

|                      |                |                      |
|----------------------|----------------|----------------------|
| Rev. Date:<br>3/4/09 | Rev. No.:<br>6 | Policy #:<br>QMS-001 |
|----------------------|----------------|----------------------|

# Quality Manual

**“Uncontrolled Copy”**

Mike Nichols  
General Manager

*ORIGINAL IN RED*  
Signature

3/4/09  
Date

Mick Whelan  
Quality Manager

*ORIGINAL IN RED*  
Signature

3/4/09  
Date

### TABLE OF CONTENTS

| <u>Section</u>                               |  | <u>Page</u> |
|--|--|-------------|
| REVISION HISTORY                             |  | 3           |
| 1. INTRODUCTION                              | 1.1 Site Information                             | 4           |
|  | 1.2 Mission Statement                            | 4           |
|  | 1.3 Quality Policy                               | 4           |
|  | 1.4 Goals and Objectives                         | 4           |
|  | 1.5 Values                                       | 4           |
|  | 1.6 Process Approach                             | 5           |
| 2. APPLICATION                               | 2.1 General                                      | 6           |
|  | 2.2 Scope  | 6           |
|  | 2.3 Control of Quality Manual                    | 6           |
| 3. REFERENCES                                | 3.1 Reference Documents                          | 7           |
|  | 3.2 Supporting Documents                         | 7           |
|  | 3.3 Terms and Definitions                        | 7           |
| 4. QUALITY MANAGEMENT SYSTEM                 | 4.1 General Requirements                         | 8           |
|  | 4.2 Documentation Requirements                   | 9           |
| 5. MANAGEMENT RESPONSIBILITY                 | 5.1 Management Commitment                        | 11          |
|  | 5.2 Customer Focus                               | 11          |
|  | 5.3 Quality Policy                               | 11          |
|  | 5.4 Planning                                     | 11          |
|  | 5.5 Responsibility, Authority, and Communication | 12          |
|  | 5.6 Management Review                            | 13          |
| 6. RESOURCE MANAGEMENT                       | 6.1 Provision of Resources                       | 14          |
|  | 6.2 Human Resources                              | 14          |
|  | 6.3 Infrastructure                               | 14          |
|  | 6.4 Work Environment                             | 15          |
| 7. PRODUCT REALIZATION                       | 7.1 Planning of Product Realization              | 15          |
|  | 7.2 Customer-Related Processes                   | 15          |
|  | 7.3 Design and Development                       | 16          |
|  | 7.4 Purchasing                                   | 16          |
|  | 7.5 Production and Service Provision             | 17          |
|  | 7.6 Control of Monitoring and Measuring Devices  | 18          |
| 8. MEASUREMENT, ANALYSIS,<br>AND IMPROVEMENT | 8.1 General                                      | 18          |
|  | 8.2 Monitoring and Measurement                   | 18          |
|  | 8.3 Control of Nonconforming Product             | 19          |
|  | 8.4 Analysis of Data                             | 20          |
|  | 8.5 Improvement                                  | 20          |

### REVISION HISTORY

The substantive changes made to this document are described below:

| Rev. No. | Date     | Brief Description of the Substantive Changes  | Initiated by:               |
|----------|----------|---|-----------------------------|
| 0        | 02/05/02 | Initial Release.  | John W. Yore, Pres.         |
| 1        | 09/2005  | Reviewed and changes made   | Mike Nichols<br>Mick Whelan |
| 2        | 12/05/05 | Added key processes to the General Requirements   | Mike Nichols<br>Mick Whelan |
| 3        | 1/10/06  | Changes made to QMS from 11/18/05 ISO Audit 1.4, 2.2, 4.2.3, 5.3, 5.4.1, 5.6.1, 5.6.2, 6.2.2, 7.4.3, 8.2.1, 8.2.2   | Mike Nichols<br>Mick Whelan |
| 4        | 3/1/06   | Combined Procedures FSR 006 and FSR 007   | Mike Nichols<br>Mick Whelan |
| 5        | 3/17/08  | Changes made to QMS: <b>2.2</b> updated Scope. <b>4.1</b> from Sales, Purchasing, Receiving, Warehousing, and Shipping to Sales, Purchasing, Warehousing, Resource Management, and Measurement Analysis. <b>4.2 c.</b> from FSR 001- FSR 012 to FSR 001 – FSR 010. <b>4.2 d.</b> from FSR 006 to FSR 009. <b>4.2.3</b> from FSR 006 to FSR 009. <b>4.2.4</b> From FSR 002 to FSR 009. <b>5.5.1.1</b> Updated Org. Chart. <b>5.6.1</b> from quarterly to monthly. <b>6.2.2</b> Form 319 Rev.1 <b>7.2.1</b> add FSR 001, 003, 004, 005, 008. <b>7.2.2</b> From FSR 010 to FSR 001, 002, 003. <b>7.4.1</b> From FSR 011 to FSR 002. <b>7.4.3</b> From FSR 003, 004, and 011 to FSR 002, 003, 005. <b>7.5.1</b> From FSR 012 to FSR 004. <b>8.2.1</b> to every other quarter and customer report cards added. <b>8.2.2</b> From FSR 005 to FSR 010. <b>8.3</b> From FSR 009 to FSR 006. <b>8.5.2</b> From FSR 001 to FSR 008. <b>8.5.3</b> From FSR 001 to FSR 008. | Mick Whelan                 |
| 6        | 3/4/09   | Upgraded to 2008 standards. 1.6 Process Approach added. 4.1 added Quality, Receiving, Order Pulling. Removed Resource Management.   | Mick Whelan                 |

