6.1	General	16
5.6.2	Review Input	16
5.6.3	Review Output	17
6.	RESOURCE MANAGEMENT	18
6.1	Quality Resources	18
6.2.1	General	18
6.2.2	Competence, Awareness and Training	19
6.3	Infrastructure	19
6.4	Work Environment	20
7.	PRODUCT REALIZATION	22
7.1	Realization Planning	22

7.2 Customer-Related Processes .....	<a href="#">22</a>
7.2.1 Identify Customer’s Product Requirements .....	<a href="#">22</a>
7.2.2 Review of Requirements Related to the Product .....	<a href="#">23</a>
7.2.3 Review Customers’ Product Requirements .....	<a href="#">23</a>
7.2.4 Customer Communication .....	<a href="#">23</a>
7.2.5 Communicate with Our Customers .....	<a href="#">23</a>
7.3 Product Development .....	<a href="#">23</a>
7.3.1 Plan Design and Development .....	<a href="#">24</a>
7.3.2 Design and Development Inputs .....	<a href="#">24</a>
7.3.3 Design and Development Outputs .....	<a href="#">24</a>
7.3.4 Design and Development Review .....	<a href="#">25</a>
7.3.5 Design and Development Verification .....	<a href="#">25</a>
7.3.6 Design and Development Validation .....	<a href="#">25</a>
7.3.7 Control of Design and Development Changes .....	<a href="#">26</a>
7.4 Purchasing .....	<a href="#">26</a>
7.4.1 Purchasing Process .....	<a href="#">26</a>
7.4.2 Purchasing Information .....	<a href="#">26</a>
7.4.3 Verification of Purchased Product .....	<a href="#">27</a>
7.5 Production and Service Provision .....	<a href="#">27</a>
7.5.1 Control of Production and Service Provision .....	<a href="#">27</a>
7.5.2 Validation of Processes for Production and Service Provision .....	<a href="#">28</a>
7.5.3 Identification and Traceability .....	<a href="#">28</a>
7.5.4 Customer Property .....	<a href="#">29</a>
7.5.5 Preservation of Product .....	<a href="#">29</a>
7.6 Control of Monitoring and Measuring Devices .....	<a href="#">29</a>
8. MEASUREMENT, ANALYSIS & IMPROVEMENT .....	<a href="#">31</a>
8.1 General .....	<a href="#">31</a>
8.1.1 Perform Remedial Processes .....	<a href="#">31</a>
8.2 Monitor and Measure Quality .....	<a href="#">31</a>
8.2.1 Customer Satisfaction .....	<a href="#">31</a>
8.2.2 Internal Audit .....	<a href="#">31</a>
8.2.3 Monitoring and Measurement of Processes .....	<a href="#">32</a>
8.2.4 Monitoring and Measurement of Product .....	<a href="#">32</a>
8.3 Control of Nonconforming Product .....	<a href="#">33</a>
8.4 Analysis of Data .....	<a href="#">33</a>
8.5 Improvement .....	<a href="#">34</a>
8.5.1 Continual Improvement .....	<a href="#">34</a>
8.5.2 Corrective Action .....	<a href="#">35</a>
8.5.3 Correct Actual Nonconformities .....	<a href="#">35</a>
8.5.4 Preventive Action .....	<a href="#">35</a>
GLOSSARY .....	<a href="#">37</a>

APPENDIX A - ACHIEVING ISO CERTIFICATION .....	<a href="#">A-1</a>
ISO 9000 CERTIFICATION .....	<a href="#">A-2</a>
REQUIREMENTS AND PROCESS TO BECOME ISO 9000 COMPLIANT .....	<a href="#">A-2</a>
Employee resources .....	<a href="#">A-2</a>
Process Steps .....	<a href="#">A-2</a>
Choosing a Registrar .....	<a href="#">A-2</a>
Process to Quality Documentation .....	<a href="#">A-4</a>
Procedures and Work Instructions .....	<a href="#">A-5</a>
Objectives and Plans .....	<a href="#">A-5</a>
QUALITY AUDITS .....	<a href="#">A-5</a>
Internal Audit .....	<a href="#">A-5</a>
Pre-assessment Audit .....	<a href="#">A-5</a>
Second Internal Audit .....	<a href="#">A-6</a>
Training .....	<a href="#">A-6</a>
Nonconformance Issues .....	<a href="#">A-6</a>
Registration Audit .....	<a href="#">A-7</a>

# 1. INTRODUCTION

## 1.1 General

Quality programs are necessary to control the quality of products thereby reducing errors, cost, and rework. The Bishop Group, Inc. Ensures quality support of its clients by maintaining a quality program commensurate with the size of the company.

Our Quality Program is established along the lines of ISO 9000 and tailors requirements to fit company mission and size. The program is tailored to grow as the company grows with the expected end result being ISO 9000 certification at some time in the future. Toward that end, the Quality Program is outlined in an ISO 9000 compliant form with the most essential early elements fully developed and place keepers (hooks and handholds) in place for additional implementation as the company grows and expansion of quality procedures become appropriate.

## 1.2 Definitions

Certain terms are used in this document to refer to positions of individuals in The Bishop Group, Inc. These are defined below.

### 1.2.1 Officers

Officers are the most senior management. The term includes President, Chief Engineer, Secretary, and similar positions. With the exception of Chief Engineer, all officers are identified by the use of terms like Vice President for Human Resources. The Vice President for Human Resources would be an Officer of The Bishop Group; the Director of Human Resources would not.

### 1.2.2 Management

Management includes all officers and other employees with titles such as Manager, Director, etc.

### 1.2.3. Employees

Employees includes managers, officers, and non-management employees.

### 1.2.4 Non-Management Employees

Non-management employees are employees who are neither management nor officers of the firm.

### 1.2.5 Board of Directors

Members of the Board of Directors are specifically exempt from the requirements of the Quality Program unless they hold other positions or offices of the company.

## **2. BACKGROUND**

Our Quality Program is based on the requirements of ISO 9000. We plan to be ISO 9000 certified at some time in the future.

The entire process of ISO certification requires coordination of organizations on an international scale. Often times, the roles these organizations play within the process can be confusing. The following sections will familiarize you with ISO, the standards and the growing market of ISO certification:

### **2.1 ISO 9000 Standards**

The ISO 9000 Standards are generic in nature, and they were designed to apply and appeal to all manners of business. Although most organizations use these generic standards, some industries seeking a set of quality standards have developed modified versions over time. These specific industry adaptations include QS 9000 (automotive), TL 9000 (telecommunications) and AS 9000 (aerospace).

The ISO 9000 standards are produced by an international consensus with the aim of creating global standards of product and service quality. These sets of standards form a Quality Management System (QMS) and are applicable to any organization regardless of product, service, organizational size, or whether the company is public or private. ISO's main objective is to facilitate international trade by providing a single set of standards of both systemic and international orientation.

In 1987 the first 9000 quality standards were published by ISO. These standards were then revised in 1994, and then again in 2000. Prior to ISO 9000:2000, an organization could be certified against one of three quality systems: ISO 9001, ISO 9002 or ISO 9003.

When determining which standard to adopt, the primary factor to consider is the expectations of your organization's customers. If the customers of your organization would not benefit from a specific adoption of one of the ISO derivative standards, then ISO 9001:2000 is most appropriate.

ISO Standards are continually reviewed in order to improve their effectiveness. Currently, the cycle for review is five years, with the newest version of the ISO 9000 Standard having been released in December 2000 and appropriately named ISO 9000:2000.

