

**pima VALVE, inc.**

*Lone Butte Industrial Park*

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# **QUALITY MANUAL**

**Conforming to ISO 9001:2008**

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## 1.0 COMPANY DESCRIPTION

### *Our Origin*

Founded in 1967 and located 18 miles southeast of Phoenix, Arizona on the Gila River Indian Reservation, PIMA VALVE, INC. is a leader in the marine valve industry. Our leadership is sustained by a commitment to what we consider are the basic manufacturing requirements. Produce high quality products from top grade materials; Employ the best available people and equipment; Continually increase machining capabilities; Remain flexible to meet and exceed customer requests; Maintain a safe and efficient facility.

People make the difference, therefore only the best will do. The average tenure among our employees is 18 years. We continually cross train personnel to perform a multitude of functions, thereby maximizing the potential of both operator and equipment. Tight manufacturing tolerances mandate machine designs that allow consistent component reproduction. Our modern CNC equipment, mills and lapping machines ensure a perfect fit every time.

Our flexibility includes recognizing and embracing industry advancements. Motor operated valve applications have increased in recent years. PIMA VALVE answers customer requests by adapting any valve configuration to hydraulic, pneumatic or electric operation per furnished requirements. The result is a sophisticated piece of equipment using the latest technology.

Matching production requirements with shop capacity, our senior staff provides accurate production schedules. We do not provide arbitrary dates to receive awards but actual, reliable delivery commitments. We understand that customers rely on our ability to get the job done right on time as promised. We will not disappoint...our commitment is to meet the customers' delivery requirements.

## 2.0 QUALITY MANUAL DESCRIPTION

- 2.1 The purpose of this manual is to define the policies employed by PIMA VALVE INC. to establish and maintain an effective Quality Management System (QMS). The QMS is actively maintained to ensure product or service quality, customer and employee satisfaction, profitability, and continuous improvement.
- 2.2 Circulation of this manual is controlled by the Quality Assurance Manager, who maintains a master index listing the location of all controlled copies.

- 2.3 The contents of this manual are confidential. The Quality Manual *shall not* be circulated to other parties without the Quality Assurance Manager’ authorization.
- 2.4 Sections 4 – 8 of this manual are organized generally in accordance with elements 4 – 8 of the ISO 9001:2008 International Standard. Where necessary, sub-tier procedures support the policies defined herein by detailing major quality-related processes. References to these procedures are highlighted by **boldface** type. Procedures referenced in this manual and functions responsible for applying them are listed in the table below.

PROCEDURE NAME	PROC. NO.	FUNCTIONS RESPONSIBLE							
		Executive Management	Senior Management	Manufacturing Management	Sales / Customer Service	Internal Auditors	Purchasing & Warehouse Staff	Q. A. & Calibration Staff	Document Control Staff
Management Responsibility	OP-1	X							
Contract Review	OP-2		X		X				
Document and Data Control	OP-3	X	X	X	X	X	X	X	X
Submittal and Approval of New & Revised Controlled Documents	OP-4	X	X	X					X
Procedure for Revision Control of Prints and Specifications	OP-5	X	X	X	X	X	X	X	X
Supplier Quality System for Purchased Material	OP-6	X	X	X	X				X
Control of Customer Supplied Product	OP-7	X	X	X	X		X	X	
Product Identification and Traceability	OP-8	X	X	X	X	X	X	X	X
Process Control	OP-9	X	X	X	X	X	X	X	X
Inspection and Testing	OP-10	X							X
Control of Inspection, Measuring, and Test Equipment	OP-11	X							X
Inspection and Test Status	OP-12	X					X	X	
Control of Nonconforming Product	OP-13	X					X	X	
Corrective and Preventive Action	OP-14	X	X	X		X		X	
Product Handling, Receiving, Packaging, Preservation, and Delivery	OP-15	X					X	X	
Control of Quality Records	OP-16	X	X	X	X	X	X	X	X
Internal Quality Audits	OP-17	X				X		X	
Training	OP-18	X	X	X					
Statistical Techniques	OP-19	X				X			X

- 2.5 References to procedures may apply directly to the procedure cited, or to work instructions that support the procedure cited.
- 2.6 Within the context of this manual, the terms “PIMA VALVE” and “the company” are synonymous with PIMA VALVE INC.
- 2.7 The scope of the Quality Management system is: Manufacturer of Marine and Commercial Valves.
- 2.8 The ISO 9001:2008 clauses listed below are not applicable to PIMA VALVE'S Quality Management System:
  - a) 7.3 (Design & Development) – At present, the company does not perform Design of Products.

