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	Sealing Equipment Products Company - Quality Manual (Rev. 11-19-2009)	
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Reviewed Quality Assurance Manager Signature/Date	Approved by President Signature/Date	
<i>Larry Jobman 10/31/06</i>	<i>Garry Dodson 10/31/06</i>	

1. Scope

1.1 General

Sealing Equipment Products Company developed and implemented the Quality Management System (QMS) described in this manual to help our organization operate with increased effectiveness, consistency and customer satisfaction. Our QMS utilizes the process approach and quality management principles contained in the international standards ISO 9001: 2008.

This standard also specifies additional requirements for a quality management system for the aerospace industry. The additional requirements are shown in bold, italic text.

It is emphasized that the quality management system requirements specified in this standard are complementary (not alternative) to contractual and applicable law and regulatory requirements.

1.2 Application

Our QMS complies with all applicable requirements contained in ISO 9001:2008 covers the design and provision of all company products, and encompasses all operations at our facility located at 123 Airpark Industrial Road and 2400 County Road 87, Alabaster USA 35007. The following table identifies ISO 9001: 2008 requirements not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our QMS

ISO 9001: 2008 Requirements EXCLUSION TABLE

Clause or Sub-clause	Exclusion	Justification
7.4.3	Verification of Purchased Product (at source)	Sealing Equipment Products Company does not verify purchased product at source.
7.5.2	Validation of (special) Processes for Product and Service Provision	Sealing Equipment Products Company does not perform or outsource any process where the resulting output cannot be verified by subsequent monitoring or measurement.

2. Reference Documents.

The following external documents contain provisions which, through reference in this manual, constitute provisions of our QMS:

ISO 9000, Quality management systems – Fundamentals and vocabulary

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ISO 9001, 2008, Quality management systems – Requirements

ISO 9004, Quality management systems – Guidelines for performance improvements

A separate document QSML (Quality System Master List), lists the standard Quality Procedures (QP's), Deployment Flow Charts (DFCs), and other internal documents referenced in this manual which define the key top level processes for implementing our quality policy.

The latest edition of each referenced document applies. *QP 4.2.3* contains procedures governing the control of these and other QMS documents. Note: documents are referenced throughout this manual only by document number; see Appendix A for complete titles.

3. Terms and Definitions.

Our QMS uses the same internationally recognized terms, vocabulary and definitions given in ISO 9000: 2008.

Acronyms, terms, vocabulary and definitions unique to our organization, customers, industry and region and referenced throughout our QMS are contained in Appendix A, Terms and Definitions.

4. Quality Management System

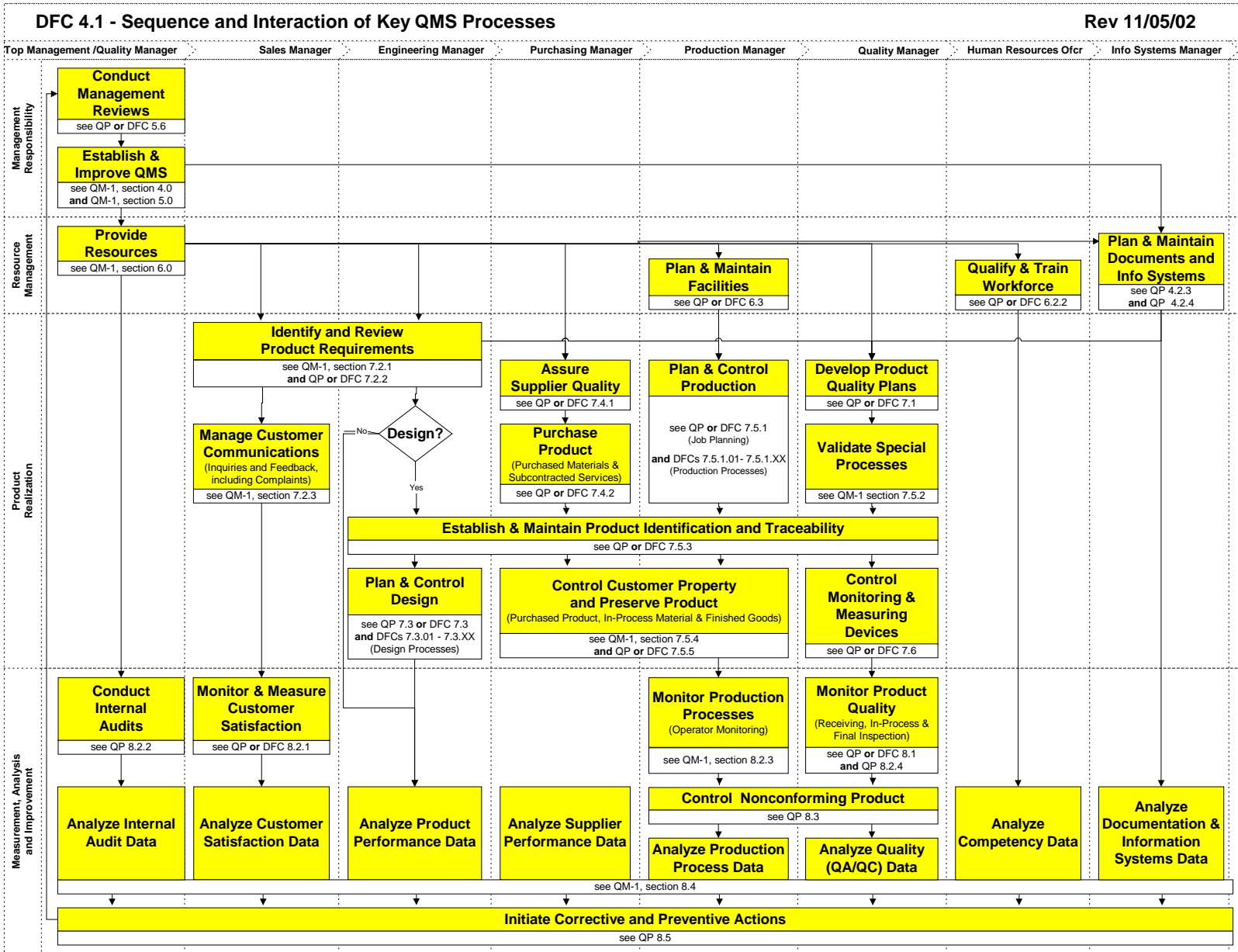
4.1 General requirements

Our QMS is that part of our overall management system which implements our quality policy, and it establishes processes for providing products which also includes the repair and servicing of Mechanical Seals. Our products will meet or exceed customer requirements, and satisfy ISO 9001: 2008 quality system requirements.

The processes needed for our QMS include those required by ISO 9001: 2008 as well those required by our customers, and a number of product/service realization processes unique to our business and operations. Responsibilities for and the sequence and interaction of all of our QMS processes are detailed in standard Quality Procedures (QPs) and, where appropriate, visually depicted in Deployment Flow Charts (DFCs).

Responsibilities for and the overall sequence and interaction of the QMS processes described in this manual are depicted in *DFC 4.1*.

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4.2 Documentation requirements

4.2.1 General

Our QMS includes documented statements of our quality policy and objectives, documented procedures required by ISO 9001: 2008 and other documentation needed to ensure effective operation and process control.

The QMS documentation developed is appropriate to the size and type of our organization, the complexity and interaction of our processes, and the competence of our personnel. QMS documents and data may be in hard copy or electronic media. QMS documentation includes this quality manual, QPs, DFCs, and other internal and external documents and data needed to manage, perform or verify work affecting process or product quality.

We use QPs to implement and manage many of our key QMS processes; we use DFCs if/where a visual depiction of the process flow best communicates the sequence, interaction and responsibilities of all involved. We also develop and control work instructions, job training instructions, and other documents and data as appropriate and needed to effectively manage our QMS.

Our Quality management system documentation will include quality system requirements imposed by the applicable regulatory authorities.