The previous ISO 9000 family of standards contained 20 required elements. To adjust to the changing needs of users and customers of the ISO Standard, ISO TC 176 revised the ISO 9000 family of standards, merging them together in some cases and changing the focus from procedures to processes. The new standard requires only six procedures, allowing more

companies to introduce their quality processes into the equation as they seek certification and maintain compliance.

ISO 9001, ISO 9002, and ISO 9003 standards have been consolidated into the single revised ISO 9001:2000 Standard. The ISO 9001:2000 Standard replaces the ISO 9001:1994, ISO 9002:1994 and ISO 9003:1994 standards. The old ISO 9002 and ISO 9003 series of standards have been discontinued. (Although, an organization can continue to be certified to these standards until December 2003 if they so choose.)

## **2.2 Implementation of ISO 9000 Requirements**

To the extent possible, the key points in the 20 elements have been integrated into the new standard. The five sections in our quality program which address ISO 9000 requirements are:

- 4 Quality Management System
- 5 Management Responsibility
- 6 Resource Management
- 7 Product Realization
- 8 Measurement, Analysis and Improvement

From within these five sections, the six documented procedures required by ISO 9000 and addressed in our quality plan are:

- 4.4.3 Control of Documents
- 4.4.4 Control of Records
- 8.2.2 Internal Audits
- 8.3 Control of Nonconforming Product
- 8.5.2 Corrective Actions
- 8.5.3 Preventive Actions

### **3. QUALITY POLICY**

It is the policy of The Bishop Group, Inc. To deliver high quality products, on time, and at a fair price.

#### **3.1 High Quality Products**

Products shall conform to requirements, be free from defects (including typos), and shall be presented in a professional format reflecting superior industry quality.

#### **3.2 On-Time Delivery**

Products shall be delivered in a timely manner as reflected in our agreements with our clients. Every effort shall be expended to ensure we meet our agreements on time. Associates and subcontractors shall be monitored to ensure timely submission of their products to us.

#### **3.3 Fair Price**

We are in business to make a profit. We will not undertake a project we do not believe we can complete with a fair and reasonable profit.

#### **3.4 Continuous Improvement**

We have a strong commitment to continuously improve the quality of our products and the quality of our quality program. All employees and officers of the company shall ensure conformance to requirements and strive to improve our processes to meet quality objectives. Processes shall be subject to continuous review to ensure that they remain suitable.

## **4. QUALITY MANAGEMENT SYSTEM**

The Quality Management System (QMS) addresses some basic areas. In this section we consider who will have ultimate responsibility for the system, look at what kinds of resources will be needed, figure out how to measure the quality of our processes and “output,” and put actions in place to ensure that desired results will be achieved.

The quality management system consists of three major components: the quality program plan, the quality deficiency data base, and the quality improvement plan.

The President of The Bishop Group, Inc. has ultimate responsibility for the quality of its products.

### **4.1 Business Quality Processes**

The business processes of our quality system are described below.

#### **4.1.1 Contractual Processes**

Contractual Processes identify work and obligate The Bishop Group to perform. Contractual processes also establish the schedule of deliverables and client obligations such as providing client-held information and payment for services received. The Bishop Group, its vendors and its clients are involved in contractual processes.

Contracts may be formal (signed by both parties) or informal, i.e. an agreement to perform based on a proposal. In both cases, cost schedule, and deliverables shall be clearly stated in writing before work commences.

#### **4.1.2 Personnel Processes**

Personnel processes include performance evaluation, setting of salary and bonuses, and general personnel information. Personnel performance evaluation shall include identification and discussion of quality issues. All other personnel processes are specifically excluded from the quality program.

#### **4.1.3 Other Business Processes**

Other business processes including record management, timekeeping, payroll, marketing, and similar functions are included in the quality program.

Measurement, analysis, and improvement are discussed in detail in Section 8.

### **4.2 Quality Management Processes**

Our Quality Management Processes are described below.

#### **4.2.1 Management Review**

*Management review means that all products prepared by The Bishop Group will be reviewed by management prior to submission. The review will normally be conducted after the peer review or 24-hour rule has been completed.*

#### **4.2.2 Peer Review**

Peer review means that all products prepared by The Bishop Group will be reviewed prior to submission. The review will normally be conducted by an individual not preparing the document.

#### **4.2.3 24-Hour Rule**

The 24-Hour Rule means that a document not subjected to peer review may be reviewed by the preparer but after the review and revision, the document shall be retained for 24 hours, and re-read prior to delivery.

#### **4.2.4 Feedback**

Client feedback on product quality is always welcome. Attention to feedback from clients is paramount in ensuring we are on the right track. Quality problems identified by a client will be handled as the number one priority in any project.

#### **4.2.5 Quality Non-Conformities**

Quality Deficiency Reports (QDRs) will be used as a method of documenting and tracking all quality deficiencies and non-conformities. Quality deficiencies and non-conformities will be tracked through the use of our quality data base. Copies of a client's QDRs will be provided to the client if requested or required by contract.

#### **4.2.6 Quality Data Base**

The Quality Data Base shall be used to:

Implement our quality management system,

Serve the key quality system processes,

Manage process performance,

Improve our quality management system,

Monitor process performance,

Improve process performance,

*Address urgent requirements,*

*Addressing training issues.*

### **4.3 Documentation Requirements**

All work performed by The Bishop Group shall be documented. The documentation generally follows the business process and includes a proposal, contract, working papers, and final deliverables. Quality management begins with the proposal and follows through delivery and acceptance of the final deliverables.

#### **4.3.1 Correspondence**

Correspondence is any letter, memo, or email formally conveying a business position of The Bishop Group. All correspondence will be prepared on letterhead paper and will be signed by the author or another appropriate person. When email is used to state a business position, a copy of the email shall be filed in the correspondence folder and a formal confirming letter shall follow within 24 hours. Email shall not be used as formal correspondence.

Contractual correspondence, or correspondence with potential contractual impact may be faxed but shall always be followed with the original via US Mail, Fedex, UPS, or similar service.

#### **4.3.2 Proposals**

A proposal is prepared and submitted with a cover letter to a prospective client. Once the contract has been awarded, the proposal may be invoked as the contract or a separate contract may be invoked. The contract statement of work and the proposal must be in agreement before the contract is signed.

#### **4.3.3 Contracts**

The contract is the binding document between The Bishop Group and its client. The contract generally takes precedence over other documents such as the proposal. A contract is valid when there is agreement, consideration, and ability to perform. Whenever a contract appears to be in question, management and the client shall be informed immediately. Items frequently requiring attention include the schedule, scope of work, and quality of interim products.

The requirement for review of contracts when questions arise cannot be overstated. When in doubt, look at the contract. Still in doubt? Refer to management.

#### **4.3.4 Working Papers**

Working papers shall be used to document the process and activities of the project. Working papers shall reflect details as they become available and should be prepared as a working copy of a final project report. Working papers will be prepared as working drafts of a final project report. They shall be numbered as reports with the characters "WP" preceding the number as "WP02-01" and re-identified as a report "R02-01" if provided as a final report. The contents of working papers will vary to reflect the type of project.

#### **4.3.5 Working Drawings**

Working drawings are preliminary drawings which have not been signed and released or drawings which have been signed and released but are currently undergoing revision.