- b) 7.5.2 (Validation of Processes) – At present, the company does not perform any Special Processes.

### **3.0 APPROVALS AND REVISION HISTORY**

- 3.1 The President and Quality Assurance Manager are responsible for approving the Quality Manual for technical accuracy and compliance with the Quality Policy.
- 3.2 The Quality Assurance Manager is also responsible for approving the Quality Manual for compliance with ISO 9001:2008 and format consistency.
- 3.3 Revisions may be suggested by all staff members, but must be approved by the President and Quality Assurance Manager prior to implementation.
- 3.4 Each revision's description and date is recorded on the Revision History (below). Revised copies are distributed at the direction of the Quality Assurance Manager to those recorded on the master index.
- 3.5 Superseded Quality Manual revisions are maintained for a minimum of 3 years.
- 3.6 The President and Quality Assurance Manager review the manual periodically to reaffirm its currency and adequacy.

#### **REVISION HISTORY**

<b>Rev No</b>	<b>Revision Description</b>	<b>Apvd By</b>	<b>Date</b>
NEW	Revised Quality Policy	AJL/RDZ	8-17-05
NEW	Original Issue replacing ISO9002-1994	AJL/RDZ	9-15-05
A	Revised Function Responsibility Matrix – 2.4	AJL/RDZ	9-29-05
B	Added 8.2.4 Monitoring and Measurement of Product	AJL/RDZ	1-24-06
C	Corrected Functions Responsibility Matrix adding QA to Corrective and Preventive Action and Internal Quality Audits.	AJL/RDZ	7-11-06
D	5.6.1 Changed semi-annually to annually	AJL/RDZ	4-8-10
E	2.7 Changed scope from “Manufacturer of Marine Valves” to Manufacturer of Marine and Commercial Valves	AJL/RDZ	8-5-10
F	Updated to conform to ISO 9001:2008; Added Table 1 (pg18), modeled after Annex B of referenced document	AJL/AMM	12-15-11

## **4.0 QUALITY MANAGEMENT SYSTEM**

### **4.1 GENERAL**

PIMA VALVE, INC. has established a Quality Management System to achieve the company's Quality Policy, ensure product or service quality, and promote continuous improvement. The QMS has been instituted in accordance with the requirements of ISO 9001:2008, and is comprised of:

- a) Quality Policy and Objectives.
- b) Quality Manual, which defines the company's policies for achieving quality.
- c) Operating Procedures, which define major processes.
- d) Work Instructions, which define specific tasks.
- e) Project Management Plans, which define specific project requirements.
- f) Quality Records, which provide evidence of processes performed and results achieved.
- g) Drawings, specifications, and standards.
- h) Equipment calibration system.
- i) Employee training programs.
- j) Subcontractor evaluation and control programs.
- k) Document, Data, and Record control systems.
- l) Corrective and Preventive Action systems.
- m) Performance measurement system.
- n) Internal Auditing, to verify QMS compliance and adequacy.
- o) Management Review, to analyze QMS performance, initiate improvement measures, and assign resources accordingly.

### **4.2 DOCUMENTATION REQUIREMENTS**

4.2.1 **General** – All policies, procedures, and records comprising the company's Quality Management System, specifically those cited by clause 4.1, are documented via hard-copy or electronic means.

4.2.2 **Quality Manual** – Refer to Section 2.

4.2.3 **Control of Documents** – All documents comprising the Quality Management System, including those of external origin, are controlled in accordance with procedures **Document and Data Control – QMS Documents OP-3, Submittal and Approval of New & Revised Documents OP-4, and Procedure for Revision Control of Prints and Specification OP-5**. Control measures include:

- a) Review and approval of documents for adequacy prior to initial release.

- b) Periodic review, update, and re-approval of existing documents as required.
- c) Clear document identification, revision indication, and current revision status.
- d) Availability of current and relevant documents at all locations where quality-related activities are performed.
- e) Periodic audits to confirm document presence, revision status, and legibility.
- f) Identification and controlled distribution of documents of external origin determined by Pima Valve, Inc to be necessary for the operation and planning of the Quality Management System.
- g) Prompt removal of obsolete documents from all points of issue and use, or other measures to preclude unintended use.
- h) Identification of obsolete documents retained for legal or knowledge-preservation purposes.
- i) Maintenance of a master index which indicates the current revision status of each controlled document, and the location of each controlled copy.