### 1. INTRODUCTION

#### 1.1 Site Information

Company Name: Florida Seal & Rubber LLC  
Street Address: 10350 Fisher Ave.  
City, State, Zip: Tampa FL 33619-7838  
Phone: (800) 282-1601, (813) 681-5502  
Fax: (813) 654-2525  
# of Employees: 17  
Web Page: <http://www.flaseal.com>

#### 1.2 Mission Statement

Florida Seal & Rubber LLC is committed to provide superior quality products and services that consistently exceed our customer's expectations.

#### 1.3 Quality Policy Statement

Florida Seal & Rubber LLC is committed to meeting customer requirements and satisfaction in the products and services we provide. We achieve this goal through a performance excellence approach of focusing on the customer, implementing an effective Quality Management System, and a team effort towards continuous improvement.

#### 1.4 Goals & Objectives

The goals and objectives of FSR are to be the supplier of choice for sealing solutions. We will achieve this by building shareholder value through a commitment to high ethical standards and a superior performance culture focused on customers, employees and financial results.

#### 1.5 Values

All team members will have:

Honesty & Ethics  
Respect  
Humility  
Commitment  
Integrity  
Customer First Focus

|                      |                |                      |
|----------------------|----------------|----------------------|
| Rev. Date:<br>3/4/09 | Rev. No.:<br>6 | Policy #:<br>QMS-001 |
|----------------------|----------------|----------------------|

**1.6 Process Approach**

Florida Seal and Rubber LLC has determined the following set of process activities will produce the desired customer satisfaction outcome.

## 2. APPLICATION

### 2.1 General

The purpose of this Quality Manual is influenced by FSR's environment; change to that environment; and the risks associated in that environment to help:

- demonstrate and consistently provide product that will enhance customer's satisfaction and meeting customer requirements
- specify the policy requirements, and processes used for continuous improvement of the FSR Quality Management System in accordance with internationally recognized standards
- emphasize and describe a process approach that links requirements, responsibilities, processes, and their interactions together
- maintain registration to International Standard ANSI/ISO/ASQ Q9001 by an accredited third-party registrar.
- maintain approved status with customers selecting to do business only with suppliers registered to ISO9001 or higher.

### 2.2 Scope

Florida Seal and Rubber is a distributor of rubber sealing products including Backup Rings, Composite Seals, Custom Rubber Products, Custom Molded, EMI/RFI Shielding, Extrusions, Gaskets, Hydraulic Seals, Metal Seals, Molded Shapes, Packing', Rotary Seals, Sheet Goods, Teflon Seals and Thermal Management Products.

The QMS, herein also referred to as the "Quality Manual", is based on the International Standard ANSI/ISO/ASQ Q9001-2008, QMS requirements. Since the requirements of the International Standard are generic and intended to be applicable to any size and organizational structure, and products it provides. Any requirement that cannot be applied due to the nature of an organization and its product may be considered for exclusion. Therefore, the following is a list of such exclusions for this organization:

Exclusions:    Reason/Justification:

**7.3 complete    As a distributor, this organization does not engineer product for manufacturing.**

### 2.3 Control of Quality Manual

This document will be reviewed and maintained by the organization's management representative for quality (herein also referred to as the Quality Manager or QC Manager). This manual will be maintained in accordance with the current Companies varying needs, the products it provides, the processes it employs, and stakeholder requirements. Input will be solicited from appropriate Company representatives prior to initiating substantive changes.