#### **4.3.6 Final Deliverables**

Final deliverables are those required by the contract to be delivered as final products. Final deliverables shall be delivered with a forwarding letter stating the deliverables are final.

### **4.4 Quality System**

The Quality System is documented in this section. The types of areas that need to be looked at specifically are procedures, planning, and operations. This section describes what we do to control quality in these areas. We also need to retain quality records, which are documents (i.e. inventory control listings, travelers, work orders, signed contracts, etc.) that prove that a procedure was followed.

#### **4.4.1 Quality System Documents**

The Quality System Documents are the Quality Program (this document), certain written records which document that a procedure was followed (e.g. travelers, inventory control listings, work orders, signed contracts, etc. ) and other records which trace or document the performance of a procedure or completion of a deliverable. Quality deficiency reports, and reports normally generated from the quality data base are also quality records.

As our business matures we need to develop additional documents to implement our quality system and reflect what our organization does.

#### **4.4.2 Quality Manual**

The Quality Program, Report 02-03, (this document) serves as the Quality Manual for The Bishop Group.

The Quality Manual:

Documents our procedures.

Describes how our processes interact.

Defines the scope of our quality system.

#### **4.4.3 Control of Documents**

The proper control of documents means that we need to ensure that all of the documents in our QMS have been appropriately identified, reviewed, authorized, issued and distributed. We need to take care that old, obsolete documents are not being used, and that they are stored in a secure location if they are needed for reference. We also need to make sure that any external documents that we use in our QMS are identified in our system and that the access to these documents is controlled.

All documents, except working papers and preliminary drawings, shall be approved before distribution.

Working papers and preliminary drawings shall be clearly identified as such and shall contain a date indicating the latest change or revision.

References to working papers and preliminary drawings shall include the date of latest change or revision.

Management shall:

Provide the correct version of documents at points of use.

Review and re-approve documents when they are updated.

Specify the current revision status of documents.

Monitor documents that come from external sources.

Prevent the accidental use of obsolete documents.

Preserve the usability of quality documents.

#### **4.4.4 Control of Quality Records**

Ensure all documents we retain prove our QMS is in compliance with stated business practices and standard operational procedures. These documents must be legible and easily retrievable.

Quality documents are permanent records and as such they should never be discarded, deleted, or destroyed. Inactive quality records shall be archived annually. Open quality records (QDRs, uncompleted work orders and contracts, etc.) shall not be archived until completion. We must have a consistent policy for retaining both active and inactive documents. See *The Bishop Group, Inc. Company Practices and Standard Operating Procedures, report 02-04*, for details.

## **5. MANAGEMENT RESPONSIBILITY**

### **5.1 Management**

An effective quality program requires the involvement and commitment of management.

#### **5.1.1 Importance of Quality**

Management shall promote the importance of quality:

Promote the need to meet customer requirements.

Promote the need to meet regulatory requirements.

Promote the need to meet statutory requirements.

#### **5.1.2 Quality Management System**

Management shall develop a quality management system:

Support the development of a quality system.

Formulate the organization's quality policy.

Set the organization's quality objectives.

Provide quality resources.

#### **5.1.3 Quality Implementation**

Management shall implement our quality management system:

Provide resources to implement your quality system.

Encourage personnel to meet quality system requirements.

#### **5.1.4 Quality Improvement**

Management shall improve our quality management system:

Perform quality management reviews.

Provide resources to improve the quality system.

## **5.2 Customer Focus**

The goal of the QMS is to improve customer satisfaction. Management shall ensure that the QMS identifies customer satisfaction requirements in each important area of service or product delivery. The QMS should work to make sure that these customer satisfaction requirements are fulfilled.

### **5.2.1 Customer Satisfaction**

Management shall identify customer satisfaction requirements and expect our organization to identify customer satisfaction requirements.

Management shall meet our customers' requirements and expect our organization to meet customer requirements.

Management shall enhance customer satisfaction and expect our organization to enhance customer satisfaction.

## **5.3 Quality Policy**

It is the policy of The Bishop Group, Inc. To deliver high quality products, on time, and at a fair price.

### **5.3.1 High Quality Products**

Products shall conform to requirements, be free from defects (including typos), and shall be presented in a professional format reflecting superior industry quality.

### **5.3.2 On-time Delivery**

Products shall be delivered in a timely manner as reflected in our agreements with our clients. Every effort shall be expended to ensure we meet our agreements on time. Associates and subcontractors shall be monitored to ensure timely submission of their products to us.

### **5.3.3 Fair Price**

We are in business to make a profit. We will not undertake a project we do not believe we can complete with a fair and reasonable profit.

### **5.3.4 Continuous Improvement**

We have a strong commitment to continuously improve the quality of our products and the quality of our quality program. All employees and officers of the company shall ensure

conformance to requirements and strive to improve our processes to meet quality objectives. Processes shall be subject to continuous review to ensure that they are still suitable.

## **5.4 Planning**

Management shall carry out quality planning.

### **5.4.1 Quality Objectives**

Management shall ensure measurable and consistent quality objectives are established and communicated throughout our organization.

Management shall formulate our quality objectives:

Ensure that objectives are set for functional areas.

Ensure that objectives are set at organizational levels.

Ensure that objectives facilitate product realization.

Ensure that objectives support the quality policy.

Ensure that objectives are measurable.

### **5.4.2 QMS Planning**

We plan so that desired goals are achieved. We must ensure that our QMS addresses and achieves the goals that we have set, and make sure that as we continually improve and change our QMS that our goals remain consistent: continuous improvement and customer satisfaction.

Management shall plan our quality management system:

Plan the development of our quality management system.

Plan the implementation of our quality management system.

Plan the improvement of our quality management system.

Plan the modification of our quality management system.

## **5.5 Responsibility, Authority and Communication**

Management shall control our quality system.

### **5.5.1 Responsibility and Authority**

Effective communication and management requires that everyone know what their responsibilities are and to whom they report. To accomplish this goal, it is important to identify responsible parties and describe how much authority they have. Sometimes, it may not be clear that the responsible party does not have the authority to make necessary changes. These types of situations should be identified immediately.

Management shall define responsibilities and authorities in writing:

Clarify responsibilities and authorities.

Communicate responsibilities and authorities.

### **5.5.2 Management Representative**

Management shall appoint the management representative to:

Oversee our quality management system.

Report on the status of our quality management system.

Support the improvement of our quality management system.

The Management Representative shall have operational responsibility for our QMS. The duties of the Management Representative has with respect to the QMS includes:

Ensuring that processes needed for our QMS are established, implemented and maintained.

Reporting on the performance of the QMS and improvements needed.

Promoting awareness of customer requirements throughout our organization.

### **5.5.3 Internal Communication**

Management shall support internal communications to allow for feedback from the employees to management:

Ensure that internal communication processes are established.

Ensure that communication occurs throughout the organization.

## **5.6 Management Review**

Top management has the responsibility to make sure that the QMS is operating effectively.

### **5.6.1 General**

Top management shall review certain aspects of the QMS to make sure that the goals are being achieved and to look for ways to improve the QMS. These meetings need to be documented as to when they took place and what was discussed.

Management shall review the quality management system to:

Evaluate the performance of our quality system.

Evaluate whether our quality system should be improved.