4.2.4 **Control of Records** – Quality records are maintained to demonstrate conformance to specified requirements and effective operation of the Quality Management System. **Control of Quality Records OP-16** defines methods for identification, location, storage, retention, and disposal of records.

## **5.0 MANAGEMENT RESPONSIBILITY**

### **5.1 MANAGEMENT COMMITMENT**

PIMA VALVE, INC. senior management is firmly committed to the pursuit of product or service quality, customer satisfaction, regulatory compliance, and continuous improvement. This commitment is demonstrated through rigorous application of the Quality Management System, as defined herein.

### **5.2 CUSTOMER FOCUS**

Senior management is also committed to the achievement of customer confidence, through the determination and meeting of customer requirements and expectations. (Refer to clause 7.2.)

### **5.3 QUALITY POLICY**

An overall Quality Policy articulating senior management's commitment to quality has been devised and approved by the President. This policy is stated below:

*The Quality Policy of Pima Valve, Inc. is based on customer satisfaction. We strive for continuous improvement in our Quality Management System, to attain the objectives of our company: Supplying products that meet or exceed our customer's requirements; providing a service that results in customer satisfaction; Continuous development of a dependable vendor base. We are committed to continuous improvement in quality, and the assessment of the Quality Management System to assure its suitability to meet the requirements of our company and the requirements of our customers.*

*The Quality Management System is regularly reviewed by senior management for adequacy, and for its ability to meet established goals. Specifically:*

- *Increased customer satisfaction through on-time delivery of defect-free products and services and complaint free performance.*
- *Development of a reliable subcontractor base, capable of defect-free product and service delivery to the company.*
- *Increased employee proficiency and job satisfaction through awareness, training, and development programs.*
- *Maximization of company profits through elimination of quality problems and related costs.*
- *Consistent and ongoing regulatory compliance.*
- *Continual improvement with regards to the above-stated goals.*

*The commitment to implement a successful Quality Policy begins with an organization's executive management. As President, I therefore affirm my commitment to this policy. We recognize that we are all responsible for the quality of our work, and must remain quality-conscious in all of our activities.”*

**Allen J. Link**

President

December 15, 2011

## 5.4 PLANNING

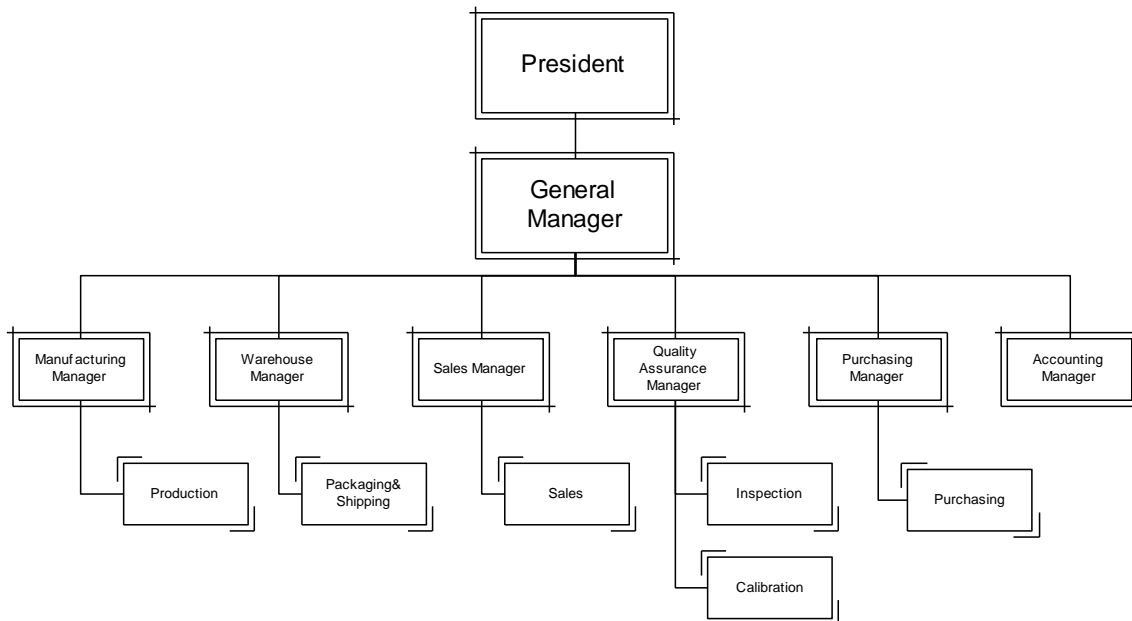
5.4.1 **Quality Objectives** – In accordance with the goals cited by the Quality Policy, relevant service and operational objectives are established and monitored during Management Reviews. (Refer to clause 5.6.)

