PIMA VALVE, INC.
Lone Butte Industrial Park

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BOX 5010 • CHANDLER, ARIZONA 85226-5127

QUALITY MANUAL

Conforming to ISO 9001:2015

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0.1 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 and services from top grade materials; Employ the best available people and resources; 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 resources. Tight manufacturing tolerances mandate machine designs that allow consistent component reproduction. Our modern CNC resources, 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 resource 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.

0.2 QUALITY MANUAL DESCRIPTION

0.2.1 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 quality of products and services, customer and employee satisfaction, profitability, and continuous improvement.

0.2.2 Circulation of this manual is controlled by the Quality Assurance Manager, who maintains a master index listing the location of all controlled copies.

0.2.3 The contents of this manual are confidential. The Quality Manual *shall not* be circulated to other parties without the Quality Assurance Manager' authorization.

0.2.4 Sections 4 – 10 of this manual are organized generally in accordance with elements 4 – 10 of the ISO 9001:2015 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 at the end of Section 0.2.

0.2.5 References to procedures may apply directly to the procedure cited, or to work instructions that support the procedure cited.

0.2.6 Within the context of this manual, the terms "PIMA VALVE" and "the company" are synonymous with PIMA VALVE INC.

		FUNCTIONS RESPONSIBLE							
PROCEDURE NAME	**PROCEDURE NO.**	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		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
External Provider Quality System for Externally Provided Material	**OP-6**	X	X	X	X			X	
Control of Customer Supplied Products and Services	**OP-7**	X	X	X	X		X	X	
Product and Service 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: Receiving, In-Process, Final	**OP-10**	X						X	
Control of Inspection, Measuring, and Test Resource	**OP-11**	X						X	
Inspection and Test Status	**OP-12**	X					X	X	
Control of Nonconforming Products and Services	**OP-13**	X					X	X	
Corrective and Preventive Action	**OP-14**	X	X	X		X		X	
Product and Service Handling, Receiving, Packaging, Preservation, and Delivery	**OP-15**	X					X	X	
Control of Quality Record	**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	
Lot Identification	**OP-21**	X		X		X		X	X
Design and Development	**OP-22**	X	X	X	X	X	X	X	X

0.3 APPROVALS AND REVISION HISTORY

0.3.1 The President and Quality Assurance Manager are responsible for approving the Quality Manual for technical accuracy and compliance with the Quality Policy.

0.3.2 The Quality Assurance Manager is also responsible for approving the Quality Manual for compliance with ISO 9001:2015 and format consistency.

0.3.3 Revisions may be suggested by all staff members, but must be approved by the President and Quality Assurance Manager prior to implementation.

0.3.4 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.

0.3.5 Superseded Quality Manual revisions are maintained for a minimum of 3 years.

0.3.6 The President and Quality Assurance Manager review the manual periodically to reaffirm its currency and adequacy.

REVISION HISTORY

Rev No	Revision Description	Approved By	Date
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
G	Revised to conform to ISO 9001:2015	AJL/AMM	11-4-16

1.0 SCOPE

This document specifies the requirements of the Quality Management System of PIMA VALVE, INC., for the manufacture, repair, service and sale of Marine and Commercial valves and components for the US Government and Commercial customers. This document also applies to external and internal issues affecting the requirements of interested parties (i.e. customers).

PIMA VALVE, INC. does not perform design of Products.

This Quality Management System applies to all processes, activities, and employees located at:

6525 W Allison Rd
P.O. Box 5010
Chandler, AZ 85226
480-646-8456

2.0 NORMATIVE REFERENCES

The following document, and supporting documents, are normatively referenced in the governing specification. Unless otherwise specified, ISO 9001:2015 applies.

3.0 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions of ISO 9001:2015 apply.

4.0 CONTEXT OF PIMA VALVE, INC

4.1 UNDERSTANDING PIMA VALVE, INC. AND ITS CONTEXT

Pima Valve shall determine external and internal issues relevant to its purpose and ability to achieve the goals of the Quality System. Relevant issues will be monitored and updated by the company in accordance with 9.1.1-9.1.3 of this manual.

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

PIMA VALVE, INC. shall determine interested parties (i.e. customers) that are relevant to the Quality Management System, and the requirements of these parties. PIMA VALVE, INC. shall monitor and review information about these parties and their requirements. Additional information about these procedures is detailed throughout this manual.