### **5.6.2 Review Input**

Regularly scheduled management review meetings should be held quarterly. These meetings shall address the following areas:

- Internal audit results
- Customer feedback
- How processes and products have been measuring up
- Status of previously identified problems
- Items identified for follow-up in previous management reviews
- Planned process or product changes that could affect quality
- Recommendations for improvement generated through the operation of the QMS
- Employee feedback or previous management meetings

The Quality Manager shall examine management review inputs:

Examine audit results.

Examine product conformity data.

Examine opportunities to improve.

Examine feedback from customers.

Examine process performance information.

Examine corrective and preventive actions.

Examine changes that might affect your system.

Examine previous quality management reviews.

### **5.6.3 Review Output**

After management review meetings are held, there should be follow up actions taken if, as a result of the meetings, top management decided that the effectiveness of the QMS can be improved. These improvements could mean that customer requirements could be better evaluated or better met, or that there is a need for additional resources to support the QMS.

The Quality Manager shall generate management review outputs:

Generate actions to improve our quality system.

Generate actions to improve our products.

Generate actions to address resource needs.

## **6. RESOURCE MANAGEMENT**

We have a responsibility to make sure that the goals of the Quality Management System (QMS) are met. The best plan in the world won't be successful if there are not enough people, materials and support to make sure it can be successful. These resources should be sufficient to implement and maintain the QMS. Additionally, we need to have enough resources to make sure that the goals of continuous improvement and meeting customer satisfaction are also met.

### **6.1 Quality Resources**

Quality resources include human resources, training, infrastructure, and work environment.

Management shall provide quality system resources:

Identify quality resource requirements.

Identify resources needed to support the quality system.

Identify resources needed to improve customer satisfaction.

Provide resources needed to support the quality system.

Provide resources needed to improve customer satisfaction.

### **6.2 Human Resources**

#### **6.2.1 General**

We must assess the skills and competencies of our employees and consider whether they have the skills and abilities to perform the tasks that have been assigned to them. Areas of competency to address would include prior education, training and experience.

Management shall:

Ensure that our personnel have the right experience.

Ensure that our personnel have the right education.

Ensure that our personnel have the right training.

Ensure that our personnel have the right skills.

## **6.2.2 Competence, Awareness and Training**

We have a responsibility to see that our employees have enough training to be effective at the tasks that have been assigned to them. We can accomplish this objective by hiring trained and competent personnel. We must also have a plan in place for providing training where there may be gaps in needed skills and for bringing new needed skills to our existing work force. The assessment of our employees skills, our training plans, and actual training provided must all be documented.

Management shall:

Define acceptable levels of competence.

Identify training and awareness needs.

Deliver training and awareness programs.

Evaluate effectiveness of training and awareness.

Maintain a record of competence.

## **6.3 Infrastructure**

The infrastructure for a QMS can be described as including the workspace, the equipment and the supporting services involved in creating our organization's products or services. Our organization needs to determine, provide and maintain the infrastructure needed to achieved the planned results.

Management shall identify quality infrastructure:

Identify infrastructure needs.

Identify building needs.

Identify workspace needs.

Identify hardware needs.

Identify software needs.

Identify utility needs.

Identify equipment needs.

Identify support service needs.

Senior Management shall provide needed infrastructure:

Provide needed buildings.

Provide needed work spaces.

Provide needed hardware.

Provide needed software.

Provide needed utilities.

Provide needed equipment.

Provide needed support services.

All employees shall maintain our infrastructure:

Maintain our buildings.

Maintain our work spaces.

Maintain our hardware.

Maintain our software.

Maintain our utilities.

Maintain our equipment.

Maintain our support services.

#### **6.4 Work Environment**

The work environment of our organization needs to enhance the ability of employees to perform effectively in order to meet quality expectations. Elements of a good work environment include:

- Ability of the employee to be creative and become involved
- Clean work areas
- Proper safety rules and equipment
- Ergonomically appropriate work areas

- Pollution control
- Ability to interact with others

Management shall provide quality environment:

Identify needed work environment.

Identify factors needed to ensure products meet requirements.

Manage needed work environment.

Manage factors needed to ensure products meet requirements.

## **7. PRODUCT REALIZATION**

Product realization deals with the steps and processes that our organization goes through to deliver finished goods or services. An effective Quality Management System (QMS) needs to develop a comprehensive approach to getting from the starting point to the finish line. This approach must be planned out and the important steps and stages must be written down.

### **7.1 Realization Planning**

Management shall:

- Plan product realization processes.
- Define product quality objectives and requirements.
- Identify product realization needs and requirements.
- Develop product realization processes.
- Develop product realization documents.
- Develop product realization record-keeping systems.
- Develop methods to control quality during product realization.

### **7.2 Customer-Related Processes**

ISO 9000 requires we assess our organization's product or process requirements. We need to consider all manner of requirements. These requirements could come from the customer, could be mandated by law or could be generally accepted standards within our industry. The first place to start is to check any standard contracts or oral agreements that our sales department uses. Any modifications to these standard agreements should be considered as well.

#### **7.2.1 Identify Customer's Product Requirements**

Management and project personnel shall:

- Identify the requirements that customers want us to meet.
- Identify the requirements that are dictated by the product's use.
- Identify the requirements that are imposed by external agencies.

Identify the requirements that our organization wishes to meet.

### **7.2.2 Review of Requirements Related to the Product**

After you determine what the product or service requirements are, we need to review to make sure that we are meeting these requirements. The logical sequence to perform this review would be to make sure:

- The requirements are define
- The organization has the ability to meet the requirements
- Process or production changes are reviewed and documented

### **7.2.3 Review Customers' Product Requirements**

Management and project personnel shall:

Review requirements before accepting orders from customers.

Maintain a record of your product requirement reviews.

Control changes in product requirements.

### **7.2.4 Customer Communication**

An effective QMS will address communications with an organization's customers. We should ensure that customers have readily available information regarding our product offerings, the status of contract negotiations or the handling of orders, and how they can provide feedback to us or express any complaints.

### **7.2.5 Communicate with Our Customers**

Management shall:

Develop a process to control communications with customers.

Implement our customer communications process.

## **7.3 Product Development**

In order to effectively plan the design and development process, we need to follow three steps:

1. Clearly define the stages involved in the process.
2. Identify the responsible parties for each of those stages.

3. Review that these responsibilities have been carried out effectively.

### **7.3.1 Plan Design and Development**

Management shall:

Define product design and development stages.

Clarify design and development responsibilities and authorities.

Manage interactions between design and development groups.

Update design and development plans as changes occur.

### **7.3.2 Design and Development Inputs**

In order to properly design and develop an effective product or service we must consider all relevant factors. To some degree, we should address the marketability of the product or service since we need to consider the customer. However, the critical areas to consider in a QMS are performance, legal and regulatory, and any other requirements, such as industry, or organization standard practices.

Management shall:

Specify product design and development inputs.

Record product design and development input definitions.

Review product design and development input definitions.

### **7.3.3 Design and Development Outputs**

Information included in the output of design and development should include sufficient information to show that the requirements specified in the inputs document are being met by the product as designed, and how potential risks have been mitigated. It should also include information on how the product is to be built, including such things as specifications, purchasing, testing, the records and documentation required during manufacturing, training requirements, user and customer information, and any other information needed by our organization to build and use the product so that it meets the requirements. This process should be documented and approved.

Management shall:

Create product design and development outputs.

Approve design and development outputs prior to release.

Use design and development outputs to control product quality.