Our organization shall ensure that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authorities representatives shall have access to quality management system documentation.

4.2.2 Quality manual

This manual is that part of our QMS that defines the scope of our QMS and documents the policy, procedures and processes we will implement to implement our quality policy and achieve our quality objectives.

When referencing the documented procedures, the relationship between the requirements of this International Standard and the documented procedures shall be clearly shown.

4.2.3 Control of documents

The Quality Manager has overall responsibility for ensuring that all QMS documents, including forms used to create quality records, are controlled. *QP 4.2.3* and *DFC 4.2.3.01* and *DFC 4.2.3.02* provide procedures necessary to:

- a) approve documents for adequacy prior to issue.
- b) review, update as necessary and re-approve documents.
- c) identify the current revision status of documents.
- d) ensure that relevant versions of applicable documents are available at points of use.
- e) ensure that documents remain legible, readily identifiable and retrievable.
- f) ensure that documents of external origin are identified and their distribution controlled.

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- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The organization shall coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

4.2.4 Control of records

The Quality Manager has overall responsibility for ensuring that all records required for the QMS are controlled and maintained to provide evidence of conformance to requirements and effective operation of the QMS. Records may be in the form of hard copy or electronic media. *QP 4.2.4* and *DFC 4.2.4* provide procedures necessary to control all records, including documentation that describes:

- a) results of processes performed, including identification of the individual performing the activity.
- b) product/process evaluation for acceptance criteria.
- c) procedures, drawings or instructions used to perform an activity, including revision or date of document.
- d) identification of material, parts, or equipment used in the making of the product.
- e) personnel, material or equipment qualifications.
- f) pertinent technical records from sub-contractors.

The documented procedure shall define the method for controlling records that are created by and/or retained by suppliers.

Records shall be available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

4.3 Configuration Management

Sealing Equipment Products Co., Inc. will establish, document and maintain a configuration management process appropriate to the product.

NOTE Guidance on configuration management is given in ISO 10007.

5. Management Responsibility

5.1 Management commitment

Top management provides evidence of its commitment to the development and improvement of the quality management system through both words and actions.

Our quality policy statement (see *section 5.3*) documents and communicates the importance of meeting or exceeding all applicable requirements (including customer, regulatory and legal requirements) by continually improving our processes, products, and services.

We ensure that our quality policy is understood, implemented, and maintained at all levels of the organization through our printed and verbal reinforcement of the quality policy statement and corporate level improvement objectives established and reviewed during management reviews conducted in accordance with *QP or DFC 5.6*, and through operational objectives established

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and reviewed during employee performance reviews conducted in accordance with *QP or DFC 6.2.2*.

All managers demonstrate their commitment to the development and improvement of the QMS through the provision of necessary resources (see *section 6.1*) and through their direct involvement in the internal audit process (see *QP 8.2.2*) and continual improvement activities (see *QP 8.5*).

5.2 Customer focus

Our quality vision & objective statement articulates our commitment to our customers: *Sepco's Vision is a commitment to "Complete Customer Satisfaction" and Sepco's Objective is Zero defects, 100% on time delivery, at a competitive price.* In order to meet the foregoing vision and objective on a daily basis, unspecified requirements and other customer expectations must be determined, understood, and converted into requirements, and processes and systems must be established and maintained to meet or exceed these requirements.

We work hard to be an active partner with our customers through regular customer visits by our Sales personnel and customer service representatives, trade shows, joint planning sessions involving senior managers from our company and those of our key customers, daily contact with our customers through our Customer Service staff, customer audits of our facilities, and through our interactive web site: *Sepcousa.com*. These communications and interactions ultimately yield clear, explicit customer requirements and expectations in the form of a contractual agreement or customer specification. The Vice President of Sales has overall responsibility for ensuring that these requirements are met or exceeded with the overall aim of achieving high levels of customer satisfaction; see *QP or DFC 7.2.2* and *QP or DFC 8.2.1*.

5.3 Quality policy

“We will achieve customer satisfaction
by continually improving processes, products and services
to ensure they consistently meet or exceed requirements”

Our quality policy statement indicates our commitment and focuses on what is important to us as an organization: *achieving customer satisfaction*; and it prescribes the method by which we accomplish this: *by continually improving processes, products, and services to ensure they consistently meet or exceed requirements*. Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing key corporate level performance measures and related improvement objectives (see *section 5.4.1*).

We ensure that our quality policy is communicated and understood at all levels of the organization through documented training, regular communication, and reinforcement during annual management reviews (see *QP or DFC 6.2.2*).

Our quality policy statement is controlled by inclusion in this manual, and is reviewed annually during management review meetings (see *QP or DFC 5.6*) for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

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Our overall quality goal is to achieve our quality policy, and maintain the integrity of and continually improve a QMS that satisfies international requirements for ISO registration. At the corporate level, responsible managers will monitor and measure performance in the areas outlined below and, where needed, establishes measurable improvement objectives annually.

- Customer Satisfaction: The Vice President of Sales; see *QP or DFC 8.2.1*.
- Supplier Performance: The Director of Purchasing; see *QP or DFC 7.4.1*.
- Overall QMS Effectiveness: The Quality Manager; see *QP 8.5*.
- Overall Operational Efficiency: The President with input from the Production Control and Information Systems Manager.
- Competency and Training Effectiveness: The Human Resources Officer (HRO) with input from the Managers or Supervisors; see *QP or DFC 6.2.2*.
- Overall Product Performance: The Product Design Manager; see *QP or DFC 7.3*
- Overall Effectiveness of Sealing Equipment Products Company's Production Operations: The President; see *QP or DFC 7.5.1, QP or DFC 7.5.5, and QP or DFC 6.3*.
- Overall Product Quality: The Quality Manager; see *QP or DFC 8.2.4*.

Annual corporate level improvement objectives will be documented deployed and reviewed for achievement and continuing suitability during management reviews conducted by top management; see *QP or DFC 5.6*.

At the operational level, all managers and supervisors will monitor and measure performance of processes within their area(s) of responsibility and, where appropriate, establish measurable improvement objectives annually. Annual operational level improvement objectives will be documented, deployed and reviewed for achievement and continuing suitability during annual management reviews conducted by responsible managers; see *QP or DFC 6.2.2*.

5.4.2 Quality management system planning

The QMS planning process involves the establishment and communication of our quality policy and objectives through issuance of this manual and its associated procedures and the provision of resources needed for its effective implementation; see *section 5.3, section 5.4.1, and section 6*. Accordingly, this manual constitutes our overall QMS implementation plan. Our management review process (see *QP or DFC 5.6*) and internal audit process (see *QP 8.2.2*) ensure the integrity of our QMS is maintained when significant changes are planned and implemented.

The Quality Manager develops a quality plan for specific products, projects or contracts whenever customer requirements exceed the capability or intent of the product/service realization and support processes described in our QMS; see *QP or DFC 7.1*.

5.5 Responsibility, authority and communication

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5.5.1 Responsibility and authority

The President sets direction and ensures the success of Sealing Equipment Products Company. Other members of top management include: the Chairman of the Board, Vice President of Sales, and the Director of Purchasing. The interrelationship of top management and other key personnel are depicted in our organization chart; see *Exhibit 5.5.1* following.