#### 2.3.1 Distribution of QMS Document

Upon approval, copies of this manual will be released. The Quality Manager will retain evidence of signature release. Electronic or hard copies of this document will be distributed, or otherwise made available to, all employees. The revision status of any electronically mailed copies or printed copies is to

be considered uncontrolled; any such copies must be compared to the original source to verify current revision status prior to use for operational purposes. This document does not contain confidential information and may be made available to organizations doing business with FSR.

### 2.3.2 Revision History

A record of revisions to this document and the resulting Operating Processes will be recorded. The revision history will contain the revision number, the effective date, and a brief description of the substantive changes.

## 3. REFERENCES

### 3.1 Reference Documents

ANSI/ISO/ASQ Q9000-2005 - Quality Management System – Fundamentals and Vocabulary

ANSI/ISO/ASQ Q9001-2008 - Quality Management System – Requirements

FSR Operating Processes

### 3.2 Supporting Documents

ANSI/ISO/ASQ Q9004-2000 - Quality Management System – Guidelines for Performance Improvements

### 3.3 Terms and Definitions

For the purposes of this organization's QMS, the terms and definitions given in ANSI/ISO/ASQ Q9000, Quality Management System — Fundamentals and Vocabulary, apply, unless otherwise defined in the respective document. Additional terms and acronyms are defined as follows:

QMS - Quality Management System

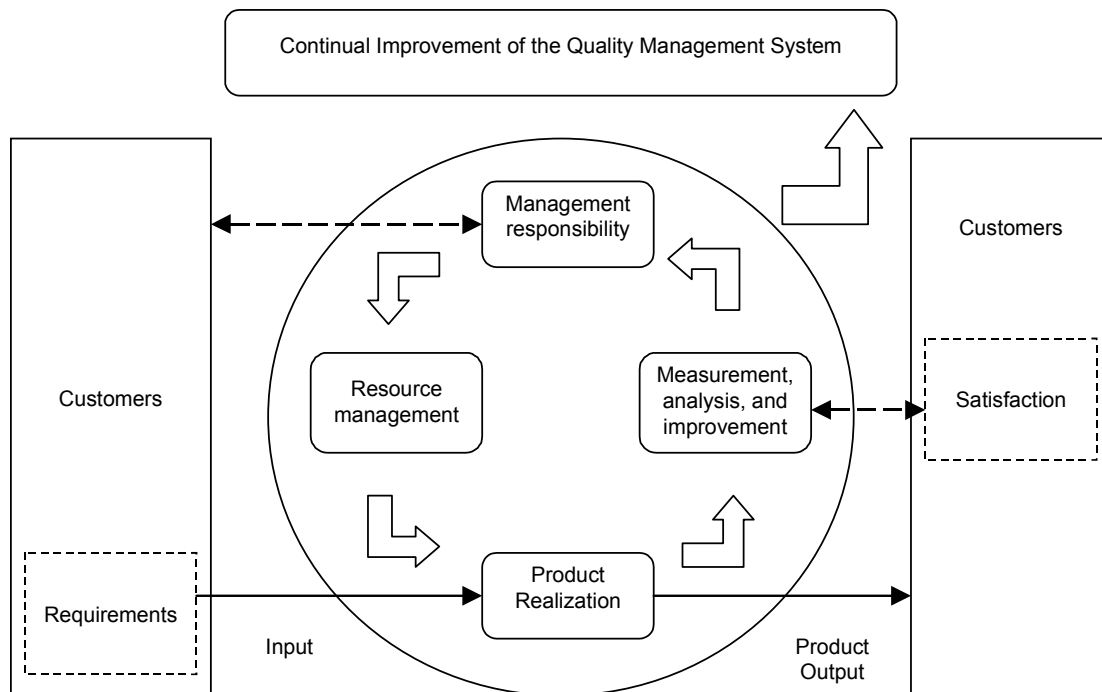
Organization – refers to all listed sites for FSR

Product – Refers to the result of a process where the output of such process may be a product (e.g., component part, assembly, system solution) or service delivered to a customer under the provisions of a contract or purchase order. “Product can also mean service”

Stakeholders – are persons or groups having an interest in the performance or success of the organization, such as customers, share holders, investors, employees, partners, suppliers, product end-users, or society.

### 4. QMS

FSR has adopted a process-based QMS based on the requirements of ANSI/ISO/ASQ Q9001-2008:



The system includes the controls to be exercised on those functions that have an effect on quality. Individual operating procedures will describe or show their respective processes at a more detailed level. From this point forward, the document outline numbers (as shown in the table of contents) correspond to the relevant paragraph numbers of sections 4 through 8 of ANSI/ISO/ASQ Q9001-2008.