5.4.2 **Quality Management System Planning** – In order to achieve quality objectives, PIMA VALVE'S Quality Management System has been established in accordance with clause 4.1. Planning is performed before changes to the QMS are implemented, to ensure quality objective achievement and system integrity. QMS changes are implemented in accordance with **Document and Data Control OP-3**.

## 5.5 RESPONSIBILITY, AUTHORITY, AND COMMUNICATION

5.5.1 **Responsibility and Authority** – Various Job Descriptions define the responsibilities, authorities, and reporting structures for all personnel that can affect product or service quality. These aspects are reviewed with all employees during orientation. (Refer to clause 6.2.2.) The company's Organization Chart defines the interrelation of PIMA VALVE'S personnel.

### Organization Chart



5.5.2 **Management Representative** – The President has appointed the Quality Assurance Manager as the Management Representative, with full responsibility and authority for all matters pertaining to quality and the Quality Management System. Specific responsibilities and authorities of the Management Representative are defined by **Management Responsibility Procedure OP-1**.

5.5.3 **Internal Communication** – Effective and appropriate communications between functions and levels regarding QMS effectiveness are promoted by senior management. Specific communications interfaces are defined within the company's Operating Procedures.

## 5.6 MANAGEMENT REVIEW

5.6.1 Management Reviews of the QMS are conducted annually to ensure continued system adequacy and effectiveness in achieving quality objectives. Reviews are planned by the Quality Assurance Manager, and

attended by Senior Managers, and other relevant management or staff members.

- 5.6.2 All aspects listed below are addressed during each annual Management Review cycle, in order to accurately assess current system performance and encourage improvement opportunities:
- a) Internal Audit results.
  - b) Customer feedback (including complaints).
  - c) Process performance, product conformity results and review of measurement requirements.
  - d) Corrective and Preventive Action status.
  - e) Action Item results (from previous Management Reviews).
  - f) Changing business and operational conditions that may affect the QMS.
  - g) Review of objectives and improvement recommendations.
  - h) Subcontractor performance results.
- 5.6.3 Management Review minutes are recorded and made available to all attendees and other affected parties. In addition to documenting the items listed in clause 5.6.2 (above), minutes clearly indicate Action Items assigned, including:
- a) QMS improvement measures and effectiveness.
  - b) Process and service improvement measures.
  - c) Resource requirements to achieve improvement.

## **6.0 RESOURCE MANAGEMENT**

### **6.1 PROVISION OF RESOURCES**

In order to achieve quality objectives, PIMA VALVE'S senior management determines and provides all necessary human and physical resources. Specific resource requirements are analyzed and assigned during Management Reviews. (Refer to clauses 5.6.3 and 6.2 – 6.4.)

### **6.2 HUMAN RESOURCES**

- 6.2.1 **Assignment of Personnel** – Only competent personnel are assigned to work that can affect conformity to product requirements or service quality. Competency is appraised based upon employee education, skills, training, and experience.
- 6.2.2 **Competence, Training, and Awareness** – The methods for competency appraisal, quality awareness development, training provision, and evaluation are defined by **Training Procedure OP-18**. Records of

employee education, skills, training, and experience are maintained.

### 6.3 INFRASTRUCTURE

In order to achieve quality objectives, PIMA VALVE'S senior management determines and provides an adequate company infrastructure, including facilities and equipment, utilities, employee workspace, and support services. Company infrastructure is assessed during planned Internal Audits. (Refer to clause 8.2.2.) **Document and Data Control Procedure OP-3** defines specific infrastructure maintenance with regards to computer networks, peripherals, and telecommunications.

### 6.4 WORK ENVIRONMENT

In order to achieve quality objectives, PIMA VALVE'S senior management provides and manages a suitable company work environment. Environmental issues considered include lighting, heating and air conditioning, cleanliness, noise levels, health and safety, and business ethics. Company work environment is assessed during planned Internal Audits. (Refer to clause 8.2.2.)