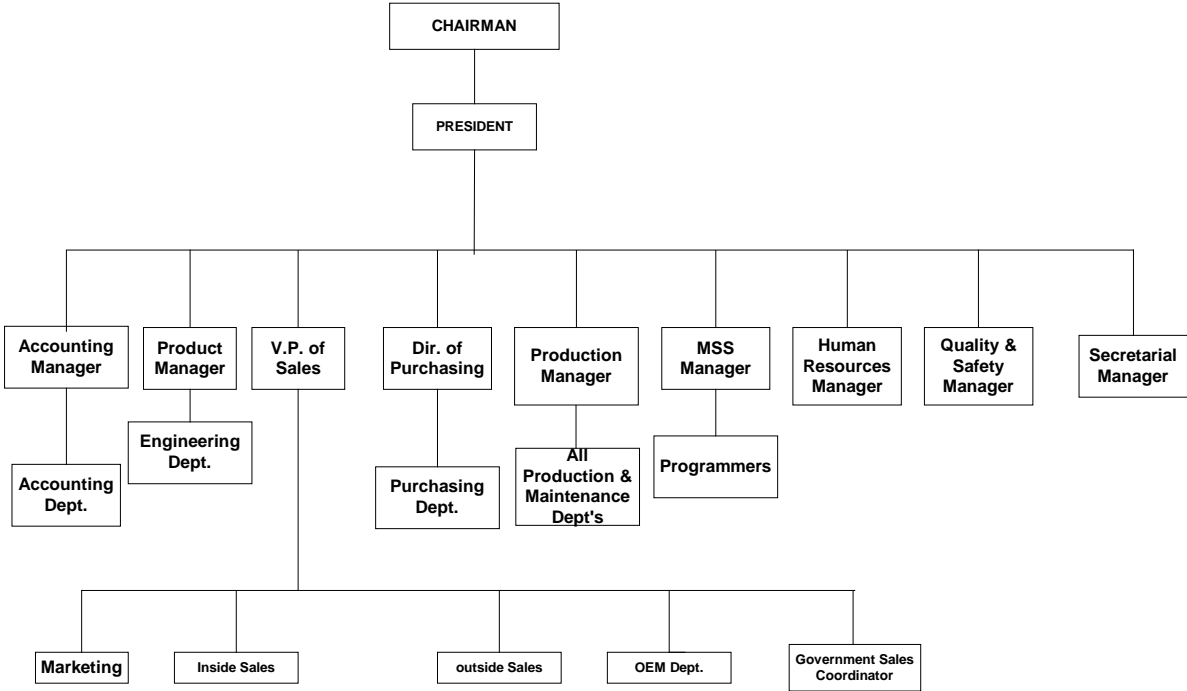


Exhibit 5.5.1
ORGANIZATION CHART
as of (11/05/02)

Overall QMS responsibility and authority is as follows:

Top Management – Members of top management are ultimately responsible for the quality of Sealing Equipment Products Company’s products and services since they control the systems and processes by which work is accomplished. Top Management is responsible for strategic planning, development and communication of our quality policy, QMS Planning, including the establishment and deployment of corporate level objectives, and the provision of resources needed to implement and improve the QMS. Top Management also conducts QMS management reviews.

Management – All officers, managers, supervisors and team leaders are responsible for execution of the strategic plan and implementation of the policy, processes and systems described in this manual. All managers are responsible for planning and controlling QMS processes within their area(s) of responsibility, including the establishment and deployment of operational level objectives, and the provision of resources needed to implement and improve these processes. Managers also conduct employee performance reviews.

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Employees - All employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform. Employees also identify and report any known or potential problems and recommend related solutions through the internal audit and/or corrective/preventive action processes.

Detailed responsibilities and authorities for QMS implementation and improvement are contained in lower level documents referenced throughout this manual and other QMS documents including procedures, flow charts, job descriptions, work instructions, etc.

5.5.2 Management representative

The ISO Management Representative (**Quality Manager**) is appointed as Sealing Equipment Products Company's management representative with delegated responsibilities for ensuring that a quality system is established, implemented, and maintained in accordance with ISO 9001: 2008 requirements, for reporting to Top Management on performance of the QMS, for promoting awareness of customer requirements throughout the organization, and for ensuring that the performance of the QMS is reviewed for effectiveness, continuing suitability and the need for improvement.

The ISO Management Representative has the organizational freedom to resolve matters pertaining to quality.

5.5.3 Internal communication

We communicate information regarding QMS processes and their effectiveness through documented training, the internal audit and corrective/preventive action processes, and regular formal and informal communications as

- The ISO Management Representative posts information on quality bulletin boards throughout the facility to convey information regarding customer requirements, and the status and importance of quality activities. Note: internal audits (see *QP 8.2.2*) are also used to communicate this information to employees.
- The Safety Manager posts information on safety bulletin boards throughout the facility to convey information regarding the status of the Safety and Environmental Management Program, and related statutory/regulatory requirements. Note: safety inspections are also used to communicate this information to employees.
- The HRD posts information on employee bulletin boards throughout the facility to convey information regarding employee benefits, programs, involvement opportunities, and applicable statutory/regulatory requirements. The Marketing Manager is also responsible for publication of Sealing Equipment Products Company's newsletter, (*The Scoop*).
- The Marketing Manager ensures that consistent and effective formal communication is facilitated through publication of the company newsletter and through our interactive web site: sepcousa.com

All officers, managers and supervisors, are responsible for establishing internal communications as needed to convey to their employees the relevance and importance of their activities; typically this information is conveyed through managers & supervisor's meetings, cross-functional

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improvement projects, and (internal memos). Communications regarding how employees contribute to the achievement of objectives is conveyed to employees during annual performance reviews; see *QP or DFC 6.2.2*.

5.6 Management review

5.6.1 General

Top Management conducts a management review meeting annually to ensure the continuing suitability, adequacy, and effectiveness of the QMS in accordance with provisions contained in *QP or DFC 5.6*. The primary inputs reviewed include data that measures the conformance and performance of our QMS. Conformance is primarily assured through internal audits and demonstrated through a review of internal audit results and our demonstrated ability to correct/prevent problems. Performance is primarily assured through the deployment of corporate/operational level objectives and demonstrated through a review of our demonstrated ability to achieve desired results. The primary output of management review meetings are actions taken to make necessary changes to our QMS, including our quality policy (see *section 5.3*) and corporate level improvement objectives (see *section 5.4.1*), and the provision of resources needed to implement these actions.

5.6.2 Review input

The management review meeting includes a review of current performance and opportunities for improvement related to follow-up actions from earlier management reviews and changes that could affect the QMS. Also reviewed for status and continuing suitability are the corporate level quality objectives related to: Customer Satisfaction, Supplier Performance, Overall QMS Effectiveness, Operational Efficiency, Competency and Training Effectiveness, Overall Product Quality and Overall Product Performance; see *section 5.4.1*.

5.6.3 Review output

At a minimum, outputs from management review meetings include new/revised corporate level improvement objectives and any related actions required for improvement of the QMS and its processes, improvement of product related to customer requirements, and provision of resource needs. Results of management review meetings are recorded and maintained by the ISO Management Representative; see *QP or DFC 5.6*.

6. Resource Management

6.1 Provision of resources

Appropriate resources, including trained employees, are identified and provided throughout the documented quality system. These include the resources needed to ensure implementation and improvement of the QMS and our products/services, conduct audits, and implement other actions aimed at enhancing customer satisfaction.

6.2 Human resources

6.2.1 General

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We believe that our employees are our most valuable assets and we do our best to help them achieve their full potential through *continual* education and training; see *QP or DFC 6.2.2*.

6.2.2 Competence, awareness and training. The competency of people assigned responsibilities defined in the QMS is determined on the basis of education, training, skills, and experience. The HRD has overall responsibility for administering Sealing Equipment Products Company Human Resource Management programs; see *QP or DFC 6.2.2*.

6.2.2.a *Need Determination*. We determine competency needs, including employee training and awareness needs, through a variety of methods. Top management identifies emerging competency needs during the strategic planning process. These emergent needs are converted into job descriptions for the type and number of positions that need to be filled through external recruitment, internal reassignment/promotion, or subcontracting actions. The HRD, with input from responsible managers & supervisors, evaluates and qualifies applicants for specific job openings on the basis of documented or demonstrated competencies. Where possible, we help existing employees qualify for new/changed jobs through the provision of appropriate education and training, including on-the-job-training. The HRD, with input from responsible managers and supervisors establishes and maintains job descriptions for each position held at Sealing Equipment Products Company to document the specific competencies needed to ensure the quality of Sealing Equipment Products Company's products and services. Responsible managers, officers and supervisors re-evaluate employee competencies and evaluate employee performance against established objectives through our annual performance review process. Employee competency and training records are maintained by the HRD.