#### 4.1 General Requirements

The organization will establish, document, implement and maintain a QMS and continually improve its effectiveness in accordance with the requirements of the International Standard Q9001-2008.

The organization has / will:

- Determined that the key processes for the FSR QMS are: **Management, Sales, Purchasing, Quality, Receiving and Warehouse, Order Pulling and Shipping** applications throughout the organization.
- Determined that **FSR 001- FSR 010** (see 1.6) is the best sequence and interaction of these processes,
- Determined that **FSR 010 Internal Audits**, are used to ensure that the criteria and methods for the operation and control of the processes are effective,

- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Monitor, measure where applicable, and analyze these processes via **Management Reviews**,
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes will be managed by the organization in accordance with the requirements of the International Standard. Where the organization chooses to outsource any process that affects product conformity to requirements, the organization will ensure control over such processes. The type and extent of control to be applied to these outsourced processes will be defined within the QMS.

## 4.2 Documentation Requirements

### 4.2.1 General

The FSR QMS documentation will include at a minimum:

- a) Documented statements of a quality policy (1.3) and quality objectives,(1.4)
- b) Florida Seal and Rubber Quality Manual,
- c) Documented procedures / processes and records required by the International Standard, (*see FSR 001 – FSR 010*) (*see 4.2.4*)
- d) Documents including records determined by the organization to be necessary to ensure the effective planning, operation and control of its processes, (*see FSR 009 Quality Records / Document Retention and Control*)

### 4.2.2 QMS Manual

FSR has established and is maintaining a QMS manual (also referred to as the quality manual) that includes:

- a) The scope of the QMS, including details of and justification for any exclusions (see 2.2),
- b) The documented procedures / processes established for the QMS, or reference to them see **FSR 001 – FSR 010**, and
- c) A description of the interaction between the processes of the QMS.

The FSR QMS Documentation Structure is outlined into 6 levels:

**Quality Manual** – *Section I*. This document, which are essential policies, requirements, and information statements.

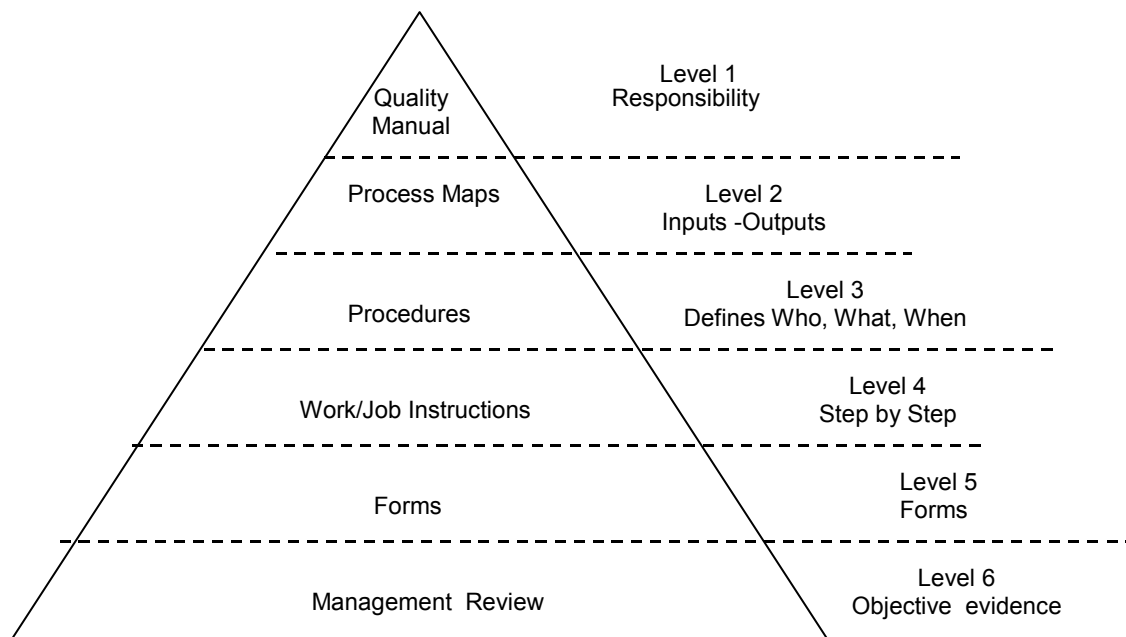
**Process Maps** – *Section II*. Clear directions to the Key Processes of FSR. These include inputs and outputs.