4.3 DETERMINING THE SCOPE OF THE QMS

SEE 1.0

4.4 QUALITY MANANGEMENT SYSTEM AND ITS PROCESSES

4.4.1 PIMA VALVE, INC. has established a Quality Management System to achieve the company's Quality Policy, ensure product and service quality, and promote continuous improvement. The QMS has been instituted in accordance with the requirements of ISO 9001:2015, and is comprised of:

- Quality Policy and Objectives
- Quality Manual, which defines the company's policies for achieving quality
- Operating Procedures, which define major processes, including:

  - Process owners
  - Responsibilities and authorities
  - Inputs and outputs
  - Risks and opportunities
  - Critical and supporting resources
  - Criteria for effectiveness of the process
  - Quality objectives
- Work Instructions, which define specific tasks
- Project Management Plans, which define specific project requirements
- Quality Records, which provide evidence of processes performed and results achieved
- Drawings, specifications, and standards
- Resource calibration system
- Employee training programs
- Subcontractor evaluation and control programs
- Document, Data, and Record control systems
- Corrective and Preventive Action systems
- Performance measurement system
- Internal Auditing, to verify QMS compliance and adequacy
- Management Review, to analyze QMS performance, initiate improvement measures, and assign resources accordingly

4.4.2 Throughout the year, metrics data is collected by process owners and measured to be presented during the Management Review, in order that adjustments may be made and goals set to achieve long-term continual improvement.

- Specific quality objectives are defined for each process in their respective Operating Procedure
- Metrics, along with current standings and goals for each objective, are recorded for Management Review

5.0 LEADERSHIP

5.1 LEADERSHIP AND COMMITMENT

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

- Taking accountability for the effectiveness of the Quality Management System

- Ensuring the Quality Policy and Objectives are established and compatible with company goals
- Ensuring integration into other business process, as appropriate
- Promoting awareness of the process approach
- Ensuring resources are available for effective Quality Management
- Communicating the importance of effective Quality Management and conforming to the Quality Management System requirements
- Ensuring intended results are achieved
- Engaging, directing, and supporting personnel to contribute to Quality System effectiveness
- Promoting continual improvement
- Supporting other management roles and their related areas of responsibility

5.1.2 CUSTOMER FOCUS

Senior management is also committed to the achievement of customer satisfaction, through the determination and meeting of customer requirements and expectations, addressing risks and opportunities that affect product and service conformance, regulatory or statutory requirements, and improving customer satisfaction. (Refer to clause 8.1.)

5.2 POLICY

5.2.1 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 and services that meet or exceed our customer's requirements; providing a service that results in customer satisfaction; Continuous development of a dependable external provider 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
November 4, 2016

5.2.2 COMMUNICATING THE QUALITY POLICY

The Quality Policy shall be:

- Available and maintained as documented information
- Communicated, understood and applied within the organization
- Available to relevant interested parties, as appropriate