6.2.2.b *Provision*. Training needs identified as a result of the need determination activities discussed above are passed on to the HRD for appropriate planning and timely provision. We develop and provide training that balances organizational competency needs with the development and career needs of our employees. In addition, Quality Improvement Process Training and ISO 9000 Awareness Training are provided to all employees. Further, when a QMS process is established or significantly changed, employees involved in the specific process are trained prior to deployment of the new or changed QP, DFC, work instruction or other QMS documentation. The Quality Manager maintains records of all QMS training completed.

6.2.2.c *Effectiveness*. We evaluate the effectiveness of all actions taken to meet competency needs. Training provided is evaluated through immediate feedback from the employee and the manager, officer, or supervisor who identified the training requirement. Training effectiveness is collected and documented by the responsible manager for each training event; see *QP or DFC*

6.2.2. The HRD, with input from other responsible managers and supervisors, monitors and measures the overall effectiveness of training and other actions taken to meet competency needs and provides related recommendations to top management for review and action; see *QP or DFC 5.6*.

6.2.2.d *Employee Contributions*. We ensure that our employees are aware of the relevance and importance of their activities and how they contribute to the achievement of our quality objectives. This is accomplished through awareness training, QMS training, qualification reviews, and participation in the internal audit and continual improvement processes.

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6.3 Infrastructure

The President has overall responsibility for identifying, providing and maintaining the resources needed to achieve product conformance, including workspace and associated facilities, equipment, hardware and software, and supporting services. The Maintenance Manager has overall responsibility for facilities and equipment maintenance; for additional information, see *section 7.1, section 7.5.1* and *QP or DFC 6.3*. The Information Systems Manager has overall responsibility for establishing and maintaining our information management systems.

6.4 Work environment

We provide employee benefits, job and schedule flexibility, interesting work, and involvement of our employees in an empowered environment of *continual* improvement. We engender total participation by involving employees in internal audit and *continual* improvement activities. The HRO has overall responsibility for identifying, implementing and maintaining effective employee benefit and workforce involvement programs.

We monitor and improve workplace safety, health, and ergonomics including adherence to good manufacturing practices, safety team meetings, and training. A suitable working environment is maintained to ensure product quality. The Safety Manager has overall responsibility for identifying, implementing and maintaining safety and environmental management systems, processes and controls needed to ensure product conformance and meet customer, statutory or regulatory requirements.

NOTE: Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

7. **Product Realization**

7.1 Planning of product realization

Our QMS identifies, plans for and documents our product and service realization processes to ensure consistency with all applicable requirements, including customer requirements, statutory/legal requirements, as well as Sealing Equipment Products Company's product/service performance objectives (see *section 5.4.1*). The outputs of product/service realization planning include the specific methods, facilities, equipment, people and materials/support services needed to achieve all desired results for a particular product, service, or contract. Product/service planning also includes the identification of verification and validation activities, the criteria for acceptability; and the records necessary to provide confidence of product conformance.

The elements of product/service realization planning that apply to all products/services are addressed in this manual and its associated procedures and other lower level documents. When customer specified requirements are beyond the control or capability of our established QMS, the Quality Manager has overall responsibility for developing and implementing a specific quality plan for that process, product or contract; see *QP or DFC 7.1*.

Our approach to process management involves determining what the customer wants, developing processes and systems capable of meeting these requirements, ensuring that process inputs are appropriate, monitoring and measuring process activity and outputs to ensure desired results are achieved, and improving the process as needed to reduce variation, eliminate waste, and enhance

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customer satisfaction. Monitoring and measurement activity employs the use of statistical techniques, as appropriate; see *QP or DFC 8.1*.

In planning product realization, Sealing Equipment Products Co., Inc. shall determine the identification of resources to support operation and maintenance of the product.

7.2 Customer-related processes

Achieving our quality policy “to meet or exceed customer requirements” requires that we determine, understand, and consistently meet or exceed our customers’ requirements and expectations, and that we establish effective communication systems with our customers with regards to product information, inquiries, contract or order handling and related changes, and customer feedback, including complaints. These efforts are described below. The Sales Manager has overall responsibility for developing and implementing effective customer-related processes; also see *QP or DFC 7.2.2* and *QP or DFC 8.2.1*.

7.2.1 Determination of requirements related to the product

Sales personnel generate quotes/bids and negotiate final contracts/orders and Customer Service personnel receive customer orders for standard (catalog) items or for items included previously bid or negotiated. Requirements for most major customers are identified in contracts documented and reviewed annually. Where no annual contract exists, an order constitutes a contract, and we ensure that the customer’s requirements are clearly identified.

Applicable customer requirements include product requirements specified by the customer, including the requirements for availability, delivery and support; product requirements not specified by the customer but necessary for intended or specified use; and obligations related to product, including regulatory and legal requirements; see *QP or DFC 7.2.2*.

7.2.2 Review of requirements related to the product

Sales or Customer Service personnel review customer requirements identified during the determination process to ensure that they are clearly stated, understood, and recorded. This includes ensuring that product requirements are defined; that where the customer provides no documented statement of requirement the customer requirements are confirmed before acceptance; that contract or order requirements differing from those previously expressed are resolved; and that we have the ability to meet defined requirements; see *QP or DFC 7.2.2*.

We ensure that these criteria are met prior to making a delivery commitment. Where product requirements are changed, we ensure relevant documents are amended and relevant personnel are made aware of the changed requirements; see *QP or DFC 7.2.2*.

The review of requirements related to the product shall ensure that risks (e.g., new technology, short delivery time scale) have been evaluated.

7.2.3 Customer communication

Product information is available through a number of different channels. First, Sales and Customer Service personnel provide product information directly to customers including verbal and printed information on our standard product offerings as well as customized information for unique customer applications. Second, Engineering personnel provide technical assistance and

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related information as needed. Third, our Information Systems Manager maintains a user/customer friendly web site, sepcousa.com which contains extensive product information, including specifications and applications information, an exhaustive list of contacts of use to both customers and suppliers, and an electronic customer feedback form.

Inquiries are handled by our Sales or Customer Service personnel depending on the nature of the inquiry or who made initial contact; see *QP or DFC 7.2.2*.

We pay particular attention to customer feedback, including *customer complaints* and customer satisfaction. We have a toll-free number and a wide sales network to encourage and address customer feedback, particularly customer complaints. *Customer satisfaction* is evaluated on an on-going basis by customer contact personnel, i.e. Sales and Customer Service personnel; also see *QP or DFC 8.2.1*.

7.3 Design and development. Design and development processes are employed at Sealing Equipment Products Company to transform customer requirements into specifications, products, processes or systems. At Sealing Equipment Products Company, the terms design and development are used synonymously and are referred to hereafter only as “design”. Processes related to the provision all products/services are discussed in *section 7.5.1*; the process for designing products/services for which Sealing Equipment Products Company has design responsibility is discussed in this section. Design records, including design plans, design review results, results of design verification and validation activities, and design change review and approval results are recorded and maintained in accordance with *QP or DFC 7.3* and *QP 4.2.4*. The Engineering Manager maintains a list of products/services for which Sealing Equipment Products Company has design responsibility and has overall responsibility for managing the design engineering, technical and administrative support processes defined in *QP or DFC 7.3* and depicted in *DFC 7.3.01 – DFC 7.3.XX*.

7.3.1 Design planning

The Engineering Manager assigns a qualified Engineer to serve as the Design Project Leader for each new design project. The Design Project Leader uses project management planning tools (available software etc.) to establish a Design Plan that, at a minimum, identifies design stages, ***- in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control***, predetermined design reviews, scheduled verification and validation activities. Design plans are retained in a Design Folder established and maintained for each design project by the Design Project Leader.