## 7.0 PRODUCT REALIZATION

### 7.1 PLANNING OF PRODUCT REALIZATION

Prior to the realization of product, PIMA VALVE, INC. conducts planning to insure that the customer's requirements can be met prior to acceptance of the order. Resulting Plans are consistent with the Quality Management System, and the organization's operating methods include:

- a) Product and Service requirements and objectives.
- b) Product specific process, documentation, and resource requirements.
- c) Review and approval requirements, including product acceptance criteria.
- d) Records requirements of process and product realization.

### 7.2 CUSTOMER-RELATED PROCESSES

7.2.1 **Determination of Requirements** – Prior to generation of a customer proposal, PIMA VALVE, INC. determines all pertinent customer, regulatory, and company requirements, whether specified or implied. This includes requirements related to both delivery and post-delivery, as required.

7.2.2 **Review of Requirements** – Prior to proposal submission, order acceptance, or change order acceptance, PIMA VALVE, INC. reviews all pertinent requirements in accordance with **Contract Review Procedure OP-2**. Reviews are recorded. Each review ensures that:

- a) Product and Service requirements are defined.

- b) PIMA VALVE, INC. is able to meet defined requirements.
- c) Requirements differing from those previously expressed are resolved.

7.2.3 **Customer Communication** –Customer communication with regards to proposals, orders, and order amendments is defined by **Contract Review Procedure OP-2. Corrective and Preventive Action Procedure OP-14** defines customer communication with regards to complaints and other feedback. At all times, communication shall be courteous, professional, and straightforward.

### 7.3 DESIGN AND DEVELOPMENT (NOT APPLICABLE)

### 7.4 PURCHASING

7.4.1 **Purchasing Process** – PIMA VALVE, INC. ensures that all purchased product or subcontracted services, if required, conform to specified requirements. Moreover, that supplier's services and subcontractors are controlled, dependent upon the effect that the services may have on the subsequent service delivered to the customer.

- a) **Supplier Quality System for Purchased Material Procedure OP-6** defines the purchase of product and subcontracting services, if applicable. Supplier records are maintained.
- b) The selection criteria and evaluation of suppliers and subcontractors, if applicable, is defined by **Supplier Quality System for Purchased Material Procedure OP-6**. Records of evaluation, performance, and corrective actions are maintained.

7.4.2 **Purchasing Information** – Prior to transmittal, PIMA VALVE, INC. ensures that all Purchase Orders clearly specify requirements for product and subcontracted services, where applicable, including (where appropriate):

- a) Service, process, procedure, or equipment approval, including approval at the subcontractor's facility prior to product or service realization or delivery.
- b) Applicable specifications, standards, or quality management system requirements.
- c) Personnel qualifications.

7.4.3 **Verification of Purchased Product or Services** – Prior to use or delivery to the customer, PIMA VALVE, INC. verifies that all products or services, if applicable, meet specified requirements.

### 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 **Control of Production and Service Provision** – PIMA VALVE, INC. conducts all activities under controlled conditions. Controlled conditions

include:

- a) Availability of drawings, specifications, and other information that defines production or service requirements.
- b) Availability of appropriate Work Instructions and equipment.
- c) Availability and use of suitable measuring and monitoring equipment.
- d) Verification of product or services at appropriate stages, as defined by **Inspection: Receiving, In-Process and Final Procedure OP- 10.**

7.5.2 **Process Validation for Production and Service Provision** – Not Applicable. (Refer to clause 2.8.)

7.5.3 **Identification and Traceability** –PIMA VALVE, INC. provides lot identification when required. Status is indicated throughout product realization when required. Specific methods utilized for identification, traceability, status, and maintenance of records are defined by **Product Identification and Traceability Procedure OP-8.**

7.5.4 **Customer Property** – Customer property is controlled and subjected to verification prior to use, in accordance with **Customer Supplied Product Procedure OP-7.** In all cases, PIMA VALVE, INC. ensures that:

- a) Customer property is clearly identified, and safeguarded against damage or loss.
- b) The customer is advised of any damage or loss.
- c) Records of customer property receipt and disposition are maintained.