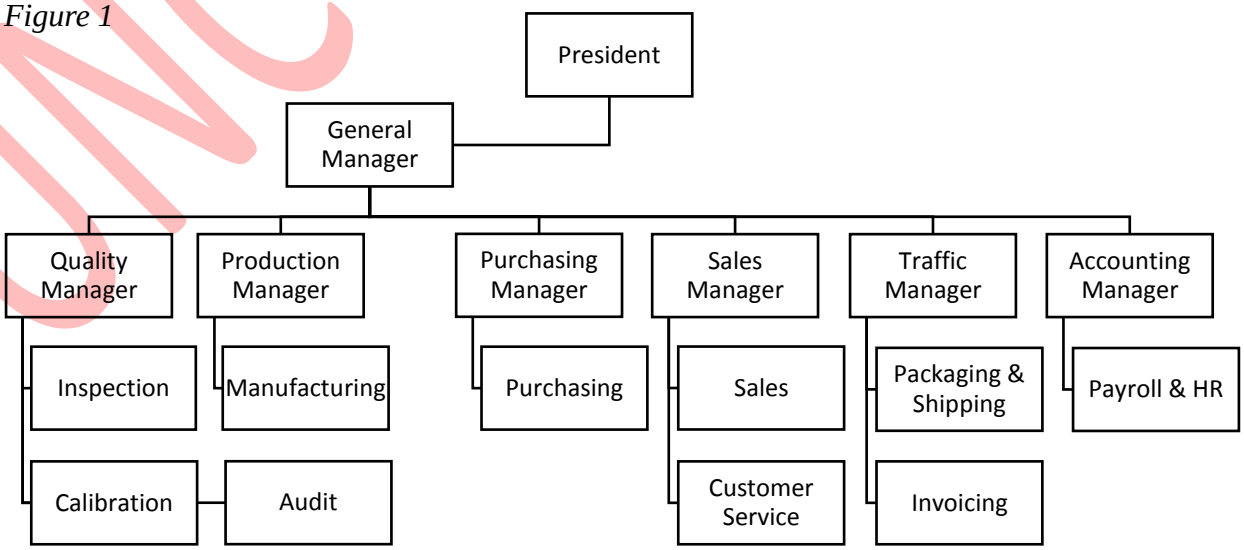
5.3 ORGANIZATIONAL ROLES, RESPONSIBILITY, AUTHORITY

Executive management has assigned responsibilities (**Management Responsibility Procedure OP-1**) and authorities for all relevant roles in the company. These are communicated through the Organization Chart (see ***Figure 1*** below).

The President has appointed the Quality Assurance Manager with full responsibility and authority for all matters pertaining to quality and the Quality Management System, including:

- Conformance of this Quality Manual to its governing document
- Reporting performance of the Quality Management System and opportunities for improvement
- Ensuring promotion of Customer Focus throughout the organization

Figure 1



6.0 PLANNING

6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

PIMA VALVE, INC. considers risks and opportunities when taking actions within the Quality Management System, as well as when implementing or improving the system; likewise, these are considered relative to products and services.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

PIMA VALVE, INC**.** utilizes its process objectives, as discussed in 4.4, as the main quality objectives for the Quality Management System. These include overall product-related quality objectives; additional product-related quality objectives may be defined in work instructions or customer requirements. Process objectives shall:

a) Be consistent with the Quality Policy

b) Be measureable

c) Take into account applicable requirements

d) Be relevant to conformity of products and services, and enhance customer satisfaction

e) Be monitored

f) Be communicated

g) Be updated as appropriate

6.3 PLANNING OF CHANGES

Planning is performed before changes to the Quality Management System are implemented, to ensure quality objective achievement and system integrity.

When PIMA VALVE, INC. determines changes to the Quality Management System to be necessary, the company shall consider:

a) The purpose of the changes

b) The integrity of the Quality Management System

c) The availability of resources

d) The allocation or reallocation of responsibilities and authorities

7.0 SUPPORT

7.1 RESOURCES

7.1.1 GENERAL

In order to achieve quality objectives, PIMA VALVE'S senior management determines the capabilities necessary, human and physical resources, and needs to be obtained from external and internal providers. Specific resource requirements are analyzed and assigned during

Management Reviews. Customer satisfaction is enhanced by meeting customer expectations (Refer to clauses 7.1.2 –7.2 and 9.3.3).

7.1.2 PEOPLE

Only competent personnel are assigned to work that can affect conformity to product and service requirements or service quality. Competency is appraised based upon employee education, skills, training, and experience.

7.1.3 INFRASTRUCTURE

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

7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

In order to achieve quality objectives, PIMA VALVE'S senior management provides and manages a suitable company environment for the operation of processes. Environmental issues considered include lighting, heating and air conditioning, cleanliness, noise levels, health and safety, and business ethics. Company environment for the operation of processes is assessed during planned Internal Audits. (Refer to clause 9.2.)

7.1.5 MONITORING AND MEASURING RESOURCES

7.1.5.1 GENERAL

PIMA VALVE, INC. determines monitoring and measuring requirements (**Control of Inspection, Measuring, and Test Resource Procedure OP-11**) that will ensure product and service conformity, and selects resources accordingly. Moreover, the company verifies that this resource is properly maintained.

7.1.5.2 MEASUREMENT TRACEABILITY

Resources are labeled (**Control of Inspection, Measuring, and Test Resource Procedure OP-11**) with calibration status and next calibration due date.