Where appropriate, due to complexity, the organization shall give consideration to the following activities:

- structuring the design effort into significant elements;***
- for each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element shall be reviewed to ensure consistency with requirements.***

The different design and development tasks to be carried out shall be defined according to

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specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements.

7.3.2 Design inputs

The Design Project Leader defines design input requirements including, the functional and performance requirements as derived from customer input, legal and regulatory requirements which apply, useful information or experience from previous similar design efforts, and other necessary requirements. Before finalizing documentation of required inputs, the Design Project Leader resolves any incomplete, ambiguous or conflicting requirements; see *QP or DFC 7.2.2* and *QP or DFC 7.3*.

7.3.3 Design outputs

The Design Project Leader ensures that design output will comply with the design input requirements, include information needed for production and service provision (see *section 7.5*), include or reference acceptance criteria, indicate design characteristics critical to the safe and proper operation of the product, be approved before issuance; see *QP or DFC 7.3. and identify key characteristics, when applicable, in accordance with design or contract requirements.*

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained shall be defined by our organization; for example:

- *drawings, part lists, specifications;*
- *a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product;*
- *information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.*

7.3.4 Design review

During the evolution of each product design or process development, the Design Project Leader conducts design reviews as planned; see *QP or DFC 7.3*. All functions concerned with the stage being reviewed are represented at the review. Design reviews are intended to assure that requirements are being fulfilled; when they are not, the Design Project Leader utilizes input from those involved in the review to propose a remedy for each identified problem *and to authorize progression to the next stage.*

7.3.5 Design verification

The Design Project Leader ensures design verification activities are carried out as planned; see *QP or DFC 7.3*. Design verification activities are intended to determine if design output meets design input requirements; design reviews can be a form of design verification.

NOTE: *Design and/or development verification may include activities such as:*

- *performing alternative calculations,*

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- *comparing the new design with a similar proven design, if available,*
- *undertaking tests and demonstrations, and*
- reviewing the design stage documents before release.

7.3.6 Design validation

The Design Project Leader ensures design validation is carried out as planned; see *QP or DFC*
 7.3.6 Design validation is performed to ensure the product or service resulting from design efforts performs as intended for all specified or known uses/applications.

NOTE:

- *Design and/or development validation follows successful design and/or development verification.*
- *Validation is normally performed under defined operating conditions.*
- *Validation is normally performed on the final product, but may be necessary in earlier stages prior to product completion.*
- *Multiple validations may be performed if there are different intended uses.*

7.3.6.1 Documentation of Design and/or Development Verification and Validation: *At the completion of design and/or development, the organization shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.*

7.3.6.2 Design and/or Development Verification and Validation Testing: *Where tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:*

- a. test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;*
- b. test procedures describe the method of operation, the performance of the test, and the recording of the results;*
- c. the correct configuration standard of the product is submitted for the test;*
- d. the requirements of the test plan and the test procedures are observed;*
- e. the acceptance criteria are met.*

7.3.7 Control of design changes

The Design Project Leader ensures all design changes are identified, documented, reviewed, approved and communicated to all affected organizations and functions; see *QP or DFC* 7.3. Control includes the assessment of the impact of changes upon component parts and completed products including those that have already been delivered. Control also includes the determination of treatment required for each change, which may include verification or

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validation.

Our organization's change control process shall provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.

7.4 Purchasing

We work in partnership with our suppliers to ensure that purchased products and services meet all applicable requirements.

7.4.1 Purchasing process

The type and extent of control over the purchasing process is dependent upon the effect on subsequent realization processes and their output, as well as consideration of other characteristics including: the type of product; the potential impact of the product on our processes, products, or services; the results of supplier evaluations and past performance; and applicable regulations.

The Purchasing Manager defines and documents the supplier approval process, including criteria for selection, the extent of control to be exercised, and periodic evaluation; see *QP or DFC 7.4.1*. Suppliers are evaluated and selected based on their ability to supply products or services in accordance with our requirements. The results of evaluations and follow/up actions are recorded; additionally, we maintain a master list of approved suppliers.

Our organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources.

Our organization will:

- a. maintain a register of approved suppliers that includes the scope of the approval;***
- b. periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;***
- c. define the necessary actions to take when dealing with suppliers that do not meet requirements;***
- d. ensure where required that both the organization and all suppliers use customer-approved special process sources;***
- e. ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.***

7.4.2 Purchasing information: Purchasing information shall 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
- c) quality management system requirements
- d) the name or other positive identification, and applicable issues of specifications,***

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- drawings, process requirements, inspection instructions and other relevant technical data,*
- e) requirements for design, test, examination, inspection and related instructions for acceptance by the organization,*
 - f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,*
 - g) requirements relative to*
 - supplier notification to organization of nonconforming product and*
 - arrangements for organization approval of supplier nonconforming material,*
 - h) requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval,*
 - i) right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and*
 - j) requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.*

Purchasing documents contain the appropriate data to clearly and fully describe requirements for purchased materials and services; including, where appropriate, requirements for approval or qualification of product, procedures, processes/systems, equipment, and personnel.

The Purchasing Manager ensures that all purchasing documents are reviewed for completeness and adequacy prior to issuance or placement of an order; see *QP or DFC 7.4.2*.

7.4.3 Verification of purchased product

The Quality Manager ensures that incoming product is approved prior to release; see *QP or DFC 8.2.4*. In some cases, criteria for approval of incoming product will be specified in a product quality plan (see *QP or DFC 7.1*) and may include data submitted by the supplier, including statistical data, certificates of conformance, etc. The Quality Manager, plans and implements appropriate statistical techniques to verify purchased product; see *QP or DFC 8.1*. All requirements for approval of purchased product and/or supplier procedures, processes, equipment, personnel, and/or quality systems will be specified in applicable purchasing documents; see *QP or DFC 7.4.2*.

Neither we, nor our customers currently perform verification activities at our suppliers' premises. Should we or our customers choose to do so in the future, the Quality Manager will document the intended verification arrangements and method of product release.

Where our organization or our customer intends to perform verification at our supplier's premises, we shall state the intended verification arrangements and method of product release in the purchasing information.

Verification activities may include:

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a. obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control,

b. inspection and audit at supplier's premises,

c. review of the required documentation,

d. inspection of products upon receipt, and

e. delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material.

Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements.

Verification by the customer shall not be used by the organization as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

7.5 Production and service provision

7.5.1 Control of production and service provision: *Planning shall consider, as applicable:*

- the establishment of process controls and development of control plans where key characteristics have been identified,*
- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization*
- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and*
- special processes (see 7.5.2).*

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

7.5.1.a Information. Information inputs to the process include both product characteristics and appropriate work instructions containing specific work methods and/or other pertinent information. The President, through Product Line Team Leaders, Production Shift Supervisors

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and Production Control Supervisors, ensures that all appropriate information including final product specifications, raw material characteristics and the required product parameters, is provided to production personnel throughout the product/service provision process. Such information is provided through job schedules/plans, production team meetings and work instructions posted in areas where they are needed.

7.5.1.b Work Instructions. The necessity for and required detail of work instructions is dependent upon the knowledge, skills, and abilities of our employees and the complexity of the work process. Since all production-related processes are performed by competent employees (see *QP or DFC 6.2.2*) the need for detailed written work instructions is minimal. Product Line Team Leaders, with input from Engineering, Quality and other technical personnel identify critical production/service work steps in Work Instructions posted in areas where they are needed.

7.5.1.c Equipment. The Maintenance Manager ensures that the suitability and availability of all equipment and facilities used for production and service operations; see *QP or DFC 6.3*.

7.5.1.d Monitoring and Measurement Devices. The Quality Manager ensures that monitoring and measurement devices capable of meeting our measurement requirements are available for use during production and service provision; see *QP or DFC 7.6*.