#### **7.3.4 Design and Development Review**

After we determine what the design and development requirements are, we need to review to make sure that we are meeting these requirements. Employees who have been involved in the process should be used to perform this review and determine that the design and development processes are in fact meeting the requirements, problems are identified and solutions are proposed. We need to retain records of design and development review.

Management shall:

Perform product design and development reviews.

Record product design and development reviews.

#### **7.3.5 Design and Development Verification**

Once we have planned and reviewed the design and development process, we need to test, or verify, that the final output did in fact meet the requirements. There are a variety of methods that we could use to perform these tests. The particular situation will dictate the best method to use. We must maintain the records of the test results, and any follow up actions taken.

Management shall:

Carry out product design and development verifications.

Record product design and development verifications.

#### **7.3.6 Design and Development Validation**

After the design outputs have been verified, validation is performed under actual operating conditions. If the product has multiple uses, each use may be validated separately. The methods for validation defined in the design output should be followed. Whenever possible, the validation of a new product or service should be performed prior to delivery to the customer.

Management shall:

Perform product design and development validations.

Record product design and development validations.

### **7.3.7 Control of Design and Development Changes**

Designs are often changed to accommodate custom orders, to try to improve performance, to accommodate a changing input component, or for some other valid reason. The standard requires we identify and document these Engineering Change Requests (ECRs). We also need to analyze the changes prior to implementation and consider what the total impact of the changes may be. We need to maintain records of these analyses, and any follow up actions taken.

Management shall control and manage design and development changes:

Identify changes in product design and development.

Record changes in product design and development.

Review changes in product design and development.

Verify changes in product design and development.

Validate changes in product design and development.

Approve changes before they are implemented.

## **7.4 Purchasing**

Management shall control the purchasing function.

### **7.4.1 Purchasing Process**

We need a controlled process for dealing with our suppliers. We need to establish criteria for how we evaluate and choose our vendors. These criteria should be based on the suppliers' ability to meet our order specifications. We need procedures to ensure that purchased product meets our specifications. Finally, we must maintain records that show how the purchased product was evaluated, and what we did when we discovered problems.

Management shall control the purchasing process:

Ensure that purchased products meet requirements.

Ensure that suppliers meet requirements.

### **7.4.2 Purchasing Information**

Purchasing information describes the product to be purchased. It can be included on contracts, purchase orders or other documents. Our QMS should make sure that the purchasing information meets the requirements, and addresses when and what type of approval is required. We should also describe any particular conditions for the purchasing information to comply with specific requirements in our QMS.

Project personnel shall document product purchases:

Describe the products being purchased.

Specify the requirements that must be met.

### **7.4.3 Verification of Purchased Product**

We will need to put in place inspection procedures, when and where appropriate, for our purchased products. The most explicit purchase orders may still not be complied with. Since we need to determine that the products and services ordered meet our predetermined specifications, we need to test to some degree to ensure that these specifications were in fact met. We also need to document the results of these tests.

Project personnel shall verify purchased products:

Verify purchased products at your own premises.

Verify purchased products at suppliers' premises (when required).

## **7.5 Production and Service Provision**

Management shall control operational activities.

### **7.5.1 Control of Production and Service Provision**

Planning and production activities should take place in a controlled environment. A controlled environment means that our employees have use of, and access to, instructions on how to do their jobs and all of the equipment necessary to assemble and test the product or deliver the service. This controlled environment should exist from the time product requirements are developed to the time the product or service is delivered.

Management shall control production and service provision:

Control production and service processes.

Control production and service information.

Control production and service instructions.

Control production and service equipment.

Control production and service measurements.

Control production and service activities.

### **7.5.2 Validation of Processes for Production and Service Provision**

Validation demonstrates that proper application of the processes can achieve the planned results. When it is not possible to verify the finished good or service through monitoring or measurement our QMS should call for validation. Validation is particularly important where deficiencies are not identified until the product is in use, or the service is delivered. When validation is appropriate, our QMS will need to define the criteria for the following areas involved in the process:

- Approval of validation procedures and equipment
- Qualification of personnel
- Backup plan if validation fails

Management shall validate production and service provision:

Prove that special processes can produce planned outputs.

Prove that process personnel can produce planned results.

Prove that process equipment can produce planned results.

### **7.5.3 Identification and Traceability**

When a product is being tested or measured, at any point in the production cycle, it must be identified. This identification should provide for traceability or the ability to follow the product throughout the production process, both physically and through documentation.

Project personnel shall identify and track our products:

Establish the identity of our products.

Maintain the identity of our products.

Identify the status of our products.

Record the identity of our products.

#### **7.5.4 Customer Property**

Special care must be taken when a customer provides their property for use or incorporation into the product. We need to identify and protect customer property provided and maintain records of lost, damaged or unsuitable customer property.

Project personnel shall protect property supplied by customers:

Identify property supplied to you by your customers.

Verify property supplied to you by your customers.

Safeguard property supplied to you by your customers.

#### **7.5.5 Preservation of Product**

ISO 9000 requires our organization to maintain procedures for the handling, storage, packaging, preservation, and delivery of parts and products throughout all processes.

Project personnel shall preserve our products and components:

Preserve products and components during internal processing.

Preserve products and components during final delivery.

#### **7.6 Control of Monitoring and Measuring Devices**

Monitoring and test equipment can be central to any effective QMS. Because of this fact, ISO 9000 puts an emphasis on carefully managing and maintaining these devices. QMS procedures are necessary to determine that appropriate monitoring and measuring methods and equipment are used to achieve planned results. Processes need to be established to ensure that monitoring and measuring is consistently carried out according to acceptable standards. Measuring or monitoring equipment shall be protected from damage or unplanned adjustment. Records of monitoring and measuring results must be maintained and assessed. If test results indicate that equipment is not properly calibrated, any remedial actions taken should be documented.

Engineering shall control monitoring devices:

Identify monitoring and measuring needs.

Identify the monitoring and measuring that should be done.

Select monitoring and measuring devices.

Select devices that meet your monitoring and measuring needs.

Calibrate monitoring and measuring devices.

Perform calibrations.

Record calibrations.

Project personnel shall protect monitoring and measuring devices:

Protect devices from unauthorized adjustment.

Protect devices from damage or deterioration.

Project personnel shall validate monitoring and measuring software:

Validate monitoring and measuring software before you use it.

Revalidate monitoring and measuring software when necessary.

Project personnel shall use monitoring and measuring devices:

Use devices to ensure that our products meet requirements.

## **8. MEASUREMENT, ANALYSIS & IMPROVEMENT**

### **8.1 General**

To determine that our Quality Management System (QMS) is improving, we will have to develop some monitoring and measurement techniques to measure its effectiveness. Once we develop these techniques, we will need to demonstrate that the QMS is in fact increasing in effectiveness.

#### **8.1.1 Perform Remedial Processes**

Management shall plan remedial processes:

Plan how remedial processes will be used to assure conformity.

Plan how remedial processes will be used to improve the system.

Management shall implement remedial processes:

Use remedial processes to demonstrate conformance.

Use remedial processes to improve quality management system.

### **8.2 Monitor and Measure Quality**

#### **8.2.1 Customer Satisfaction**

Since one of the goals of our QMS is to meet customer requirements, we need to determine how to measure our customers' satisfaction with our product and services.

Management shall monitor and measure customer satisfaction:

Identify ways to monitor and measure customer satisfaction.

Monitor and measure customer satisfaction.

Use customer satisfaction information.