7.5.5 **Preservation of Deliverables** – PIMA VALVE, INC. preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. Preservation is maintained through proper handling, storage, packaging, and delivery, in accordance with **Product Handling, Receiving, Packaging, Preservation, Storage and Delivery Procedure OP-15.**

## 7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

PIMA VALVE, INC. determines monitoring and measuring requirements that will ensure product and service conformity, and selects equipment accordingly. Moreover, the company verifies that this equipment is properly maintained in accordance with **Control of Inspection, Measuring, and Test Equipment Procedure OP-11.**

- a) Equipment is labeled with calibration status and next calibration due date.
- b) Equipment is calibrated or verified, or both, prior to use, and at scheduled intervals thereafter.

- c) Equipment is calibrated or verified in accordance with documented procedures.
- d) Calibration records are maintained for all calibrations performed, which certify traceability to the NIST.
- e) When equipment is found out of calibration, the implications of previous inspections and tests are assessed and results recorded.
- f) Proper equipment storage and handling practices are observed, to ensure calibration maintenance.
- g) Inspection, testing, and calibration are performed under environmental conditions that are suitable to equipment utilized.
- h) Equipment is safeguarded against adjustments that might invalidate their calibration.
- i) The company exercises similar measures where applicable to verify the adequacy of jigs, fixtures, and computer software utilized for inspection or testing.

## **8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT**

### **8.1 GENERAL**

In order to demonstrate conformity service and product requirements, and to ensure Quality Management System conformity and continuous improvement, PIMA VALVE, INC. plans and institutes appropriate measurement, analysis, and improvement measures.

### **8.2 MONITORING AND MEASUREMENT**

8.2.1 **Customer Satisfaction** – In order to determine customer satisfaction levels, PIMA VALVE, INC. senior management monitors information regarding customer perception of the company's ability to satisfy requirements. Solicitation programs are planned and monitored during Management Reviews. Service non-conformances and customer feedback are also monitored during Management Reviews. (Refer to clause 5.6.2.)

8.2.2 **Internal Audit** – Internal Audits of all quality-related processes and functions are conducted at planned intervals to ensure that the QMS is effectively implemented and maintained, and is operating in accordance with the company's Quality Policy and the requirements of ISO 9001:2008. **Internal Quality Audits Procedure OP-17** defines the internal auditing process.

- a) Each audit is scheduled based upon the importance of the function being audited, as well as previous audit results.

- b) Each audit is planned and conducted in a systematic manner. Prior to auditing a function, the audit criteria and scope are defined.
- c) Trained auditors are assigned based upon their objectivity and impartiality. Auditors do not audit their own work.
- d) Department managers ensure any necessary corrections and corrective actions raised within their departments are processed in a timely and effective manner. (Refer to clause 8.5.2.)
- e) Audit records are maintained, including audit results, corrective actions taken, and follow-up activities.

8.2.3 **Monitoring and Measurement of Processes** – Relevant QMS processes are monitored during Internal Audits. (Refer to clause 8.2.2.) Critical processes are measured to demonstrate their ability to achieve planned results. Specific measurement requirements are established during Management Reviews. (Refer to clause 5.6.2.) Correction and corrective action is taken, as appropriate, for processes that do not achieve planned results. (Refer to clause 8.5.2.)

8.2.4 **Monitoring and Measurement of Product** – Relevant QMS product characteristics are monitored during Internal Audits. (Refer to clause 8.2.2.) Product characteristics are verified that product requirements have been met. Inspections are performed at appropriate stages to verify product status, and sampling inspection is used as a means of verification. Corrective action is taken for products that do not achieve planned results. (Refer to 8.5.2.)

8.2.4.1 Measurement requirements for product acceptance are documented and include criteria for acceptance and / or rejection with record of the measurement results, and identification of the person(s) accepting or rejecting the part.

8.2.4.2 The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by the relevant authority and, where applicable, by the customer.

### 8.3 CONTROL OF NONCONFORMING PRODUCT

Nonconforming products are identified and controlled to prevent their unintended use or delivery to the customer, in accordance with **Control of Nonconforming Product Procedure OP-13**.

- a) Authorities for the review and disposition of nonconforming products are specified.
- b) Nonconforming products may be accepted by customer concession or reworked to achieve conformance.

- c) If nonconforming products are reworked, they are subjected to re-verification. (Refer to clauses 7.4.3 and 7.5.1.d)
- d) If nonconforming products are detected following delivery to the customer, the company initiates measures commensurate with actual or potential effects of the nonconformance.
- e) Records of product nonconformance, review, disposition, and approval are maintained.