**Procedures** – *Section III*. In support of the Quality Manual to provide instructions on how the policy statements are to be interpreted and implemented at the departmental level. These procedures will contain, at a minimum: procedure number, revision, effective date, revision history, owner, approver, purpose, scope, responsibilities, description and form(s) required, if any.

**Work Instructions** – *Section IV*. will instruct staff at departmental level on how to perform specific duties as it relates to the Quality Manual and Procedures. It is the responsibility of each Departmental Manager to compile these instructions detailing who, what and how. Work Instructions will be maintained at the current status and be accessible to the departmental personnel who may need them at all times.

**Forms** – *Section V*. All current forms used by FSR to conduct business.

**Management Review** – *Section VI*. Goals set and measured by management to ensure customer satisfaction and continued improvement.



### 4.2.3 Control of Documents

Documents required by the QMS will be controlled. Records are a special type of document and will be controlled according to the requirements given in 4.2.4. **Ref. FSR 009 Process Map / Procedure.** Documents will be disposed after 10 years. All disposable documents will be placed in special locked trash can or on a pallet for ProShred to shred onsite.

A documented procedure will be established to define the controls needed: **FSR 009**

- To approve documents for adequacy prior to issue,
- To review and update as necessary and re-approve documents,
- To ensure that changes and the current revision status of documents are identified,
- To ensure that relevant versions of applicable documents are available at points of use,
- To ensure that documents remain legible and readily identifiable,
- To ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the QMS are identified and their distribution controlled, and
- To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

### 4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the QMS will be controlled. FSR's documented procedure will be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records. (**Ref. FSR 009 Process Map / Procedure**). Records will remain legible, readily identifiable and retrievable. Documents and records will be disposed after 10 years. All disposable documents and records will be placed in special locked trash can or on a pallet for ProShred to shred onsite.

### 5. MANAGEMENT RESPONSIBILITY

#### 5.1 Management Commitment

Top management will provide evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness by:

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements
- b) Establishing the quality policy (see **1. 3**)
- c) Ensuring that quality objectives are established (see **1. 4**)
- d) Conducting management reviews (see **5.6.1**)
- e) Ensuring the availability of resources (see **6.1**)

#### 5.2 Customer Focus

Top management will ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

#### 5.3 Quality Policy

Top management will ensure that the quality policy is appropriate to the purpose of the organization, includes a commitment to comply with requirements while continually improving the effectiveness of the QMS, provide a framework for establishing and reviewing quality objectives, is communicated and understood within the organization, and is reviewed for continuing suitability.

See Company Quality Policy Statement in section **1.3**.

#### 5.4 Planning

##### 5.4.1 Quality Objectives

Top management will ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.(see **1.4**) The quality objectives will be measurable (ref. 5.6.2 Management Review Input) and consistent with the quality policy. **See Management Review**

##### 5.4.2 QMS Planning

Top management will ensure that:

the planning of the QMS is carried out in order to meet the requirements referenced in 4.1, as well as the quality objectives and the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