#### **8.2.2 Internal Audit**

Internal audits, in the most basic sense, are double checks performed by our personnel to determine that required procedures are being followed. ISO 9000 required we perform internal

audits on each area covered by our QMS. All audits must be documented and address the following:

- Scope (what areas are to be tested and to what degree they will be tested)
- Methods to be used (such as interview or review of documentation)
- Who is responsible to perform the audit

Management shall plan and perform regular internal audits:

Set up an internal audit program.

Develop an internal audit procedure.

Plan your internal audit projects.

Perform regular internal audits.

Solve problems discovered during audits.

Verify that problems have been solved.

### **8.2.3 Monitoring and Measurement of Processes**

ISO 9000 requires us to measure that our processes produce desired results. If planned results are not achieved, corrective action must be taken and the effectiveness of the processes must be examined.

Management shall monitor and measure quality processes:

Use suitable methods to monitor and measure our processes.

Take action when our processes fail to achieve planned results.

### **8.2.4 Monitoring and Measurement of Product**

During the production process, we need to monitor and measure the product in order to determine that requirements are met. We need to document the following:

- The product meets acceptance criteria.
- The product is reviewed prior to release.
- The person who authorized the product to be released to the customer.

Project personnel shall monitor and measure product characteristics:

Verify that product characteristics are being met.

Keep a record of product monitoring and measuring activities.

### **8.3 Control of Nonconforming Product**

Nonconforming product is any product or service that does not measure up to requirements. Nonconforming product can be identified at any point in the production process: upon receipt of raw materials, finished goods inspection or anywhere in between. We need to define, and document procedures to control, identify, and prevent use of nonconforming products. To the extent possible, we need to control nonconforming product by taking action to eliminate or correct it. We are also allowed to release it with customer consent. We need to maintain records documenting processes and actions taken.

Management shall control nonconforming products:

Develop a procedure to control nonconforming products.

Define how nonconforming products should be identified.

Define how nonconforming products should be handled.

Management shall identify and control our nonconforming products:

Eliminate or correct product nonconformities.

Prevent the delivery or use of nonconforming products.

Avoid the inappropriate use of nonconforming products.

Project personnel shall re-verify nonconforming products that were corrected:

Prove that corrected products now meet requirements.

Project personnel shall control nonconforming products after delivery or use.

Project personnel shall control events when we deliver or use nonconforming products:

Maintain records of nonconforming products.

Describe our product nonconformities.

Describe the actions taken to deal with nonconformities.

### **8.4 Analysis of Data**

ISO 9000 requires our organization to collect information on the functioning of the QMS and to analyze the information collected to evaluate the effectiveness and efficiency of our system. Information collected and analyzed should include information related to specific quality objectives. As stated in ISO 9000, these objectives are that customer requirements are met and that the QMS is continuously improving. The other area to be specifically evaluated relates to the performance of our suppliers. Statistics should be used when appropriate to control processes and product characteristics.

Management shall analyze quality information:

Define quality management information needs.

Define the information we need to evaluate our quality system.

Define the information we need to improve our quality system.

Management and project personnel shall collect quality management system data:

Monitor and measure the suitability of our quality system.

Monitor and measure the effectiveness of our quality system.

Management shall provide quality management information:

Provide information about our customers.

Provide information about our suppliers.

Provide information about our products.

Provide information about our processes.

## **8.5 Improvement**

All employees shall make quality improvements.

### **8.5.1 Continual Improvement**

Management shall improve our quality management system:

Use our audits to generate improvements.

Use our quality data to generate improvements.

Use our quality policy to generate improvements.

Use our quality objectives to generate improvements.

Use our management reviews to generate improvements.

Use our corrective actions to generate improvements.

Use our preventive actions to generate improvements.

As added emphasis, the goal of achieving a continuously improving QMS is restated.

### **8.5.2 Corrective Action**

Corrective Action Requests, commonly referred to by the acronym CAR, are controlled documents that reflect the actions taken to fix problems related to an organization's QMS. These problems can be "nonconformances" where the QMS does not measure up to the requirements of ISO 9000 or, more commonly, problems that have occurred as our organization goes about producing its finished goods or services. Effective corrective action must be documented and call for the following:

- Identifying the problem
- Examining the root cause of the problem
- Putting a plan in place to prevent recurrence
- Evaluating the effectiveness of the plan.

### **8.5.3 Correct Actual Nonconformities**

Management shall review our nonconformities:

Determine what causes our nonconformities.

Evaluate whether we need to take corrective action.

Develop corrective actions to prevent recurrence.

Take corrective actions when they are necessary.

Record the results that your corrective actions achieve.

Examine the effectiveness of your corrective actions.

### **8.5.4 Preventive Action**

The same actions taken in the immediately preceding step relating to corrective actions should also be taken with respect to problems that have yet to occur, preventive actions.

Effective preventive action calls for identifying the potential problem, examining the root cause, putting a plan in place to prevent recurrence and evaluating the effectiveness of the plan. Naturally, all of the above must be documented.

All personnel shall prevent potential nonconformities:

Detect potential nonconformities.

Identify the causes of potential nonconformities.

Management and engineering personnel shall:

Study the effects of potential nonconformities.

Evaluate whether we need to take preventive action.

Develop preventive actions to eliminate causes.

Take preventive actions when they are necessary.

Record the results that our preventive actions achieve.

Examine the effectiveness of our preventive actions.

## GLOSSARY

### Conformity:

ISO 9001, ISO 9002, and ISO 9003 list many quality system requirements. If your organization meets these requirements, you can say that it conforms to these requirements. You can say that it is behaving in conformity with these requirements. You can say that it is in conformance.

### Contract review:

A contract review is a set of activities that you must carry out to ensure that all customer orders or contracts specify all the quality requirements you must meet and to ensure that you can meet these requirements.

### Corrective actions:

Corrective actions are steps that are taken to remove the causes of an existing nonconformity or to make quality improvements.

### Customers:

A customer is anyone who receives products or services from a supplier. A customer can be either external or internal to the supplier organization. You are a supplier organization if you provide products or services to customers.

### Design review:

A design review is a set of activities whose purpose is to evaluate how well a potential product (a design) meets all quality requirements. During the course of this review, problems must be identified and solutions must be developed.

### Design validation:

Design validation is a process whose purpose is to examine products and to use objective evidence to confirm that these products meet user needs.

### Design verification:

Design verification is a process whose purpose is to examine design outputs and to use objective evidence to confirm that outputs meet input requirements.

### Elements:

Elements include responsibilities, authorities, relationships, functions, policies, procedures, practices, processes, and resources. Quality system elements combine to form a quality system.

### Entity:

An entity could be a product, process, person, activity, machine, service, system, department, company, institution, or organization.

#### Internal quality audit:

Internal audits are carried out by your personnel. Internal quality audits examine the elements of a quality system in order to evaluate how well these elements comply with quality system requirements.

#### Nonconforming products:

When one or more characteristics of a product fail to meet specified requirements, it is referred to as nonconforming product. When a product deviates from quality requirements, it fails to conform.

#### Nonconformity:

ISO 9001, ISO 9002, and ISO 9003 list quality system requirements. When your organization deviates from these requirements a nonconformity occurs. When a product, process, procedure, system, or structure deviates from ISO requirements, a formal nonconformity exists.

#### Organization:

An organization is a company, corporation, firm, or institution that has its own functions and administration. It can be either incorporated or unincorporated, or privately or publicly owned.