7.5.1.e Monitoring Activities. The Production Control Manager, through Production Shift Supervisors, ensures that production personnel monitor the quality of their own work and understand the procedures for reporting related problems and/or suspected nonconforming conditions; see *QP or DFC 7.5.1* and *section 8.2.3*. The Quality Manager, is responsible for planning and implementing in-process inspections needed to ensure process control and product quality; see *QP or DFC 8.2.4*.

7.5.1.f Release, Delivery, and Post-Delivery Processes. Release of product is dependent on its compliance with all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order. The President through the Purchasing Manager, Supervisors, and the Quality Manager, ensures that records of product approval are maintained and clearly indicate the authorizing employee; see *QP or DFC 7.5.3*. We do not currently perform post-delivery activities; see *section 7.5.5*.

g. accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product),

h. evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,

i. provision for the prevention, detection, and removal of foreign objects,

j. monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and

k. criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

7.5.1.1 Production Documentation: Production operations shall be carried out in accordance

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with approved data. This data shall contain as necessary

a. drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1), and

b. a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use.

7.5.1.2 Control of Production Process Changes *Persons authorized to approve changes to production processes shall be identified.*

The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs: *Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification.*

Storage requirements, including periodic preservation/ condition checks, shall be established for production equipment or tooling in storage.

7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities: *When planning to temporarily transfer work to a location outside the organization's facilities, the organization shall define the process to control and validate the quality of the work.*

7.5.1.4 Control of Service Operations: *Where servicing is a specified requirement, service operation processes shall provide for*

a. a method of collecting and analyzing in-service data,

b. actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,

c. the control and updating of technical documentation,

d. the approval, control, and use of repair schemes, and

e. the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).

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7.5.2. Validation of processes for production and service provision

We define processes in which the results cannot be verified by subsequent monitoring or measurement as “Special Processes.” This includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered

Our organization shall establish arrangements for these processes including, as applicable

- a) defined criteria for review and approval of the processes,
 - **qualification and approval of special processes prior to use,**
- b) approval of equipment and qualification of personnel
- b) use of specific methods and procedures,
- c) use of specific methods and procedures
- **control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,**
- d) requirements for records,
- e) revalidation will be carried out per quality plans developed by the Quality Manager; see *QP or DFC 7.1.*

7.5.3 Identification and traceability

The identification and status of product is established and maintained throughout all products. Traceability records are established and maintained as required.

The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

The Quality Manager has overall responsibility for establishing and maintaining product identification throughout all stages of design, production, installation and delivery; see *QP 7.5.3 or DFC 7.5.3.*

We establish and maintain product monitoring and measurement status through the use of both physical identification tags/labels and electronic records (VISUAL MANUFACTURING) Additionally, physical location in designated hold or production process areas is an indicator of product status. The President through the Purchasing Manager, the Dept. Supervisor, and the Quality Manager, ensures that all incoming, in-process, and final product is suitably identified and the current status is appropriately tracked and displayed in accordance with procedures detailed in *QP 7.5.3 or DFC 7.5.3, QP or DFC 8.2.4, and QP 8.3.*

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish and document controls for the media.

Where contractually required, the Quality Manager establishes and maintains appropriate traceability records in accordance with customer requirements; see *QP or DFC 7.1.* Where products are made in lots or batches we identify and record a unique lot or batch number and

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related information on the Shop Order; see *QP or DFC 7.5.1* and *QP 7.5.3 or DFC 7.5.3*.

According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:

- a. identification to be maintained throughout the product life;***
- b. all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;***
- c. for an assembly, the identity of its components and those of the next higher assembly to be traced;***
- d. for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.***

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 4.3).

7.5.4 Customer property

We identify, verify, protect and maintain customer property provided for use or incorporation into the product, applying the same process controls as we do to purchased product and other material inputs to the process. Whenever required by the customer or when customer specified requirements for property management are beyond the control or capability of our established QMS, the Quality Manager has overall responsibility for documenting and communicating such requirements in the product quality plan; see *QP or DFC 7.1*. The Quality Manager ensures that lost, damaged or unsuitable customer property is recorded on a corrective/preventive action request and immediately reported to the customer; see *QP 8.3*.

NOTE Customer property can include intellectual property, including customer furnished data used for design, production and/or inspection.

7.5.5 Preservation of product

The President, through the Purchasing Manager, Department Supervisor, Quality Manager, Maintenance Manager and Safety Manager, has overall responsibility for establishing and implementing a product handling system that ensures product conformity is preserved during internal processing and delivery to the intended destination. This system includes the handling, storage, packaging, delivery, and protection of final product as well as in-process constituents of the final product. Components and products are handled and stored in a manner that prevents damage or deterioration pending use or delivery. Each department ensures controls are implemented to prevent mixing conforming and non-conforming materials. Packing ensures specified or original manufacturing packaging is utilized. All components and products are suitably packed to prevent deterioration or damage during storage and delivery. Sealing Equipment Products Company does not currently offer any warranty service on its products nor does it perform any after sales servicing. For detailed responsibilities and additional information see *QP or DFC 7.5.5*.

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Preservation of product shall also include, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- a. cleaning;*
- b. prevention, detection and removal of foreign objects;*
- c. special handling for sensitive products;*
- d. marking and labeling including safety warnings;*
- e. shelf life control and stock rotation;*
- f. special handling for hazardous materials.*

Our organization shall ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of monitoring and measuring devices

The Quality Manager, is responsible for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measurement devices used to provide evidence of product conformance to established requirements. Related procedures are detailed in *QP or DFC 7.6* and summarized below:

We determine the measurements to be made and the accuracy required to assure conformity of our product to specified requirements. We identify and select monitoring and measurement devices and verify their capability of meeting such requirements prior to use.

Our organization shall maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

Monitoring and measuring devices are used and controlled in a manner that ensures continuing suitability; this includes ensuring that the **environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out.** We also define the processes employed for the on-going calibration, control and maintenance of monitoring and measuring devices including their identification, location, frequency/method of checks, uses/acceptance criteria and the action to be taken when results are unsatisfactory.

7.6.a All monitoring and measuring devices that can affect product quality are identified and calibrated at prescribed intervals against certified equipment having a known valid relationship to internationally or nationally known standards. Where no such standards exist, the basis used for calibration is documented.

7.6.b When monitoring and measuring devices are found to be out of calibration (or when calibration status is not known), they are adjusted or re-adjusted as necessary and the validity of

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previous measuring results is documented; actions taken are documented, including appropriate corrective/preventive actions to remedy the situation and preclude its recurrence; see *QP* 8.5.

7.6.c Appropriate calibration records are maintained to document results of calibration activities (see *QP* 4.2.4) and suitable indicators are used to show current calibration status.

7.6.d All monitoring and measuring devices are safeguarded from adjustment that would invalidate the calibration.

7.6.e All monitoring and measuring devices are handled, maintained and stored in a manner that ensures accuracy and fitness for use is maintained.

7.6.f *be recalled to a defined method when requiring calibration.*

8. Measurement, Analysis and Improvement

8.1 General

We have defined, planned, and implemented the monitoring, measurement, analysis and improvement processes needed to assure product and QMS conformity and achieve continual QMS improvement. These activities include assessment of customer satisfaction, conduct of internal audits, monitoring and measurement of processes, and the monitoring and measurement of product. *QP* or *DFC* 8.1 details procedures governing the selection and use of statistical techniques in measurement, analysis and improvement.

NOTE According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- *design verification (e.g., reliability, maintainability, safety);*
- *process control;*
- *selection and inspection of key characteristics;*
- *process capability measurements;*
- *statistical process control;*
- *design of experiment;*
- *inspection - matching sampling rate to the criticality of the product and to the process capability;*
- *failure mode and effect analysis.*

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

Customers are the reason we exist and drive our quality policy “to meet or exceed customer requirements.” Data collected by customer contact personnel during routine communications (see *section* 7.2.3) provide our primary basis for assessing customer satisfaction. The Sales

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Manager) has overall responsibility for identifying and reviewing customer requirements (see *QP or DFC 7.2.2*) and for monitoring and measuring customer satisfaction (see *QP or DFC 8.2.1*) as follows:

Customer complaints are immediately forwarded to appropriate Sales or Customer Service personnel for action. If these personnel cannot resolve the issue to the customer's satisfaction, then the complaint will be transferred to the Sales Manager for assignment to another appropriate manager or function for resolution. Customer complaints are documented and monitored through resolution through our corrective/preventive action process; see *QP 8.5*.