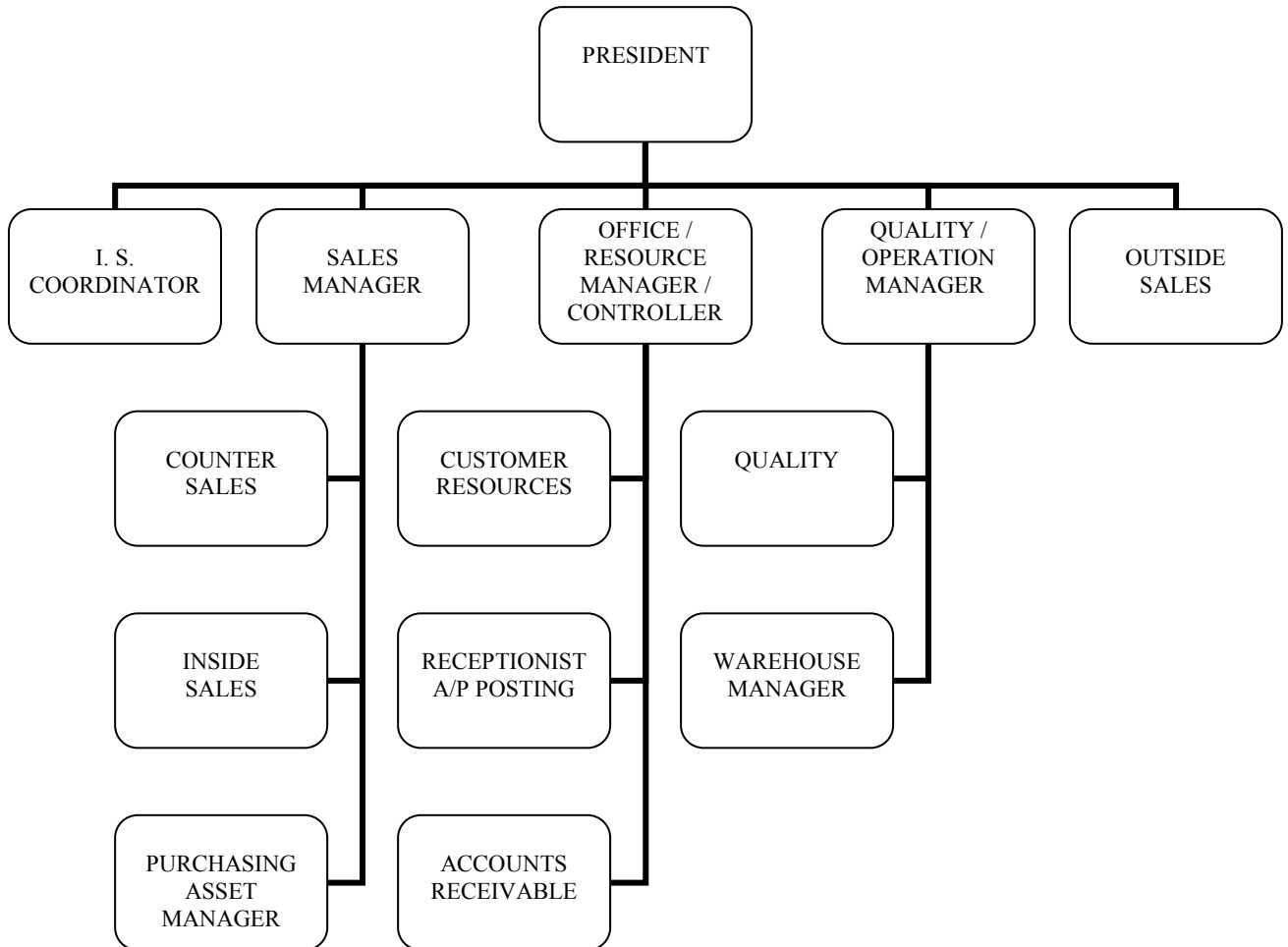
#### 5.5 Responsibility, Authority and Communication

##### 5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined and communicated within the organization.

##### 5.5.1.1 Organization Chart

The organizational structure of FSR and the relationship between management and the operational units is demonstrated in the following organizational chart:



### 5.5.2 Management Representative

FSR's management representative for quality will be referred to as the "Quality Manager". Top management has appointed this member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

ensuring that processes needed for the QMS are established, implemented and maintained, reporting to top management on the performance of the QMS and any need for improvement and ensuring the promotion of awareness of customer requirements throughout the organization.

The Quality Manager is the final authority on all quality matters pertaining to the QMS as established in the quality policies and procedures. The Quality Manager has the primary responsibility to structure the QMS, involving all departments, to ensure compliance with all quality requirements. Specifically, the Quality Manager is involved in areas such as, but not limited to, the following:

Drafting the quality policy.

Setting the quality objectives.

Reviewing the organizational relationships as they affect quality and developing proposals for improvement.

Liaison with supplier quality assurance representatives.

Auditing the QMS to determine where improvements are needed and recommending the necessary corrective action.

Internal consultant on matters relating to quality assurance.

### 5.5.3 Internal Communication

Top management will ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS.

## 5.6 Management Review

### 5.6.1 General

Top management will review the organization's QMS / Goals **monthly**, to ensure its continuing suitability, adequacy and effectiveness. This review will include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

Records from management reviews will be maintained (see 4.2.4).

### 5.6.2 Review Input

The input to management review will include information on:

- a) results of audits,
- b) customer feedback.
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the QMS, and
- g) recommendations for improvement.

### 5.6.3 Review Output

The output from the management review will include any decisions and actions related to:

- a) improvement of the effectiveness of the QMS and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs.