#### Organizational structure:

The structure of an organization is the pattern of responsibilities, authorities, and relationships that control how people perform their functions and govern how they interact with one another.

#### Preventive actions:

Preventive actions are steps that are taken to remove the causes of potential nonconformities or to make quality improvements.

#### Procedures:

Quality procedures control activities. A well-defined procedure controls a logically distinct set of activities. Such a procedure precisely defines the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which supplies and materials should be used, and which documents and records must be used to carry out the work. While procedures may be documented or undocumented, ISO usually expects them to be documented.

#### Process:

A process uses resources to transform inputs into outputs. Processes can be social, industrial, agricultural, governmental, chemical, mechanical, electrical, and so on. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out.

#### Product:

A product is an output that results from a process. Products can be tangible or intangible, a thing or an idea, hardware or software, information or knowledge, a process or procedure, a service or function, or a concept or creation. Please note that when ISO uses the term product they also mean service.

Until now ISO focused on four kinds of products: processed materials, services, software, and hardware. In the 2000 Standards, ISO takes a more abstract approach. These four items are now referred to as generic elements, not products. Most products are made up of all four elements, according to ISO.

A product is referred to as a service when service is the main element of that product. But this product may also include processed materials, hardware, and software elements. A product is referred to as a hardware product when hardware is the main element. Although, this product may contain processed materials, services, and software elements.

#### Product Realization:

ISO 9000:2000 uses the term product realization. This is a rather abstract concept, but it describes an important change in philosophy. ISO now uses a process-centric approach, rather than an product-centric approach. ISO 9000:2000 devotes an entire section to this concept (Section 7). So what does it mean? You start out with an idea and end up with a product; you've gone through the process of product realization. A product starts out as an idea. The idea is realized by following a set of product realization processes. Product realization refers to the layers of processes that are used to bring products into being.

#### Product inspection:

Product inspection is an activity that compares product characteristics with product requirements in order to establish conformity. More precisely, product inspection is an activity that compares one or more characteristics of a product with specified requirements in order to determine if the product conforms to these requirements.

#### Product nonconformity:

When one or more characteristics of a product fail to meet specified requirements, they are referred to as product nonconformities.

#### Quality:

An entity has characteristics. Some of these characteristics are derived from stated or implied needs. The set of these special need-oriented characteristics make up the quality of an entity. In short, a quality is a characteristic.

For example, the need for dependability is met by designing a dependable product. Dependability then becomes a quality (characteristic) of the product (entity).

An entity is a product, process, person, activity, machine, service, system, department, company, institution, or organization.

**Quality assurance:**

Quality assurance (Q.A.) Is defined as a set of activities whose purpose is to demonstrate that an entity meets all quality requirements. Q.A. activities are carried out in order to inspire the confidence of both customers and managers, confidence that all quality requirements are being met.

**Quality audits:**

Quality audits examine the elements of a quality system in order to evaluate how well these elements comply with quality system requirements.

Elements include responsibilities, authorities, relationships, functions, procedures, processes, and resources. Elements combine to form a quality system.

**Quality control:**

Quality control is defined as a set of activities or techniques whose purpose is to ensure that all quality requirements are being met. In order to achieve this purpose, processes are monitored and performance problems are solved.

**Quality improvement:**

Quality improvement refers to a set of activities whose purpose is to enhance the efficiency and effectiveness of the organization for the benefit of both the organization and its customers.

We believe that quality improvement ought to focus on quality, not on efficiency. Let's leave that to the "efficiency experts".

**Quality management:**

Quality management includes all the activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance, and quality improvement.

**Quality manual:**

A quality manual is a document that states your quality policy and describes your quality system. It describes the roles, relationships, functions, processes, procedures, systems, and resources that affect quality. It can be a paper manual or an electronic manual.

**Quality planning:**

Quality planning is defined as a set of activities whose purpose is to define quality system policies, objectives, and requirements, and to explain how these policies will be applied, how these objectives will be achieved, and how these requirements will be met.

**Quality plan:**

A quality plan explains how you intend to apply your quality policies, achieve your quality objectives, and meet your quality system requirements.

**Quality policy:**

A quality policy statement defines your organization's commitment to quality.

**Quality record:**

A quality record contains objective evidence that shows how well a quality requirement is being met or how well a quality system element is performing.

**Quality requirement:**

A quality requirement is a characteristic that an entity must have. For example, a customer may require that a particular product (entity) achieve a specific dependability score (characteristic).

**Quality surveillance:**

Quality surveillance is a set of activities whose purpose is to monitor an entity and review its records to prove that quality requirements are being met.

**Quality system:**

A quality system is a network of processes made up of elements. Elements include responsibilities, authorities, relationships, functions, plans, policies, procedures, practices, processes, and resources. The purpose of a quality system is to satisfy quality management requirements and to assure that customers receive quality products and services.

**Quality system element:**

Quality system elements include responsibilities, authorities, relationships, functions, plans, policies, procedures, practices, processes, and resources. Quality system elements combine to form a quality system.

**Quality system requirement:**

A quality is a characteristic. A system is a set of interrelated elements. And a requirement is an obligation. Therefore, a quality system requirement is a characteristic that a systemic element must have.

**Record:**

A record is a document that contains objective evidence which shows how well activities are being performed or what kind of results are being achieved.

**Resources:**

Resources include people, money, information, knowledge, skill, energy, facilities, machines, tools, equipment, technologies, and techniques.

Service:

Service is a customer-oriented result. This result is produced when suppliers perform activities that are oriented towards meeting customer needs.

Service delivery:

Service delivery is a customer-oriented activity. Service delivery activities are carried out by suppliers and are oriented towards meeting customer needs.

Standard:

Surprisingly, ISO does not seem to define the term standard (or at least not in ISO 8402). Since they call every chapter or publication a standard, it may just mean that all their publications are standards, by definition. However, we believe that ISO also uses the term standard to suggest the concept of an expectation, obligation, requirement, or norm that they want organizations to accept. In addition, ISO seems to use the term standard to refer to a way of being or doing things as in the phrase: "this is the standard way we do this."

Supplier:

A supplier is an organization that provides products to customers. Customers can be either internal or external to the supplier organization.

In the 1994 version of the Standards, suppliers were the organizations that wished to be certified and were referred to as suppliers because they supplied products and services to customers. Many users were confused by this terminology so ISO has replaced Suppliers with the word organization.

The term supplier now refers to the organization's supplier. The 2000 redefined term supplier replaces the old term subcontractor (which has now been dropped).

Total quality management:

Total quality management is defined as a management approach that tries to achieve and sustain long-term organizational success by encouraging employee feedback and participation, satisfying customer needs and expectations, respecting societal values and beliefs, and obeying governmental statutes and regulations.

End



## **APPENDIX A - ACHIEVING ISO CERTIFICATION**

## **ISO 9000 CERTIFICATION**

Achieving ISO certification is a combination of building a Quality Management System (QMS) and producing quality documentation that proves compliance with the ISO 9000 Standard. Once we've established our quality policies and procedures, we must begin recording evidence to prove our company is adhering to the proposed plans. The process of certification relies on building a foundation of quality based on these requirements.

### **REQUIREMENTS AND PROCESS TO BECOME ISO 9000 COMPLIANT**

There is no specified time frame for normally completing the ISO 9000 certification process. While the standard requires that you have your Quality Management System (QMS) in operation for a least 90 days prior to certification, most organizations take much more time for this process. The most important factor in determining the time frame for completion is the availability of employee resources. In a smaller organization where one person has multiple roles, and a separate quality manager role might not exist, it is quite possible that the process to get certified may take longer than it would for a much larger organization with a separate quality management team.