- Resource is calibrated or verified, or both, prior to use, and at scheduled intervals thereafter
- Resource is calibrated or verified in accordance with procedures
- Calibration records are maintained for all calibrations performed, which certify traceability to the NIST
- When a resource is found out of calibration, the implications of previous inspections and tests are assessed and results recorded
- Proper resource storage and handling practices are observed, to ensure calibration maintenance

- Quality Manual and calibration are performed under environmental conditions that are suitable to resources are utilized
- Resources are safeguarded against adjustments that might invalidate their calibration
- The company exercises similar measures where applicable to verify the adequacy of jigs, fixtures, and computer software utilized for inspection and testing

7.1.6 ORGANIZATIONAL KNOWLEDGE

PIMA VALVE, INC. shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and made available as necessary:

a) Knowledge may be obtained from internal sources, external feedback from subject matter experts, or intellectual property

b) External sources may be standards, academia, conferences, or information gathered from customers or suppliers

When addressing changing needs and trends, PIMA VALVE, INC. shall consider its current knowledge and determine how to acquire necessary additional knowledge and updates.

7.2 COMPETENCE

The methods for competency appraisal, quality awareness development, training provision, and evaluation are defined (**Training Procedure OP-18**). Records of employee education, skills, training, and experience are maintained.

7.3 AWARENESS

PIMA VALVE, INC. shall ensure that employees are aware of the Quality Policy, Quality Objectives, their contribution to the effectiveness of the Quality Management System (including benefits of improved performance), and implications of not conforming to the Quality Management System requirements.

7.4 COMMUNICATION

Effective and appropriate communications between functions and levels regarding QMS effectiveness are promoted by senior management. Communication may be initiated by any employee or external provider. Specific communications interfaces are defined within the company's Operating Procedures. Communication may include:

- Corrective or Preventive Action
- Meetings
- Internal audit results
- Data analysis
- Internal email
- Memos

7.5 DOCUMENTED INFORMATION

7.5.1 GENERAL

The Quality Management System shall include all Documented Information required by ISO 9001:2015, and determined by PIMA VALVE, INC. to be necessary to the effectiveness of the Quality Management System. The extent of the Quality Management System is based upon the following:

a) The size of PIMA VALVE, INC.

b) Complexity and interaction of its processes

c) Risks and opportunities

d) Competence of personnel

7.5.2 CREATING AND UPDATING

When creating and updating documented information, PIMA VALVE, INC. shall ensure appropriate:

- Review and approval of documents for adequacy prior to initial release
- Periodic review, update, and re-approval of existing documents as required
- Clear document identification, format, revision indication, and current revision status

7.5.3 CONTROL OF DOCUMENTED INFORMATION

All documents comprising the Quality Management System, including those of external origin, are controlled (**Document and Data Control OP-3**; **Submittal and Approval of New & Revised Documents OP-4; Procedure for Revision Control of Prints and Specification OP-5**).

7.5.3.1 Control measures include:

- Availability of current and relevant documents at all locations where quality-related activities are performed
- Protected from loss of confidentiality, improper use, or loss of integrity
- Obsolete documents are removed from points of use and protected from unintentional use
    - Obsolete documents may identified and retained for legal or knowledge preservation purposes
- A master index of controlled documents is maintained, indicating the revision level of each document

7.5.3.2 Quality Records are maintained (**Control of Quality Records OP-16**) to demonstrate conformance to specified requirements and shall include:

- Controlled distribution, access, retrieval, and use
- Periodic audits to confirm documents presence, revision status, and legibility
- Storage and preservation, including preservation of legibility

- Control of changes
- Retention and disposal

Documented information from external origin determined by PIMA VALVE, INC. to be necessary of the planning and operation of the Quality Management System shall be identified as appropriate, and controlled

Documented information retained as evidence of conformity shall be protected from unintended alterations

8.0 OPERATION

8.1 OPERATIONAL PLANNING AND CONTROL

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 (**Process Control OP-9**). Resulting Plans are consistent with the Quality Management System, and the organization's operating methods include:

- Product and Service requirements and objectives.
- Product and Service specific processes, documentation, and resource requirements.
- Review and approval requirements, including product and service acceptance criteria.
- Records requirements of process and product and service realization.

PIMA VALVE, INC. shall control planned changes and review consequences of unintended changes, taking action to mitigate adverse effects, as necessary. Externally provided processes shall be controlled. Outputs shall be suitable to PIMA VALVE, INC. operations.

8.2 REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.1 CUSTOMER COMMUNICATION

Customer communications with regards to proposals, orders, and order amendments are defined (**Contract Review Procedure OP-2; Customer Supplied Product OP-7**). Customer communication with regards to complaints and other feedback are defined (**Corrective and Preventive Action Procedure OP-14**). At all times, communication shall be courteous, professional, and straightforward. Customer communication shall include:

- Providing information related to products and services
- Handing enquiries, contracts or orders, including changes
- Obtaining customer feedback relating to products and services, including complaints
- Handling or controlling customer property
- Establishing specific requirements for contingency actions, when necessary

8.2.2 DETERMINING THE REQUIREMENTS OF PRODUCTS AND SERVICES

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, and PIMA VALVE, INC.'s ability to deliver the products and services offered.

8.2.3 REVIEW OF REQUIREMENTS FOR PRODUCTS AND SERVICES

8.2.3.1 Prior to proposal submission, order acceptance, or change order acceptance, PIMA VALVE, INC. reviews all pertinent requirements (**Contract Review Procedure OP-2**). Reviews are recorded. Each review ensures that:

- Product and Service requirements are defined.
- PIMA VALVE, INC. is able to meet defined requirements.
- Requirements differing from those previously expressed are resolved.
- Requirements not documented by the Customer are confirmed before acceptance
- Statutory and regulatory requirements are met

8.2.3.2 PIMA VALVE, INC. shall retain documented information on the results of the review, as applicable, and on any new requirements for products and services.

8.2.4 CHANGES TO REQUIREMENTS FOR PRODUCTS AND SERVICES

PIMA VALVE, INC. shall ensure that documented information is amended, and that relevant persons are made aware of the change in requirements.

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

8.3.1 GENERAL

PIMA VALVE, INC. shall establish, implement, and maintain a design and development process (**Design and Development Procedure OP-22**) that is appropriate to ensure the subsequent provision of products and services.

8.3.2 DESIGN AND DEVELOPMENT PLANNING

PIMA VALVE, INC. shall consider the following when determining stages and controls for design and development:

a) The nature, duration, and complexity of design and development activities

b) The required process states, including applicable design and development reviews

c) The required design and development verification and validation activities

d) The responsibilities and authorities involved in the design and development process

e) The internal and external resource needs for the design and development of products and services

f) The need to control interfaces between persons involved in the design and development process

g) The need for involvement of customers and users in the design and development process

h) The requirements for subsequent provision of products and services

i) The level of control expected for the design and development process by customers and other relevant parties

j) The documented information needed to demonstrate that design and development requirements have been met

8.3.3 DESIGN AND DEVELOPMENT INPUTS

PIMA VALVE, INC. shall determine the requirements essential to products and services to be designed and developed, and shall consider

a) Functional and performance requirements

b) Information derived from previous similar design and development activities

c) Statutory or regulatory requirements

d) Standards or codes of practice that PIMA VALVE, INC. has committed to implement

e) Potential consequences of failure due to the nature of the products and services

Inputs shall be complete and unambiguous. PIMA VALVE, INC. shall retain documented information on inputs.

8.3.4 DESIGN AND DEVELOPMENT CONTROLS

PIMA VALVE, INC. shall apply controls to design and development processes to ensure that:

a) The results to be achieved are defined

b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements

c) Verification activities are conducted to ensure that the design and development outputs meet input requirements

d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use

e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities

f) Documented information of these activities is retained

8.3.5 DESIGN AND DEVELOPMENT OUTPUTS

PIMA VALVE, INC. shall ensure that design and development outputs:

a) Meet the input requirements

b) Are adequate for the subsequent processes for the provision of products and services

c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria

d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision

e) Are documented

8.3.6 DESIGN AND DEVELOPMENT CHANGES

PIMA VALVE, INC. shall identify, review, and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

PIMA VALVE, INC. shall retain documented information on:

a) Design and development changes

b) The results of reviews

c) The authorization of changes

d) The actions taken to prevent adverse impacts

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PROCESSES, AND SERVICES

8.4.1 GENERAL

PIMA VALVE, INC. ensures that all externally provided processes, products, or services, if required, conform to specified requirements (**External Provider Quality System for Externally Provided Material OP-6**). Moreover, that external provider's services and subcontractors are controlled, dependent upon the effect that the services may have on the subsequent service delivered to the customer.

External provision of processes, products, and services, if applicable, is defined. External Provider records are maintained.

The selection criteria and evaluation of external providers, if applicable, is define**.** Records of evaluation, performance, and corrective actions are maintained.

8.4.2 TYPE AND EXTENT OF CONTROL

Prior to use or delivery to the customer, PIMA VALVE, INC. verifies that all products or services, if applicable, meet specified requirements. Externally provided processes shall remain under the control of this Quality Management System and are subject to verification (**External Provider Quality System for Externally Provided Material OP-6**).

8.4.3 INFORMATION FOR EXTERNAL PROVIDERS

Prior to transmittal, PIMA VALVE, INC. ensures that all Purchase (External Provision) Orders clearly specify requirements for product and services, where applicable, including (where appropriate):

a) Service, process, procedure, or resource 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.

d) External providers' interactions with PIMA VALVE, INC.

e) Control and monitoring of External Providers' performance to be applied by PIMA VALVE, INC.

f) Onsite activities by PIMA VALVE, INC. or Customer Representative

8.5 PRODUCTION AND SERVICE PROVISION

8.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

PIMA VALVE, INC. conducts all activities under controlled conditions (**Inspection: Receiving, In-Process, and Final Procedure OP-10**). Controlled conditions include:

a) Availability of drawings, specifications, infrastructure and other information that defines production or service requirements and processes, or results to be achieved.

b) Availability of appropriate Work Instructions and resources.

c) Availability and use of suitable measuring and monitoring and measuring resources.

d) Verification of product or services at appropriate stages, is defined

e) Suitable infrastructure and environment for the operation of processes

f) Appointment of competent personnel

g) Actions to prevent human error

h) Implementation of release, delivery, and post-delivery activities

8.5.2 IDENTIFICATION AND TRACEABILITY

PIMA VALVE, INC. provides lot identification when required (**Product and Service Identification and Traceability Procedure OP-8**). Status is indicated, with respect to monitoring and measurement requirements, throughout product and service realization when required (**Inspection and Test Status OP-12**). Specific methods utilized for identification, traceability, status, and maintenance of records are defined (**Lot Identification OP-21**).

8.5.3 PROPERTY BELONGING TO CUSTOMERS OR EXTERNAL PROVIDERS

Customer or External Provider property is controlled and subjected to verification prior to use (**Customer and External Provider Supplied Product Procedure OP-7**). In all cases, PIMA VALVE, INC. ensures that:

a) Customer or External Provider property is clearly identified, and safeguarded against damage or loss.

b) The Customer or External Provider is advised of any damage or loss.

c) Records of Customer or External Provider property receipt and disposition are maintained.

8.5.4 PRESERVATION

PIMA VALVE, INC. preserves the product or service 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 (**Product and Service Handling, Receiving, Packaging, Preservation, Storage, and Delivery Procedure OP-15**).

8.5.5 POST-DELIVERY ACTIVITIES

PIMA VALVE, INC. meet post-delivery requirements associated with products and services.

Determination of the extent of post-delivery activities shall consider:

a) Statutory and regulatory requirements

b) The potential undesired consequences associated with products and services

c) The nature, use, and intended lifetime of products and services

d) Customer requirements

e) Customer feedback

8.5.6 CONTROL OF CHANGES

PIMA VALVE, INC. shall review and control changes for product or service provision to ensure continuing conformity with requirements. Documented information describing the results of the review, persons authorizing the change, and necessary actions will be retained.

8.6 RELEASE OF PRODUCTS AND SERVICES

Measurement requirements for product and service 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.

The release of products or services 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.

8.7 CONTROL OF NONCONFORMING OUTPUTS

8.7.1 Nonconforming products and services are identified, segregated, and controlled to prevent their unintended use or delivery to the customer (**Control of Nonconforming Product or Service Procedure OP-13**).

- Authorities for the review and disposition of nonconforming products and services are specified.
- Nonconforming products and services may be accepted by customer concession or reworked to achieve conformance.
- If nonconforming products and services are reworked, they are subjected to re-verification. (Refer to clauses 8.4.2 and 8.5.1.d)
- If nonconforming products and services are detected following delivery to the customer, the company initiates measures commensurate with actual or potential effects of the nonconformance.

8.7.2 Records of product or service nonconformance, review, disposition, and approval are maintained.

9.0 PERFORMANCE EVALUATION

9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

9.1.1 GENERAL

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

institutes appropriate measurement, analysis, and improvement measures. See 4.4 for items monitored by PIMA VALVE, INC.

9.1.2 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 9.3.2.). This includes:

- Customer complaints
- Product returns
- On-time delivery trends
- Submittal of customer satisfaction surveys

9.1.3 ANALYSIS AND EVALUATION

Quality Management System improvement is affected through the regular collection and analysis of data relating to customer satisfaction, product and service conformity, process performance, and external provider performance. Improvement measures are instituted during Management Reviews (refer to clause 9.3.3) and through corrective and preventive actions (refer to clauses 8.5.2 and 10.2.1). Effectiveness of actions taken to address risks and opportunities are evaluated.

9.2 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 (**Internal Quality Audits Procedure OP-17**) and the requirements of ISO 9001:2015.

9.2.1 Audit description:

- Each audit is scheduled based upon the importance of the function being audited, as well as previous audit results.
- Each audit is planned and conducted in a systematic manner. Prior to auditing a function, the audit criteria and scope are defined.
- Trained auditors are assigned based upon their objectivity and impartiality. Auditors do not audit their own work.
- Department managers ensure any necessary corrections and corrective actions raised within their departments are processed in a timely and effective manner. (Refer to clause 10.2.1)
- Audit records are maintained, including audit results, corrective actions taken, and follow-up activities.
- Relevant QMS processes are monitored during Internal Audits. (Refer to clause 9.2) Critical processes are measured to demonstrate their ability to achieve planned results. Specific measurement requirements are established during Management Reviews. (Refer to clause

9.3.2.) Correction and Corrective Action is taken, as appropriate, for processes that do not achieve planned results. (Refer to clause 8.5.2.)

- Relevant QMS product and service characteristics are monitored during Internal Audits. (Refer to clause 9.2.) Product and service characteristics are verified so that product and service requirements are met. Inspections are performed at appropriate stages to verify product and service status, and sampling inspection is used as a means of verification. Corrective action is taken for products and services that do not achieve planned results. (Refer to clause 10.2.1.)

9.3 MANAGEMENT REVIEW

9.3.1 GENERAL

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.

9.3.2 MANAGEMENT REVIEW INPUTS

All aspects listed below are addressed during each annual Management Review cycle, in order to accurately assess current system performance and encourage improvement opportunities:

- Internal Audit results
- Customer feedback (including complaints)
- Achievement of Quality Objectives
- Process performance, product and service conformity results and review of measurement requirements
- Corrective and Preventive Action status
- Action Item results (from previous Management Reviews)
- Changing business and operational conditions that may affect the QMS
- Review of objectives and improvement recommendations
- Adequacy of Resources
- Effectiveness of actions taken to address risks and opportunities
- External Provider performance results

9.3.3 MANAGEMENT REVIEW OUTPUTS

Management Review minutes are recorded and made available to all attendees and other affected parties. In addition to documenting the items listed in clause 9.3.2 (above), minutes clearly indicate Action Items assigned, including:

- QMS improvement measures and effectiveness.
- Process and service improvement measures.
- Resource requirements to achieve improvement.

10.0 IMPROVEMENT

10.1 GENERAL

PIMA VALVE, INC. shall determine and select opportunities for improvement, and implement necessary measures to meet customer requirements and enhance customer satisfaction, including:

a) Improving products and services to meet requirements as well as to address future needs and expectations

b) Correcting, preventing, and reducing undesired effects

c) Improving performance and effectiveness of the Quality Management System

10.2 NONCONFORMITY AND 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 (**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

f) Make changes to the Quality Management System if required

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, including:

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

f) Make changes to the Quality Management System if required

10.2.1 Records of Corrective or Preventive Actions taken and their results are maintained.

10.3 CONTINUAL 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.