Sales personnel and Customer Service staff will utilize a very simple customer satisfaction survey form (hard copy or electronic) to ascertain the customer's overall perception of how well we are meeting their requirements and to document any recommendations for improvement. Customer survey data along with other customer feedback (including written or verbal complaints and information collected from our web site's customer feedback form) is reviewed daily by Sales personnel and Customer Service staff to initiate any corrective/preventive actions needed; see *QP 8.5*.

The Sales Manager periodically reviews customer satisfaction survey data and other customer feedback (including complaints), as well as progress towards achievement of corporate level customer satisfaction improvement objectives (see *section 5.4.1*) and provides related recommendations for review by top management; see *QP or DFC 5.6*.

8.2.2 Internal audit

Internal audit results are critical inputs to aid in assessing the effectiveness of our QMS and in identifying opportunities for improvement. Their purpose is to: determine whether the QMS conforms to ISO 9001: 2008 requirements; to determine whether the process has been effectively implemented and maintained; and to identify opportunities for improvement.

The QMS process, function or quality system element under review is effective if it is achieving the desired results or established objectives; see *section 5.4.1*. In addition, employee ideas for improving process effectiveness or efficiency are actively sought during internal audits. Internal audit results are also used to determine the scope, nature and frequency of future internal audits of processes, functions or quality system elements where ineffectiveness or inefficiency is most likely to be found. Accordingly, the internal audit process is a key method for communicating with and involving employees in continual improvement. Responsible managers may also request that the audit be used to gather "value added" data serving as input to aid in monitoring, measurement and improvement of QMS processes and systems; see *sections 8.2.3 and 8.5*.

The Quality Manager has overall responsibility for managing the internal audit process in accordance with *QP 8.2.2* and *DFC 8.2.2* as summarized below:

Internal audits are conducted in accordance with a published schedule that identifies the audit scope and frequency. The schedule is developed on the basis of status and importance of the activity to be audited and previous audit results. Each of our key QMS processes (see *DFC 4.1*) is reviewed at least once annually.

Audits are carried out by trained personnel who do not have direct responsibility for the activity

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being audited. Audit checklists are prepared and used to aid in ensuring audit consistency and comprehensiveness. Auditors record audit results and submit findings to management personnel with responsibility for the process, function or quality system element audited.

Management responsible for the area audited implement timely corrective action to eliminate detected non-conformances and their causes, and initiate other appropriate action in response to employee identified opportunities for improvement. Follow-ups are conducted to verify timely and effective implementation of the proposed action.

The Quality Manager maintains all internal audit records, including training records and results of internal audits related follow-ups; periodically reviews internal audit results as well as progress towards achievement of corporate level objectives aimed at improving overall QMS effectiveness (see *section 5.4.1*); and provides related recommendations for review by top management; see *QP or DFC 5.6*.

Detailed tools and techniques shall be developed such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools will be measured against the effectiveness of the internal audit process and overall organization performance.

Internal audits shall also meet contract and/or regulatory requirements.

8.2.3 Monitoring and measurement of processes

We apply suitable methods for monitoring and measuring all QMS processes. QMS processes depicted in *DFC 4.1* are documented measured, controlled and evaluated to ensure they are effective (i.e. achieve desired results) and to identify opportunities for improvement. The Manager or Supervisor with overall responsibility for the process develops key process measures used to quantify process effectiveness and/or efficiency:

A process is effectiveness if desired results are achieved. Effectiveness can be measured in terms of product quality, process accuracy, delivery/schedule performance, cost/budget performance, employee/function performance against established objectives, and/or customer satisfaction.

A process is efficient when resource utilization is optimal. Efficiency can be measured in terms of total resource utilization, productivity indicators, and or waste/rework costs or hours.

Since effectiveness is of primary importance to our customers and efficiency is of primary importance to management and our shareholders, achieving and improving effectiveness and efficiency of all our process is critical to our success.

As previously discussed, we primarily utilize the internal audit process (see *QP 8.2.2*) to assess QMS process effectiveness (i.e. the desired results or established objectives are achieved). Both managers and internal auditors may develop/use Process Assessment Worksheets (PAWs) as tools to aid in the definition, assessment and improvement of our key QMS processes; see *QP 8.2.2*.

Also as previously stated, production personnel monitor and report on the quality of their own

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work; see *QP or DFC 7.5.1*.

Further, the Quality Manager, is responsible for planning and implementing formal in-process inspection activities, including those using statistical techniques to ensure process control at the product, project or contract level; see *QP or DFC 7.1*, *QP or DFC 8.1* and *QP or DFC 8.2.4*.

In the event of process nonconformity, the organization shall;

a. take appropriate action to correct the nonconforming process

b. evaluate whether the process nonconformity has resulted in product nonconformity, and

c. identify and control the nonconforming product in accordance with clause 8.3.

8.2.4 Monitoring and measurement of product

The Quality Manager has overall responsibility for planning and implementing effective product monitoring and measurement systems including receiving, in-process and final inspection and test activities and the use of appropriate statistical techniques needed to ensure process control at the product, project or contract level; see *QP or DFC 7.1*, *QP or DFC 8.1* and *QP or DFC 8.2.4*.

When key characteristics have been identified, they shall be monitored and controlled.

Receiving inspection is performed to ensure quality of purchased product; see *QP or DFC 8.2.4*.

When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval.

Process monitoring is performed by production/service personnel throughout all product/service realization processes; see *QP or DFC 7.5.1*. Formal in-process inspections are performed by Quality Control personnel in accordance with the quality plan and procedures in *QP or DFC 8.2.4*. All finished product and completed service is verified by final inspections/tests specified in the quality plan and procedures in *QP or DFC 8.2.4*.

Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

Products are not released for further processing or delivery until we have objective evidence that all requirements have been met.

8.2.4.a Evidence of Conformity. Test and inspection records are maintained for a minimum of three years. These records include final inspection authority and identify and confirm that all critical parameters are in accordance with established requirements and specifications. Additionally, product samples are stored for a minimum of 3 years.

8.2.4.b Product Release and Delivery. Product is not normally released or delivered until all planned inspections and tests have been completed, and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person(s) authorizing release. In rare cases (due to customer demands and/or production emergencies) unverified product may

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be released or delivered under controlled conditions of positive recall documented and authorized by the Quality Manager and, where applicable, approved by the customer. Nonconforming (or suspect) product is identified and controlled to prevent its inadvertent use; see *QP 8.3*.

8.2.4.1 Inspection Documentation: Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include

- a. criteria for acceptance and/or rejection,*
- b. where in the sequence measurement and testing operations are performed,*
- c. a record of the measurement results, and*
- d. type of measurement instruments required and any specific instructions associated with their use.*

Test records shall show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements.

8.2.4.2 First Article Inspection: The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result.

NOTE See (AS) (EN) (SJAC) 9102 for guidance.

8.3 Control of nonconforming product

We ensure that nonconforming purchased product, in-process materials and finished product is identified and controlled to prevent inadvertent use.

NOTE The term "nonconforming product" includes nonconforming product returned from a customer.

The Quality Manager has overall responsibility for implementing an effective process for identifying, documenting, segregating, evaluating, and disposing of nonconforming product in accordance with *QP 8.3* and *DFC 8.3*, as summarized below:

The organization's documented procedure shall define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

Identification. Identification of nonconforming product originates from inspection, internal testing, or customer complaint. Employees clearly mark or otherwise identify nonconforming product. Where required by contract, responsible Sales or Customer Service personnel will notify the customer.