## 6. RESOURCE MANAGEMENT

### 6.1 Provision of Resources

The organization will determine and provide the resources needed:

- a) to implement and maintain the QMS and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

### 6.2 Human Resources

#### 6.2.1 General

Personnel performing work affecting conformity to product requirements will be competent on the basis of appropriate education, training, skills and experience. There are some employees who have been grandfathered into their positions. Any safety, quality, or machine training records will be kept in the employees files. Some FSR trainings may be outsourced to other organizations.

#### 6.2.2 Competence, Training and Awareness

The organization will:

determine the necessary competence for personnel performing work affecting conformity to product requirements. Where applicable, provide training or take other actions to achieve the necessary competence. Some background checks and trainings may be outsourced to other organizations. FSR will evaluate the effectiveness of the actions taken to ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. FSR where applicable, will maintain appropriate records of education, training, skills and experience via yearly reviews in July. **(Form 319 Rev.1)** Reviews will include any Internal Corrective Actions, Non Conformities, Customer Complaints, and all trainings completed. (see 4.2.4).

### 6.3 Infrastructure

The organization will determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.

Infrastructure includes, as applicable:

Buildings, work space and associated utilities, process equipment (both hardware and software), and supporting services (such as transport, communication, or information systems). FSR has upgraded the active directory server and software. FSR's Trulinx database and thin clients terminals adds support and increased communication to organizational and customer requirements.

### 6.4 Work Environment

FSR's Company Policies help manage the work environment needed to achieve conformity to product requirements.

## 7. PRODUCT REALIZATION

### 7.1 Planning of Product Realization

FSR has developed **FSR 001, FSR 002, FSR 003, FSR 004, and FSR 005**, as the processes needed for product realization. Planning of product realization will be consistent with the requirements of the other processes of the QMS (see 4.1).

In planning product realization, the organization will determine the following, as appropriate: quality objectives and requirements for the product; the need to establish processes, and documents, and to provide resources specific to the product; required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

### 7.2 Customer-Related Processes

#### 7.2.1 Determination of Requirements Related to the Product

The organization will determine:

- requirements specified by the customer, including the requirements for Quality, delivery and post-delivery activities, (*see FSR 001, FSR 003, FSR 004, FSR 005 and FSR 008 Process Maps / Procedures.*)
- requirements not stated by the customer but necessary for specified or intended use, where known,
- statutory and regulatory requirements applicable to the product, and
- any additional requirements considered necessary by the organization.

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

The organization will review the requirements related to the product. This review will be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders, Quality requirements of product {physical, chemical and visual}) (*see FSR 001, FSR 002, and FSR 003 Process Maps / Procedures*) and will ensure that:

- product requirements are defined,
- contract or order requirements differing from those previously expressed are resolved, and
- the organization has the ability to meet the defined requirements.
- there is customer approval for samples prior to first shipment (Sample Submission to the customer).

Records of the results of the review and actions arising from the review will be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements will be confirmed by the organization before acceptance. Where product requirements are changed, the

organization will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

### 7.2.3 Customer Communication

FSR has implemented **FSR 001, FSR 002, FSR 003, FSR 004, and FSR 005**, as effective arrangements for communicating with customers in relation to:

- a) product information,
- b) inquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

## 7.3 Design and Development

**The complete section of 7.3 does not apply see section 2.2**

## 7.4 Purchasing

### 7.4.1 Purchasing Process

The organization will ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product will be dependent upon the effect of the purchased product on subsequent product realization or the final product. (*see FSR 002 Process Map / Procedure*)

The organization will evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation will be **based upon On-Time delivery, Price, and Product Quality**. Records of the results of any evaluations and any necessary actions arising from the evaluation will be maintained (see 4.2.4). When applicable, a supplier may go to Dock to Stock when they demonstrate consistency in supplying defect free product on time, with all the designated documentation for five (5) consecutive lots.

### 7.4.2 Purchasing Information

Purchasing information will describe the product to be purchased, including where appropriate:

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) QMS requirements.

The organization will ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

### 7.4.3 Verification of Purchased Product

The organization will establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization will state the intended verification arrangements and method of product release in the purchasing information.

(*see FSR 002, FSR 003, FSR005 Process Maps / Procedures*)

### 7.5 Production and Service Provision

#### 7.5.1 Control of Production and Service Provision

The organization will plan and carry out production and service provision under controlled conditions. Controlled conditions will include, as applicable: (*see FSR 004 Process Map / Procedure*)

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring equipment,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product release, delivery and post-delivery activities.

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

The organization will validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation will demonstrate the ability of these processes to achieve planned results.