#### 8.4 ANALYSIS OF DATA

Quality Management System improvement is effected through the regular collection and analysis of data relating to customer satisfaction, service conformity, process performance, and supplier performance. Improvement measures are instituted during Management Reviews (refer to clause 5.6.3) and through corrective and preventive actions (refer to clauses 8.5.2 and 8.5.3).

#### 8.5 IMPROVEMENT

8.5.1 **Continuous Improvement** – PIMA VALVE, INC. continually strives to improve the Quality Management System through rigorous application of its Quality Policy and Objectives, internal audits, analysis of data, corrective and preventive actions, and Management Reviews.

8.5.2 **Corrective Action** – Appropriate corrective action is taken to identify the cause of nonconformity and prevent its recurrence, including those involving service non-conformances and customer complaints. Records of corrective actions taken and their results are maintained. The corrective action process is defined by **Corrective and Preventive Action Procedure OP-14**, which includes:

- a) Nonconformity review.
- b) Investigation of root cause.
- c) Evaluation of need to take action to prevent recurrence.
- d) Determination and institution of action necessary to prevent recurrence.
- e) Review of action taken to ensure effectiveness.

8.5.3 **Preventive Action** – Appropriate preventive action is taken to eliminate the causes of potential nonconformity and its occurrence. Records of preventive actions taken and their results are maintained. The preventive action process is defined by **Corrective and Preventive Action Procedure OP-14**, which includes:

- a) Determination of potential nonconformity.
- b) Investigation of root cause.
- c) Evaluation of need to take action to prevent occurrence.

- d) Determination and institution of action necessary to prevent occurrence.
- e) Review of action taken to ensure effectiveness.

Table 1 – Changes from Pima Valve, Inc. QMS Rev.E (ISO 9001:2000) to Pima Valve, Inc. QMS Rev.F (ISO 9001:2008)

Pima Valve, Inc QMS Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) Or Deletion (D)	Amended text
4.2.3	Bullet F)  Bullet G)  New Bullet G)  Bullet H)  New Bullet H)  New Bullet I)	A  Moved to Bullet G)  Moved to bullet H)  A  Now new bullet I)  A  A	<del>F) Identification and controlled distribution of documents of external origin determined by Pima Valve, Inc to be necessary for the operation and planning of the Quality Management System.</del> <del>F) Prompt removal of obsolete documents from all points of issue and use, or other measures to preclude unintended use.</del> <del>G) Identification of obsolete documents retained for legal or knowledge preservation purposes.</del>  <del>G) Prompt removal of obsolete documents from all points of issue and use, or other measures to preclude unintended use</del> <del>H) Maintenance of a master index which indicates the current revision status of each controlled document, and the location of each controlled copy.</del> <del>H) Identification of obsolete documents retained for legal or knowledge-preservation purposes.</del> <del>D) Maintenance of a master index which indicates the current revision status of each controlled document, and the location of each controlled copy.</del>
5.6.2	Bullet A)  New Bullet A)  Bullet B)  New Bullet B)  Bullet C)  New Bullet C)  Bullet D)  New Bullet D)  Bullet E)  New Bullet E)  Bullet F)  New Bullet F)  Bullet H)  New Bullet H)	Moved to Bullet E)  A  Moved to Bullet A)  A  Moved to Bullet D)  A  Moved to Bullet B)  A  Moved to Bullet H)  A  Moved to Bullet C)  a  Moved to Bullet F)  A	<del>A) Action Item results (from previous Management Reviews).</del>  <del>A) Internal Audit results.</del> <del>B) Internal Audit results.</del>  <del>B) Customer feedback (including complaints).</del> <del>C) Corrective and Preventive Action status.</del>  <del>C) Process performance, product conformity results and review of measurement requirements.</del> <del>D) Customer feedback (including complaints).</del>  <del>D) Corrective and Preventive Action status.</del> <del>E) Subcontractor performance results.</del>  <del>E) Action Item results (from previous Management Reviews).</del> <del>F) Process performance, product conformity results and review of measurement requirements.</del>  <del>F) Changing business and operational conditions that may affect the QMS.</del> <del>H) Changing business and operational conditions that may affect the QMS.</del>  <del>H) Subcontractor performance results.</del>
6.2.1	Para 1	A	Assignment of Personnel – Only competent personnel are assigned to work that can affect <u>conformity to product requirements</u> or service quality. Competency is appraised based upon employee education, skills, training, and experience.
6.2.2	Heading	D + A	Competence, <u>Training, and Awareness</u> <del>and Training</del>
7.5.1	Bullet B)	A	B) Availability of appropriate Work Instructions <u>and equipment</u> .
	Bullet C)	D + A	C) Availability and use of suitable measuring and monitoring devices <u>equipment</u> .
7.5.3	Para 1	D + A	<b>Identification and Traceability</b> –PIMA VALVE, INC. provides lot identification when required. Status is indicated <u>through delivery throughout product realization</u> when required. Specific methods utilized for identification, traceability, <del>and status, and maintenance of records</del> are defined by <b>Product Identification and Traceability Procedure OP-8</b> .
7.5.5	Para 1	D + A	Preservation of Deliverables – PIMA VALVE, INC. <del>ensures that the quality aspects of all deliverables are maintained through</del> preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. <u>Preservation is maintained through</u> proper handling, storage, packaging, and delivery, in accordance with Product Handling, Receiving, Packaging, Preservation, Storage and Delivery Procedure OP-15.
7.6	Title  Para 1	D + A  D + A	7.6 CONTROL OF MONITORING AND MEASURING DEVICES <u>EQUIPMENT</u>  PIMA VALVE, INC. determines monitoring and measuring requirements that will ensure product and service conformity, and selects devices <u>equipment</u> accordingly. Moreover, the company verifies that <u>these devices are this equipment</u> is properly maintained in accordance with Control of Inspection, Measuring, and Test Equipment Procedure OP-11.
	Bullet A)	D + A	A) <del>Devices are</del> <u>Equipment</u> is labeled with calibration status and next calibration due date.