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Documentation. The Quality Manager, through authorized Quality Control personnel, will enter the nonconformance into the corrective action system (see *QP 8.5*) identifying the nonconforming product and lot number if applicable, description of nonconformance, and location where the nonconforming product is being held pending further review or disposition.

Segregation. Nonconforming product is segregated pending evaluation and disposition.

Evaluation. The Quality Manager, through authorized Quality Control personnel, will perform the initial evaluation of nonconforming product in accordance with approved test and inspection procedures. Where needed, Engineering, Production and other technical personnel may become involved in the evaluation and recommendation for disposition.

Disposition. The results of the evaluation and resultant disposition determinations will be documented. Dispositions resulting from the evaluation of nonconforming product may include:

- rework to meet specified requirements
- regrade for an alternative application
- use as is (under customer concession or other required approval authority)
- obtain (from relevant authority) a waiver of or deviation from requirements
- return to supplier
- scrap or other disposal (in accordance with applicable environmental controls)

8.3.a. Correction and Re-verification. Reworked nonconforming product is re-verified after correction to demonstrate conformity to original requirements.

8.3.b Product Recall. In the event nonconforming product is detected after delivery or use has started, the Quality Manager will notify the customer and initiate action appropriate to the effects, or potential effects, of the nonconformity. Where appropriate, product recall will be initiated based on trace and recall data and records; see *QP or DFC 7.5.3*.

8.3.c Nonconformance Reporting. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, will be maintained in accordance with *QP 8.3*, applicable inspection and test procedures, and *QP 4.2.4*.

The organization shall not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if

- the product is produced to customer design, or

- the nonconformity results in a departure from the contract requirements.

Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by the organization as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.

Product dispositioned for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

In addition to any contract or regulatory authority reporting requirements, the organization's

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system shall provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification shall include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

NOTE Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

8.4 Analysis of data

Top management and other officers, managers and supervisors collect and analyze appropriate data using appropriate statistical techniques (see *QP or DFC 8.1*) to determine the suitability and effectiveness of elements of the QMS applicable to their area(s) of responsibility and to identify opportunities for improvement. At a minimum, data is analyzed to assess achievement of the corporate level quality objectives related to: Customer Satisfaction, Supplier Performance, Overall QMS Effectiveness (which as a minimum will include a measure of repeat internal audit findings and other internal failures and ineffective corrective/preventive actions), Overall Operational Efficiency, Competency and Training Effectiveness, and Product/Service Performance; see *section 5.4.1*.

Another tool for determining the effectiveness of our QMS and identifying opportunities for improvement is our annual assessment against the criteria established in Annex A of ISO 9004:2000. On an annual basis the Quality Manager, with input from top management and other key personnel, performs a self-assessment against these criteria and uses the results to identify current strengths and weaknesses, and to identify opportunities for improvement.

Results of data analysis together with related recommendations are presented to top management for review and action during management reviews; see *QP or DFC 5.6*.

8.5 Improvement

8.5.1 Continual improvement

At Sealing Equipment Products Company, the continual improvement process begins with the establishment of our quality policy (see *section 5.3*) and objectives for improvement based on key measures established by top management (see *section 5.4.1*). Customer satisfaction, internal audit, process and product performance data is then collected, analyzed and monitored to assess progress against objectives and identify opportunities for improvement; see *section 8*.

Corrective actions are initiated when desired results are not achieved and preventive actions are initiated to prevent the occurrence of problems or to implement other improvement actions. Actions are prioritized and implemented on the basis of data: the impact of failures/problems is used to prioritize needed corrective actions, and risks are evaluated to identify and prioritize needed preventive actions.

The effectiveness of corrective and preventive actions taken as well as the overall progress towards achieving corporate level improvement objectives is assessed through our management review process. At Sealing Equipment Products Company, our “baseline” performance begins with meeting customer and ISO 9001: 2008 requirements. We identify opportunities for satisfying the requirements of all other interested parties (i.e. shareholders, employees, society)

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through the use of the annual self assessment against improvement criteria contained in Annex A of ISO 9004.

All inputs to the management review process are used to establish new/changed improvement objectives and to initiate additional improvement actions; see *QP or DFC 5.6*.

The Quality Manager has overall responsibility for establishing and implementing an effective corrective and preventive action system in accordance with *QP 8.5* and *DFC 8.5* as summarized in the following sections.

8.5.2 Corrective action

Evidence of nonconforming product, customer dissatisfaction, and ineffective processes is used to drive our corrective action system because they indicate that a current problem exists requiring immediate correction and possible additional action aimed at eliminating or reducing the likelihood of its recurrence. Investigating and eliminating the root cause of these failures is a critical part of our continual improvement process. We apply controls and follow-up;

f) review corrective action taken

g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and

h) specific actions where timely and/or effective corrective actions are not achieved.

In addition, the Quality Manger summarizes and analyzes corrective action data to identify trends needed to assess overall effectiveness of the corrective action system and to develop related recommendations for improvement. The corrective action system is considered effective if specific problems are resolved or corrected and data indicates that the same (or similar) problems have not recurred. Results of this analysis and related recommendations are presented to top management for review and action during management reviews; see *QP or DFC 5.6*.

8.5.3 Preventive action

Data from internal audits, customer feedback, employee suggestions, and the annual self assessment against criteria contained in Annex A of ISO 9004:2000 is collected and analyzed (see *section 8.4*) to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. Investigating and eliminating the root cause of potential failures is a critical part of our continual improvement process. We apply controls and follow-up to ensure that effective preventive action is taken appropriate to the risk and impact of potential problems and losses.

In addition, the Quality Manager summarizes and analyzes preventive action data to identify trends needed to assess overall effectiveness of the preventive action system and to develop related recommendations for improvement. The preventive action system is considered effective if potential losses were avoided. Results of this analysis and related recommendations are presented to top management for review and action during management reviews; see *QP or DFC 5.6*.

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Appendix A Terms and Definitions

Acronyms:

DFC – Deployment Flowchart
HRD – Human Resources Director
QMS – Quality Management System
QP – Quality Procedure

Terms and Definitions. Terms and definitions contained in ISO 9000: 2008 apply; contact the Quality Manager to obtain or view a copy. Terms and definitions contained in this manual are not unique to our organization or business. The *Revision Record* that applies to this manual is listed in Appendix B.

Deployment Flow Charting: a technique employed at Sealing Equipment Products Company to visually depict responsibilities for and the sequence and interaction of one or more related processes; this technique is often used to supplement or replace verbiage that would otherwise be needed in a QP or other QMS document.

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Appendix B

REVISION RECORD

Rev No.	Section No.	Page No.	Description	Date
18	New ISO 9001: 2008 Quality Manual	N/A	Deleted Quality Manual, Revision No. 17 ISO 9002. Replaced with new ISO 9001: 2000 Quality Manual	11/05/02
19	Audit by URS to ISO 9001: 2008 Report Number 2004-01246-S01 Sections 4.1, 5.2 & 5.3	2,6	Added, includes the repair and servicing of Mechanical Seals under 4.1. general requirements) & Chg Quality Policy to Vision statement under 5.2 and new Quality Policy replaced Vision statement under 5.3 to comply with new standards)) Quality Manual placed on share drive with "Read Only Access"	04/15/04
20	Audit by URS to ISO 9001: 2008 Report Number 2005-01246-S01/ 50177 Section 2	29	Delete Appendix B contents that is a Master List of Key QMS Documents. Master List is actually a separate document (QSML). & is now referenced on page 2. Appendix B now becomes the quality manual Revision Record.	10/31/06
21	Sections 4,5,6,7, & 8	1,4,5,9 12 thru 25 27 thru 30 32 & 34	Replaced all references to ISO 9001: 2000 With ISO 9001: 2008.. Added AS9100 quality system requirements in accordance with Eaton Aerospace quality requirements for suppliers. <u>It is emphasized that the quality management system requirements specified in this standard are complementary.</u> CONTROLLED was added to every footer.	11/19/2009