#### **Employee resources**

There is no formula for determining the number of people required to build an effective QMS. Manpower for the certification process can vary greatly, depending on the size of the organization, the workload and the knowledge of ISO. A complete certification process will include many more people than just a core of "quality management people." These are reviewers, approvers, and many others within an organization who must get involved in the building of an effective QMS. The important thing to remember is that without buy-in from everyone – most importantly, top management – no amount of manpower will be able to build an effective QMS.

#### **Process Steps**

The steps to certification will vary with each organization.

Regardless of the reasons that have driven organizations to pursue ISO 9000 certification, the selection of the registrar who will audit the organization to the appropriate standard is important. Numerous factors should be considered when choosing a registrar. On one hand, a certificate with an accreditation mark has more recognition and credibility than one without. However, a non-accredited registrar is often less expensive and "you get what you pay for" doesn't necessarily apply.

#### **Choosing a Registrar**

Reasons for choosing a non-accredited registrar include cost and customer service. Consider the following when choosing a registrar:

## **Reputation**

The registrations granted by larger and more established registrars will often be perceived in the quality industry as having “more value as these registrars tend to be more consistent in the service they provide and more rigorous in adhering to the standard.

## **Global Presence**

A European or Asian location may be important to your organization.

## **Pre-assessment**

Most registrars should offer this service.

## **Same Employees for Pre-assessment and First Registration Audit**

Different people have different “hot spots.” Problems fixed after the pre-audit could be meaningless to a different set of employees during the first assessment.

## **Successful Registration the First Time**

Check the average of organizations that passed on the first try and how many of them has a pre-assessment.

## **Flexibility**

We have to follow the standard, but there are a lot of ways to look at the standard and apply it. Certain registrars are more flexible than others.

## **Questions for a Potential Registrar**

Instead of risking our organization’s well being by hiring an unqualified registrar, we should take time to review several candidates, based on your criteria. Here are sample questions to ask a potential registrar:

- What are your most frequently found nonconformances?
- Do you have a technical help desk? What is the turnaround time for answering questions?
- How many auditors will have experience with our business?
- Have you worked with companies our size?
- How much does each service cost?
- What will be travel expenses?

Quality documents are a central part of any compliant Quality Management System (QMS). From an organization’s quality policy, to its processes, procedures, work instructions, objectives and plans, quality documents need to be drafted, reviewed and approved.

## **Process to Quality Documentation**

The quality policy is an overall statement about quality, usually distributed, stated and given to the organization by the president, CEO or other top official. This should be a blanket statement of quality that everyone can relate to and follow within the organization. Often this document is drafted, reviewed and approved by the top management.

## **Procedures and Work Instructions**

Procedures and processes focus on the elements of the standards and how the organization will address those elements. Work Instructions are more detailed, job specific documents outlining the specific job function of an individual. Work instructions can sometimes be replaced by a more detailed and effective training plan.

The quality procedures, processes and work instructions are drafted, reviewed and approved by the individual(s) responsible for the specific areas. These documents are often approved by top management.

## **Objectives and Plans**

Objectives and quality plans are drafted to outline goals for an organization. These documents are generally created by a team of individuals, often including a member of top management and may or may not be approved by top management.

## **QUALITY AUDITS**

Quality audits are the mechanism to evaluate our QMS for conformance with ISO 9000. A series of audits lead up to the Registration Audit which determines our conformance to the requirements of ISO 9000.

### **Internal Audit**

The purpose of an internal audit is to determine that the elements of our Quality Management System (QMS) are, in fact, operating as planned. Corrective Action Requests (CARs) record the process of solving problems discovered in the audit. A proper internal audit will address all of the required elements of the ISO 9000 Standard and look for objective evidence that these elements were adequately addressed.

### **Pre-assessment Audit**

Prior to our organization undergoing a full registration audit, it is necessary to conduct a pre-assessment audit. The purpose of the pre-assessment audit is to ensure we are ready to proceed with the full registration audit. Essentially, the pre-assessment audit is a dress rehearsal for the real thing. It is recommended that we conduct a pre-assessment audit because this process allows for our organization to identify any nonconformances and implement corrective actions before the registrar's audit.

On the day of the pre-assessment audit an assessor will visit and perform an in-depth review of our organization's compliance with each element of the quality standard. Any nonconformances or observations are provided to us in writing in the pre-assessment audit report.

In many cases, the pre-assessment audit report may be available to us from the auditor on the same day, but this depends on the individual auditor. If the auditor discovers a significant

number of nonconformances, it is recommended that we postpone any final registration audit, address, correct any nonconformances, and consider conducting another pre-assessment audit. It is important to remember that a registrar's time is limited and we would rather postpone a final audit to ensure that our organization complies rather than rush the process only for the registrar to find a number of nonconformances.

## **Second Internal Audit**

After the pre-assessment audit, it is good practice to verify the effectiveness of any corrective actions taken and the correction of any nonconformances with a second internal audit. Once this has been completed and all issues have been addressed, we are ready for our registration audit. It is important to remember that all nonconformances discovered in any internal or pre-assessment audits need to be resolved prior to the arrival for the registrar for the final audit.

## **Training**

Training plans are a very important part of a Quality Management System (QMS). It is necessary to document the experience, education and training of all employees. This can be through detailed Human Resource records, which would include an employee's resume and training plan or it can include a much more inclusive center of information.

We want to provide equal training to employees while still basing training on an individual's experience level. A well-tuned organization will have training courses available for every job function to allow new employees to receive equal and complete training by qualified instructors within the organization rather than allowing new employees to be taught, ad-lib by any available veteran employee.

Training plans need to be constantly updated and an individual's training should always be evaluated. Ensuring that employees remain challenged, focused and dedicated to their job will ensure better overall quality within our organization.

## **Nonconformance Issues**

It is necessary for an organization to address nonconforming issues with its procedures, products and processes. The goal of a compliant Quality Management System (QMS) is a reduction in corrective action and certainly a proactive approach to preventive action.

If we discover flaws in our QMS or any part of the organization that could affect quality, it is necessary to record a corrective action. A corrective action is a record of the process involved as an organization seeks to identify, address and resolve the corrective action or nonconformity. We should also consider preventive action where corrective actions are monitored and quality within the organization is watched and preventive measures are implemented to ensure quality.

## **Registration Audit**

An external audit team will visit our facilities (on a mutually agreed date) to evaluate the compliance of our Quality Management System (QMS) with the requirements of the ISO 9000 Standard. During the course of the assessment, the audit team will notify us of any nonconformances they have observed. At the completion of the assessment, the audit team will verbally advise us of their recommendation. If only minor nonconformances have been noted, a recommendation for registration will be made. If major nonconformances have been noted, our organization will have to submit corrective actions. Re-assessment of corrective actions is typically completed at the next regularly scheduled surveillance audit (e.g. up to six months later).

Once we have completed and passed the registration audit, it is time for us to celebrate. ISO 9000 certification is a great accomplishment. The key to success is ongoing improvement and compliance with our QMS. Use the time between initial registration and the first Surveillance Audit to fine-tune the system and make ISO 9000 part of our everyday operations. Our QMS should be maintained at all times to ensure that the processes and procedures continue effectively.