The organization will establish arrangements for these processes including, as applicable:

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

#### 7.5.3 Identification and Traceability

Where appropriate, the organization will identify the product by suitable means throughout product realization. The organization will identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization will control the unique identification of the product and maintain records (*FSR 009*) (see 4.2.4).

#### 7.5.4 Customer Property

The organization will exercise care with customer property while it is under the organization's control or being used by the organization. The organization will identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records. (see 4.2.4).

#### 7.5.5 Preservation of Product

The organization will preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation will include identification, handling, packaging, storage and protection. Preservation will also apply to the constituent parts of a product.

### 7.6 Control of Monitoring and Measuring Equipment

The organization will determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization will establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment will

- a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification will be recorded;
- b) be adjusted or re-adjusted as necessary;
- c) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization will assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization will take appropriate action on the equipment and any product affected. Records of the results of calibration and verification will be maintained (see 4.2.4).

Confirmation of the ability of computer software to satisfy intended application would typically include its verification and configuration to management to maintain its suitability for use.

## 8. MEASUREMENT, ANALYSIS, AND IMPROVEMENT

### 8.1 General

The organization will plan and implement the monitoring, measurement, analysis and improvement processes needed:

- a) to demonstrate conformity to product requirements,
- b) to ensure conformity of the QMS, and
- c) to continually improve the effectiveness of the QMS.

This will include determination of applicable methods, including statistical techniques, and the extent of their use.

### 8.2 Monitoring and Measurement

#### 8.2.1 Customer Satisfaction

Some of the measurements used to validate the performance of the QMS, the organization will monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information will be done via customer feed back on **Opinio Surveys** and **customer report cards**. Surveys will be sent out and reviewed **every other quarter** by Quality Manager. Customer surveys **and report cards** will be part of the management review meetings.

### 8.2.2 Internal Audit

The organization will conduct internal audits at planned intervals to determine whether the QMS:

- a) conforms to the planned arrangements (see 7.1), to the requirements of the International Standard and to the QMS requirements established by the organization, and
- b) is effectively implemented and maintained.

An audit program will be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods will be defined. Potential Auditors will be trained by a Auditor with record of training kept in the Auditors Employee file. Selection of auditors and conduct of audits will ensure objectivity and impartiality of the audit process. Auditors will not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) will be defined in a documented procedure. The management responsible for the area being audited will ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities will include the verification of the actions taken and the reporting of verification results (see 8.5.2). (*see FSR 010 Process Map / Procedure*)

### 8.2.3 Monitoring and Measurement of Processes

The organization will apply suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods will demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action will be taken, as appropriate.

### 8.2.4 Monitoring and Measurement of Product

The organization will monitor and measure the characteristics of the product to verify that product requirements have been met. This will be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria will be maintained. Records will indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4). The release of product and service to the customer will not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

## 8.3 Control of Nonconforming Product

FSR has ensured that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The documented procedures, **FSR 006 and FSR 007** have been established to define the controls and related responsibilities and authorities for dealing with nonconforming product will be defined in a documented procedure.

Where applicable, the organization will deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, will be maintained (see 4.2.4).

When nonconforming product is corrected it will be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization will take action appropriate to the effects, or potential effects, of the nonconformity. *(see FSR 006, and FSR 007 Process Map / Procedure)*

### 8.4 Analysis of Data

The organization will determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This will include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data will provide information relating to:

- a) customer satisfaction (see 8.2.1),
- b) conformity to product requirements (see 7.2.1),
- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

### 8.5 Improvement

#### 8.5.1 Continual Improvement

The organization will continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

#### 8.5.2 Corrective Action

The organization will take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions will be appropriate to the effects of the nonconformities encountered.

A documented procedure will be established to define requirements for:

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken (see 4.2.4), and
- f) reviewing corrective action taken.

*(see FSR 008 Process Map / Procedure)*

#### 8.5.3 Preventive Action

The organization will determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions will be appropriate to the effects of the potential problems.

A documented procedure will be established to define requirements for:

- a) determining potential nonconformities and their causes,

|                      |                |                      |
|----------------------|----------------|----------------------|
| Rev. Date:<br>3/4/09 | Rev. No.:<br>6 | Policy #:<br>QMS-001 |
|----------------------|----------------|----------------------|

- b) evaluating the need for action to prevent occurrence of nonconformities
- c) determining and implementing action needed,
- d) records of results of action taken (see 4.2.4), and
- e) reviewing preventive action taken.

*(see FSR 008 Process Map / Procedure)*