Table 1 – Changes from Pima Valve, Inc. QMS Rev.E (ISO 9001:2000) to Pima Valve, Inc. QMS Rev.F (ISO 9001:2008)  
(cont'd)

Pima Valve, Inc QMS Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) Or Deletion (D)	Amended text
	Bullet B)	D + A	B) <del>Devices are</del> <u>Equipment is calibrated /certified or verified, or both,</u> prior to use, and at scheduled intervals thereafter. <u>Records of calibration or verification shall be maintained.</u>
	Bullet C)	D + A	C) <del>Devices are</del> <u>Equipment is calibrated /certified or verified</u> in accordance with documented procedures.
	Bullet E)	D + A	E) When <del>devices are</del> <u>equipment is</u> found out of calibration, the implications of previous inspections and tests are assessed and results recorded.
	Bullet F)	D + A	F) Proper <del>device</del> <u>equipment</u> storage and handling <u>practices</u> are observed, to ensure calibration maintenance.
	Bullet G)	D + A	G) Inspection, testing, and calibration are performed under environmental conditions that are suitable to <del>devices</del> <u>equipment</u> utilized.
	Bullet H)	D + A	H) <del>Devices are</del> <u>Equipment is</u> safeguarded against adjustments that might invalidate their calibration
8.1	Para 1	A	In order to demonstrate <del>product requirements and service conformity</del> <u>conformity to service and product requirements,</u> and to ensure Quality Management System conformity and continuous improvement, PIMA VALVE, INC. plans and institutes appropriate measurement, analysis, and improvement measures.
8.2.2	Bullet D)	A	D) Department managers ensure <u>any necessary corrections and</u> corrective actions raised within their departments are processed in a timely and effective manner. (Refer to clause 8.5.2.)
8.2.3	Para 1	A	<b>Monitoring and Measurement of Processes</b> – Relevant QMS processes are monitored during Internal Audits. (Refer to clause 8.2.2.) Critical processes are measured to demonstrate their ability to achieve planned results. Specific measurement requirements are established during Management Reviews. (Refer to clause 5.6.2.) <u>Correction and</u> corrective action is taken, <u>as appropriate,</u> for processes that do not achieve planned results. (Refer to clause 8.5.2.)
8.2.4.1	Para 1	A	Measurement requirements for product acceptance are documented and include criteria for acceptance and / or rejection with record of the measurement results, <u>and identification of the person(s) authorizing release of the product for delivery to the customer.</u>
8.2.4.2	Para 1	New paragraph A	<u>The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by the relevant authority and, where applicable, by the customer.</u>
8.5.3	Para 1	D + A	Preventive Action – Appropriate preventive action is taken to eliminate the <del>cause</del> <u>causes</u> of potential nonconformity and its occurrence. Records of preventive actions taken and their results are maintained. The preventive action process is defined by Corrective and Preventive Action Procedure OP-14, which includes: