




# **Fluidtrol Process Technologies, Inc**

**ISO 9001:2015**

**QUALITY MANAGEMENT SYSTEM**

## **Quality Manual**

**QUALITY MANUAL CHANGE HISTORY RECORD**

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**TITLE: FLUIDTROL PROCESS TECHNOLOGIES QUALITY MANUAL**

**No: NONE**

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## **INTRODUCTION**

Fluidtrol Process Technologies (FPT) has developed and implemented a quality management system to better satisfy the needs of its customers and to improve management of the company. The quality management system conforms to the requirements of international standard ISO 9001:2015. The system covers the design, production, installation, and servicing of the company's products.

The manual is divided into 10 sections with 7 sections corresponding to quality management system requirements of ISO 9001:2015 and 3 sections directly reflecting to Fluidtrol Process Technologies. It is preferred that our Suppliers establish their Quality Systems to these guidelines, but it is also understood that some elements of their system may not apply.

Each section contains specific procedural policies outlining how the general policy is carried out, and references the applicable standard operation procedures (SOP).

The purpose of this manual is to define and describe the quality management system, authorities and responsibilities of the management personnel affected by the system and to provide general procedures for all activities comprising the quality system. Additionally, this manual is to present our quality management system to our customers and to inform them what specific controls are implemented to assure product and service quality.



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### 1.0 Scope.

Design and manufacture of Corrosion Resistant Structures and Strainers for Commercial and Industrial applications.

Although, Fluidtrol Process Technologies, Inc. maintains a process for design and development for new products in the future, the organization intends to grandfather all initial design data and documentation for existing designs (FPT-SOP 8.3, sections 1 through 7) given that, critical design and development data and documentation are simply non-existent.

This quality manual and related documents make-up the quality policies and procedures at Fluidtrol Process Technologies. Each employee is required to comply with the quality policy and related procedures as it pertains to each employee's job.

### 1.1 General.

Fluidtrol Process Technologies' Quality Management System (QMS) is the means of implementing process improvements and ensuring all products and services conform to specified customer and company requirements.

### 1.2 Application.

Fluidtrol Process Technologies Quality Manual documents the systematic requirements and principles for its QMS. It governs policies, Standard Operating Procedures and Work Instructions and specifies how they relate to the overall operation of the QMS. It is consistent with Fluidtrol Process Technologies' Core Attributes, Values and Quality Policy. It assigns responsibilities and sets up authority for carrying out quality processes to consistently meet our customer's contractual requirements and quality expectations.

### 1.3 Exceptions / Exclusions.


None.

### 1.4 Quality Policy and Objectives.

#### *Quality Policy Statement.*

It is the policy of Fluidtrol Process Technologies to provide products of the highest quality in the

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respective market segments served. In all activities, Fluidtrol Process Technologies' Quality Policy is:

***" Fluidtrol's commitment is complete Customer Satisfaction through Quality Products manufactured with Innovative Techniques and Continual Improvement."***

***Objectives for Quality.***

The management at Fluidtrol Process Technologies has implemented a quality system as a means of achieving the following Quality goals: Fluidtrol Process Technologies Management has formally endorsed and established Quality objectives for this year and beyond to include:

- **Strive for 100% Customer Satisfaction Rating.**
- **Achieve 10% Scrap Reduction.**
- **95% On-Time Delivery.**

Fluidtrol Process Technologies communicates quality objectives to all employees through training, meetings, newsletters, and other means. Progress toward achieving these objectives is tracked as written in procedures and regularly publicized to employees.

To help meet these objectives, Fluidtrol Process Technologies will obtain, implement and maintain registration for a quality management system that meets the requirements of: ISO 9001:2015 Quality Management Systems – Requirements.

**1.5 Management Commitment and Approval.**

***Commitment.***

Fluidtrol Process Technologies management and employees are committed to our Quality Policy. Everyone understands their role in the QMS and works within it to help achieve our quality objectives. Management regularly reviews the performance of the quality system to assess, assure, and improve its effectiveness.

***Approval.***

This Quality Manual has been reviewed and approved on the date entered on the Document Approval/Change History Record.

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**Erik Shell / President/Management Rep**

## 2.0 Quality Management System (QMS) Structure

The QMS requirements apply to all Fluidtrol Process Technologies efforts. Fluidtrol Process Technologies QMS consists of the following elements:

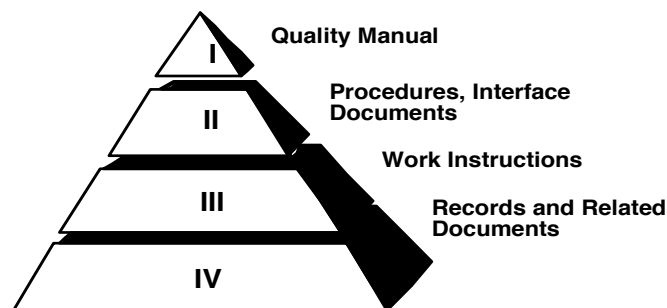
**Quality Manual (QM)** - Fluidtrol Process Technologies' quality policies, quality practices (including responsibility and authority) for activities and cross-references to Procedures (Ref. Section 2.2).

**Standard Operating Procedures (SOPs)** - Required by the International Standard or by Fluidtrol Process Technologies to define quality processes (including responsibility and authority). They also cross-reference to Work Instructions (where relevant).

**Work Instructions (WIs)** – Established by Fluidtrol Process Technologies when certain quality-intensive tasks are required.

**Records, Forms and Related Documents** – are as specified by Procedures or Work Instructions, as appropriate.


### Documentation Hierarchy



This Manual describes quality responsibilities and policies consistent with International Standard, *ISO 9001:2015 Quality Management Systems - Requirements*. When required, program specific quality plans add to the requirements of this Manual to meet specific contract requirements.

Fluidtrol Process Technologies maintains procedures consistent with requirements of this Manual for control of quality processes. The Fluidtrol Process Technologies outsourced audit team is responsible for

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maintaining an independent audit function to monitor the adherence to the requirements of this Manual and implementation of procedures. Audits verify that the organization is following the procedures, work instructions and that the QMS is maintained and effective.

This Manual is reviewed by Fluidtrol Process Technologies annually and updated as needed. The procedures and work instructions are reviewed and updated per document change procedure requirements Ref: FPT-SOP-4.4, Quality Management System and its Processes and the Fluidtrol Process Technologies intranet under the QMS Section. These documents are the most current set of QMS documents.

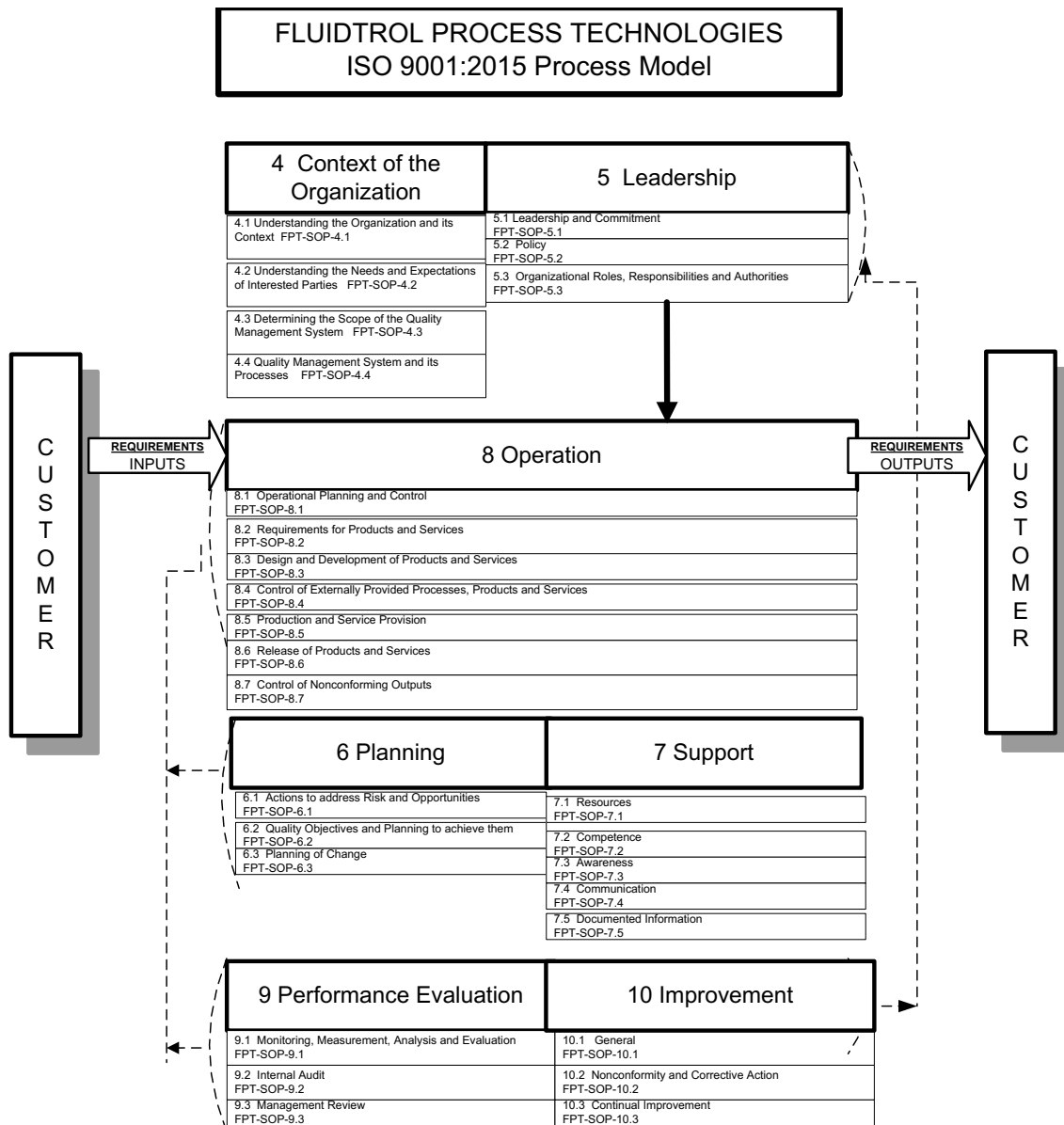
**Printing Copies from the Server:** Fluidtrol Process Technologies employees are encouraged to access the QMS documentation from a host computer. Any copy printed from the server bears a notation “This document in printed format is valid for 48 hours from *Print Date*, after which it is obsolete.” Do not print and maintain unauthorized copies of QMS documentation beyond the print date these are not controlled copies and may result in an audit finding.


The QM Change History Record (FPT-FM-4.4-4) identifies approved revisions to this manual. This form indicates the issue date for the latest release, the release number, authorized approvers, and a description of the change. The Process Owners and the Management Representative approve revisions to the Quality Manual, Procedures, or Work Instructions.

## 2.1 Matrix to Quality System Procedures

Note: Responsibility and authority is defined in Quality System Procedures; for processes not defined by procedures, responsibility and authority is defined in the relevant section of this Quality Manual. The *Fluidtrol Process Technologies Quality Manual* is structured under the new *ISO 9001:2015 (Fifth Edition) Quality Management Systems – Requirements*.

### 2.2 Fluidtrol Process Technologies Process Model



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Sections 1, 2 and 3 are unique to the QMS requirements of Fluidtrol Process Technologies.

**Non-Applicable Requirements**

*ISO 9001:2015 (Fifth Edition) Quality Management Systems –*

There are no exclusions to this Quality Management System (QMS).



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### 3.0 Company Profile.

Fluidtrol Process Technologies, Inc. (FPT) located in Huntsville, Alabama is a custom manufacturer of Corrosion resistant basket strainers for commercial aquatic systems, zoos, fresh water, sea water, industrial and chemical applications. Strainer materials include PVC, CPVC, Fiberglass, Polypropylene and PVDF.

Also for commercial aquatics, we manufacture modulating float valves (made from polypropylene) and flanged concentric/eccentric reducers (made from PVC/FRP Duel Laminate or Stainless T304).

Fluidtrol's entire line of standard industrial strainers can be customized or modified to suit specific applications or plumbing requirements. From mining operations to OEM applications, Fluidtrol has the expertise and capabilities required to produce custom basket strainers in a variety of materials, styles, and optional features.

Our wye type industrial strainers are designed for in-line piping in either a vertical or a horizontal orientation and are available in sizes 2 inches and up. Models are available in wetted parts of PVC, CPVC, PP and PVDF. An all fiberglass reinforced plastic (FPR) unit is also available. All wye units feature a cleanout port, which eliminates the need for removing the basket when performing routine cleaning. Fluidtrol manufactures wye type strainers to standards that exceed industry standards which enables operation in critical applications where high flow rates and high loading potential exist, while low pressure drops are desired.

Although, Fluidtrol Process Technologies maintains a process for design and development for new products in the future, the organization intends to grandfather all initial design data and documentation for existing designs (FPT-SOP 8.3, sections 1 through 7) given that, critical design and development data and documentation are simply non-existent.

### 3.1 Mission Statement.

It is Fluidtrol Process Technologies' mission to not only meet, but exceed our customer's expectations. We operate under a high standard of precision, quality of workmanship and customer service. Attributes driving success of our mission include:

- Striving for complete satisfaction.
- Exceeding requirements and expectations.
- Providing superior products and services on a consistent basis.
- Being pro-active.

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- Following honest and ethical practices.
- Being completely accountable for our actions.
- Performing within reasonable cost.

### 3.2 Core Attributes.

Fluidtrol Process Technologies, Inc. finds that certain *Core Attributes* are routinely used to describe the company and our employees. We reinforce our desire to maintain this reputation with every business relationship we begin, and with every customer we serve. Some of these core attributes are provided below:

- **Innovation** – Fluidtrol Process Technologies maintains a "cutting edge" atmosphere that encourages employee creativity and thinking outside the box and allows them the freedom to take the necessary risks to implement these ideas.
- **Cooperation**- Fluidtrol Process Technologies employees exhibit an unselfish will to achieve common corporate and customer goals as well as to help others succeed.
- **Experts**- Fluidtrol Process Technologies employees strive to be world-renowned leaders in their fields of expertise, continually upgrade their knowledge base and staying abreast of technological advancements and innovations.
- **Customer focused** – Fluidtrol Process Technologies employees recognize that we exist to support our customers and act accordingly by knowing who our customers are and understanding their requirements and needs.
- **Excellence** – Fluidtrol Process Technologies employees achieve the highest levels of performance, always striving to exceed company and customer expectations.
- **Integrity** – Fluidtrol Process Technologies employees are honest, trustworthy, and dependable and always strive to “do the right thing”. They lead by example and always act in a way to uphold Fluidtrol Process Technologies' ethics and our reputation.
- **Reliable** –Fluidtrol Process Technologies employees are dependable and consistently lend their efforts to solve the problems at hand and to support the goals of the organization and our customers.

### 3.3 Fluidtrol Process Technologies, Inc. Values and Vision.

Fluidtrol Process Technologies, Inc. has identified four Values, which support strategies of our business and are critical to achieving long-term success and Vision. They are enduring and are meant to guide employees in their daily work. They are also based upon Fluidtrol Process Technologies dedication to customers, employees, high ethical standards and social responsibilities.

**Teamwork** - The road to success starts with a team-minded approach. Effective teamwork among employees and with customers is the foundation upon which solid, total customer solutions are built.

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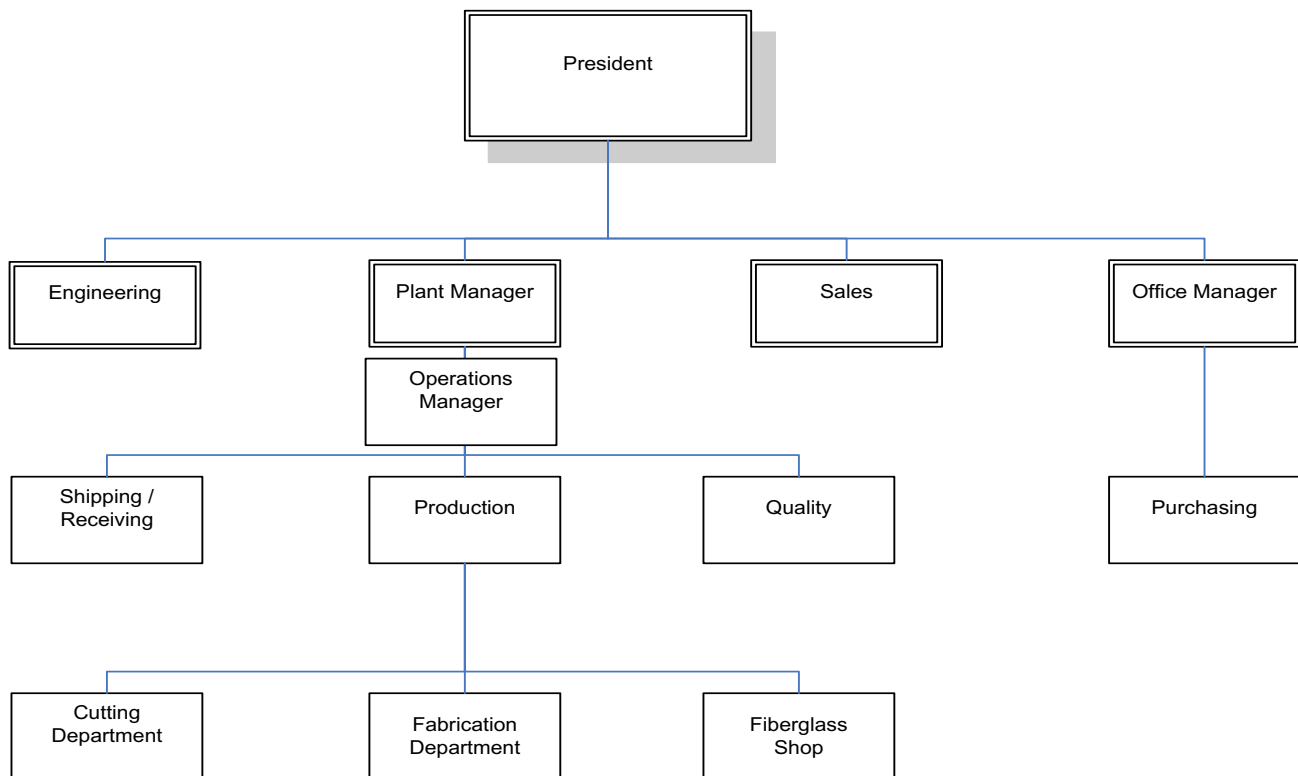
Fluidtrol Process Technologies uses the expertise of our professionals/employees to work as a single unit to efficiently deliver services, solve problems, improve processes and provide added value.

**Trust** – Fluidtrol Process Technologies builds relationships on trust with our customers and employees. We've proven that trusting relationships produce sound business practices.

**Empowerment** – Fluidtrol Process Technologies relies on the front-line support of key people to keep us a step ahead. We delegate responsibility and authority to employees who are closest to the job at hand. We stimulate and encourage initiative in each other to search for new, unique ideas and to maintain an environment of continuous learning.

**Commitment to People** - Our vision is firmly entrenched in the results we produce for the people we serve.

### 3.4 Fluidtrol Process Technologies, Inc. Organizational Chart.



#### **4.0 Context of the Organization.**

##### **4.1 Understanding the Organization and its context.**

Fluidtrol Process Technologies has determined the external and internal issues that are relevant to its purpose and its strategic direction that affects its ability to achieve the intended result(s) of its Quality Management System (QMS).

Fluidtrol Process Technologies monitors and reviews information about these external and internal issues.

##### **4.2 Understanding the needs and expectations of interested parties.**

Due to their effect or potential effect on Fluidtrol Process Technologies' ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Fluidtrol Process Technologies determines:

- a) The interested parties that are relevant to the Quality Management System (QMS),
- b) The requirements of these interested parties that are relevant to the Quality Management System.

Fluidtrol Process Technologies has monitored and reviewed information about these interested parties and their relevant requirements.

##### **4.3 Determining the Scope of the Quality Management System.**

Fluidtrol Process Technologies has determined the boundaries and applicability of the Quality Management System to establish its Scope.

When determining this scope, Fluidtrol Process Technologies has considered:

- a) The External and Internal Issues. (Ref: Para 4.1)
- b) The requirements of relative Interested Parties. (Ref: Para 4.2)
- c) Fluidtrol Process Technologies' products and services.

Fluidtrol Process Technologies applies all the requirements of ISO 9001:2015 if they are applicable within the determined scope of its Quality Management System.

The Scope of Fluidtrol Process Technologies' Quality Management System is available and maintained as documented information. The scope states the types of products and services covered, and provides

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justification for any requirement of ISO 9001:2015 that Fluidtrol Process Technologies determines is not applicable to the scope of its QMS.

Conformity of ISO 9001:2015 may only be claimed if the requirements determined as not being applicable do not affect to Fluidtrol Process Technologies' ability or responsibility to ensure the conformity of its products and services and the enhancement of Customer Satisfaction.

#### **4.4 Quality Management System and its processes.**

**4.4.1** Fluidtrol Process Technologies has established, implemented, maintained and continually improves a Quality Management System, including the processes needed and their interactions, in accordance with ISO 9001:2015.

Fluidtrol Process Technologies has determined the processes needed for the QMS and their application throughout Fluidtrol Process Technologies, and has:

- a) Determined the inputs required and the outputs expected from these processes,
- b) Determined the sequence and interaction of these processes,
- c) Determined and applied the criteria and methods, including monitoring, measurement, and related performance indicators,
- d) Determined the resources needed for these processes and ensures their availability,
- e) Assigns the responsibilities and authorities for these processes,
- f) Addresses the risks and opportunities as determined in accordance with requirements of FPT-SOP- 6.1,
- g) Evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results,
- h) Improves the processes and the QMS.

**4.4.2** To the extent necessary, Fluidtrol Process Technologies:

- a) Maintains documented information to support the operation of its processes.
- b) Retains documented information to have the confidence that the processes are being carried out as planned.

## 5.0 Leadership

### 5.1 Leadership and Commitment.

#### 5.1.1 General

Fluidtrol Process Technologies Management, demonstrates leadership and commitment with respect to the Quality Management System by:

- a) Taking accountability for the effectiveness of the QMS,
- b) Ensuring the Quality Policy and Quality Objectives are established for the QMS and are compatible with the context and strategic direction of Fluidtrol Process Technologies,
- c) Ensuring that the Quality Policy policy is communicated, understood and applied within the company.
- d) Ensuring the integration of the QMS requirements into Fluidtrol Process Technologies' business processes,
- e) Promoting the use of the process approach and risk-based thinking,
- f) Ensuring that resources needed for the QMS are availability,
- g) Communicating the importance of effective quality management and of conforming to the QMS requirements,
- h) Ensuring that the QMS achieves its intended results,
- i) Engaging, directing, and supporting persons to contribute to the effectiveness of the QMS,
- j) Promoting improvement,
- k) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### 5.1.2 Customer Focus.

Management demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met,
- b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed and,

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- c) The focus on enhancing customer satisfaction is maintained,

## **5.2 Policy.**

### **5.2.1 Establishing the Quality Policy.**

Management has established, implemented and maintained a quality policy that:

- a) Is appropriate to the purpose and context of Fluidtrol Process Technologies and supports its strategic direction,
- b) Provides a framework for setting Quality Objectives,
- c) Includes a commitment to satisfy applicable requirements,
- d) Includes a commitment to continual improvement of the QMS.

### **5.2.2 Communicating the Quality Policy.**

The Quality Policy shall:

- a) Be available and be maintained as documented information,
- b) Be communicated, understood and applied within Fluidtrol Process Technologies,
- c) Be available to relevant interested parties, as appropriate.

## **5.3 Organizational roles, responsibilities and authorities..**

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within Fluidtrol Process Technologies.

Top management shall assign the responsibility and authority for;

- a) Ensuring that the QMS conforms to the requirements of ISO 9001:2015.
- b) Ensuring that the processes are delivering their intended outputs,
- c) Reporting on the performance of the QMS and the opportunities for improvement (Ref: section 10.1), and in particular to top management,
- d) Ensuring the promotion of customer focus throughout Fluidtrol Process Technologies.
- e) Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and

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implemented.

## 6.0 Planning.

### 6.1 Actions to address risks and opportunities.

When planning for the Quality Management System (QMS), Fluidtrol Process Technologies considers the issues referred to in 4.1 and the requirements in 4.2 and determines the risks and opportunities that need to be addressed to:

- a) Give assurance that the QMS can achieve its intended result(s),
- b) Enhance desirable effects,
- c) Prevent, or reduce, undesirable effects,
- d) Achieve improvement.

### 6.2 Quality Objectives and planning to achieve them.

**6.2.1** Fluidtrol Process Technologies has established Quality Objectives at relative functions, levels and processes needed for the QMS. The Quality Objectives shall:

- a) Be consistent with the Quality Policy,
- b) Be measurable,
- c) Take into account applicable requirements,
- d) Be relevant to conformity of products and services and to enhancement of customer satisfaction,
- e) Be monitored,
- f) Be communicated,
- g) Be updated as appropriate.

**6.2.2** When planning how to achieve the Quality Objectives, Fluidtrol Process Technologies determines:

- a) What will be done,

- b) What resources will be required,
- c) Who will be responsible,
- d) When will to be completed,
- e) How the results will be evaluated.

### **6.3 Planning of changes.**

When Fluidtrol Process Technologies determines the need for changes to the QMS, the changes shall be carried out in a planned manner (see 4.4). Fluidtrol Process Technologies shall consider the purpose of the changes and their potential consequences, the integrity of the QMS, the availability of resources, and the allocation or realization of responsibilities and authorities.

## **7.0 Support.**

### **7.1 Resources.**

#### **7.1.1 General.**

Fluidtrol Process Technologies has determined and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. Fluidtrol Process Technologies considers the capabilities of and constraints on existing internal resources and what needs to be obtained from external providers.

#### **7.1.2 People.**

Fluidtrol Process Technologies has determined and provided the persons necessary for the effective implementation of its QMS and for operation and control of its processes.

#### **7.1.3 Infrastructure.**

Fluidtrol Process Technologies has determined, provided and maintained the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure can include buildings and associated utilities; equipment, including hardware and software; transportation resources; and information and communication technology.

#### **7.1.4 Environment for the operation of processes.**

Fluidtrol Process Technologies determines, provides and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. A suitable environment can be a combination human and physical factors, such as social, psychological, and physical. These factors can differ substantially depending on the products and services provided.

#### **7.1.5 Monitoring and measuring resources.**

##### **7.1.5.1 General.**

Fluidtrol Process Technologies determines and provides the resources needed to ensure valid and reliable results when monitoring and measuring is used to verify the conformity of products and services to requirements. Fluidtrol Process Technologies ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being taken and are maintained to ensure their continuing fitness for their purpose. Fluidtrol Process Technologies shall retain appropriate documented

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information as evidence of fitness for purpose of the monitoring and measuring resources.

#### **7.1.5.2 Measurement traceability.**

When measurement traceability is a requirement, or is considered by Fluidtrol Process Technologies to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to NIST standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) Identified in order to determine their status;
- c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

Fluidtrol Process Technologies shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

#### **7.1.6 Organizational knowledge.**

Fluidtrol Process Technologies has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, Fluidtrol Process Technologies shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

#### **7.2 Competence.**

Fluidtrol Process Technologies will determine the necessary competence of person(s) doing work under the control that affects the performance and effectiveness of the QMS; Ensure that these persons are competent on the basis of appropriate education, training, or experience; where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; and retain appropriate documented information as evidence of competence.

#### **7.3 Awareness.**

Fluidtrol Process Technologies ensures that persons doing work under Fluidtrol Process Technologies' control are aware of the Quality Policy; relevant Quality Objectives; their contribution to the effectiveness

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of the QMS, including the benefits of improved performance; and the implications of not conforming with the QMS requirements.

#### **7.4 Communication.**

Fluidtrol Process Technologies determines the internal and external communications relevant to the QMS, including what to communicate, when to communicate, with whom to communicate, how to communicate and who communicates.

#### **7.5 Documented information.**

##### **7.5.1 General.**

Fluidtrol Process Technologies' Quality Management System includes documented information required by ISO 9001:2015; documented information determined by Fluidtrol Process Technologies as being necessary for the effectiveness of the QMS; the complexity of processes and their interactions and the competence of persons.

##### **7.5.2 Creating and updating.**

When creating and updating documented information, Fluidtrol Process Technologies shall ensure appropriate identification and description; format; media and review and approval for suitability and adequacy.

##### **7.5.3 Control of documented information.**

**7.5.3.1** Documented information required by the QMS and ISO 9001:2015 shall be controlled to ensure it is available and suitable for use, where and when it is needed and it is adequately protected (e.g. from loss of confidentiality, improper use or loss of integrity).

**7.5.3.2** For the control of documented information, Fluidtrol Process Technologies shall address the following activities, as applicable:

- a) Distribution, access, retrieval and use;
- b) Storage and preservation, including preservation of legibility;
- c) Control of Changes;
- d) Retention and disposition.



Documented information of external origin determined by Fluidtrol Process Technologies to be necessary for the planning and operation of the QMS shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unauthorized alterations.

## **8.0 Operations.**

### **8.1 Operational planning and control.**

Fluidtrol Process Technologies plans and implements and controls processes needed to meet requirements of products and services, to ensure conformity of the QMS, and to implement the actions determined in section 6.0 by:

- a) Determining the requirements for the products and services;
- b) Establishing criteria for:
  - 1) The processes;
  - 2) The acceptance of products and services.
- c) Determining the resources needed to achieve conformity to the product and service requirements;
- d) Implementing control of the processes in accordance with the criteria;
- e) Determining , maintaining and retaining documented information to the extent necessary;
  - 1) To have confidence that the processes have been carried out as planned;
  - 2) To demonstrate the conformity of products and services to their requirements.

Fluidtrol Process Technologies controls planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. Fluidtrol Process Technologies ensures that outsourced processes are controlled (Ref 8.4).

## **8.2 Requirements for Products and Services.**

### **8.2.1 Customer Communication.**

Communication with customers includes providing information relating to products and services; handling enquires, contracts or orders, including changes; obtaining customer feedback relating to products and services, including customer complaints; handling or controlling customer property; and establishing specific requirements for contingency actions, when relevant.

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**8.2.2 Determining the requirements for Products and Services..**

When determining the requirements for the products and services, Fluidtrol Process Technologies ensures that:

- a) The requirements for the products and services are defined, including:
  - 1) Any applicable statutory and regulatory requirements;
  - 2) Those considered necessary by Fluidtrol Process Technologies.
- b) Fluidtrol Process Technologies meets the claims for products and services it offers.

**8.2.3 Review of the requirements for Products and Service.**



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**8.2.3.1** Fluidtrol Process Technologies ensures that it has the ability to meet the requirements for products and services **to be** offered to customers. Fluidtrol Process Technologies conducts a review before committing to supply products and services to a customer, to include:

- a) Requirements specified by the Customer, including the requirements for delivery and post-delivery activities;
- b) Requirements not stated by the Customer, but necessary for the specified or intended use, when known;
- c) Requirements specified by Fluidtrol Process Technologies;
- d) Statutory and Regulatory requirements applicable to the products and services;
- e) Contract or order requirements differing from those previously expressed.

Fluidtrol Process Technologies ensures that contract or order requirements differing from those previously defined are resolved. Customer requirements are confirmed by Fluidtrol Process Technologies before acceptance, when the customer does not provide a documented statement of their requirements. In some situations, such as internet sales, a formal review is impractical for each order; instead the review can cover relevant product information, such as catalogs.

**8.2.3.2** Fluidtrol Process Technologies retains documented information, as applicable on the results of the review and or any new requirements for the products and services.

**8.2.4 Changes to requirements for Products and Services.**

Fluidtrol Process Technologies ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

**8.3 Design and development of Products and Services.**

**8.3.1 General.**

Fluidtrol Process Technologies has established, maintained, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

**8.3.2 Design and development planning.**

In determining the stages and controls for design and development, Fluidtrol Process Technologies shall consider:

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- a) The nature, duration and complexity of the design and development activities;
- b) The required process stages, including applicable design and development reviews;
- c) The required design and development verification activities;
- d) The responsibilities and authorities involved in the design and development process;
- e) The internal and external resources needs for the design and development of products and services;
- f) The need to control interfaces between persons involved in the design and development processes;
- 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 interested parties;
- j) The documented information needed to demonstrate that design and development requirements have been met.

### **8.3.3 Design and development inputs.**

Fluidtrol Process Technologies shall determine the requirements essential for the specific types of products and services to be designed and developed. Fluidtrol Process Technologies considers:

- a) Functional and performance requirements;
- b) Information derived from previous or similar design and development activities;
- c) Statutory and regulatory requirements;
- d) Standards or codes of practice that Fluidtrol Process Technologies has committed to implement;
- e) Potential consequences of failure due to the nature of the products and services;

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. Fluidtrol Process Technologies shall retain documented information on design and development inputs.

### **8.3.4 Design and development controls.**

Fluidtrol Process Technologies shall apply controls to the design and development process to ensure that:

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- 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 the 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 are retained.

Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of Fluidtrol Process Technologies.

### **8.3.5 Design and development outputs.**

Fluidtrol Process Technologies ensures that design and development output meets the input requirements; are adequate for the subsequent processes for the provision of products and services; include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; and specify the characteristics of the products and services that are essential for the intended purpose and their safe and proper provision.

Fluidtrol Process Technologies shall retain documented information on design and development outputs.

### **8.3.6 Design and development changes.**

Fluidtrol Process Technologies identifies, reviews and controls 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.

Fluidtrol Process Technologies shall retain documented information on:

- a) Design and development changes;
- b) The results of reviews;
- c) The authorization of the changes;

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- d) The actions taken to prevent adverse impacts.

#### **8.4 Control of externally provided processes, products, and services.**

##### **8.4.1 General.**

Fluidtrol Process Technologies ensures that externally provided processes, products and services conform to requirements.

Fluidtrol Process Technologies determines the controls to be applied to externally provided processes, products and services when:

- a) Products and services from external providers (suppliers) are intended for incorporation into Fluidtrol Process Technologies's own products and services.
- b) Products and services are provided directly to the customer(s) by external providers as a result of a decision by the Fluidtrol Process Technologies.
- c) A process, or part of a process, provided by an external provider as a result of a decision by the Fluidtrol Process Technologies.

##### **8.4.2 Type and extent of control..**

Fluidtrol Process Technologies determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Fluidtrol Process Technologies will retain documented information of these activities and any necessary actions arising from their evaluations.

Fluidtrol Process Technologies shall:

- a) Ensure that externally provided processes remain within the control of its QMS.
- b) Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output.
- c) Take into consideration the potential impact of the externally provided processes, products and services on Fluidtrol Process Technologies' ability to consistently meet customer and applicable statutory and regulatory requirements; and the effectiveness of the controls applied by the external provider.
- d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

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### **8.4.3 Information for external providers.**

- a) Fluidtrol Process Technologies ensures the adequacy of requirements prior to their communication to the external provider. Fluidtrol Process Technologies shall communicate to external providers its requirements for the processes, products and services to be provided.
- b) The approval of products and services; methods, processes and equipment; and the release of products and services.
- c) Competence, including any required qualification of persons.
- d) The external provider's interactions with Fluidtrol Process Technologies.
- e) Control and monitoring of the external providers' performance to be applied to Fluidtrol Process Technologies.
- f) Verification and validation activities that Fluidtrol Process Technologies, or its customer, intends to perform at the external providers' premises.

## **8.5 Production and Service provision..**

### **8.5.1 Control of Production and Service provision.**

Fluidtrol Process Technologies shall implement production and service provision under controlled conditions. Controlled conditions include, as applicable:

- a) The availability of documented information that defines the characteristics of the products to be processed, the services to be provided or the activities to be performed and the results to be achieved.
- b) The availability and use of suitable monitoring and measuring resources.
- c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met.
- d) The use of suitable infrastructure and environment for the operation of processes.
- e) The appointment of competent persons, including any required qualification.
- f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.
- g) The implementation of actions to prevent human error.
- h) The implementation of release, delivery and post-delivery activities.

### **8.5.2 Identification and traceability.**

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Fluidtrol Process Technologies uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services. Fluidtrol Process Technologies shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision; and shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to ensure traceability.

### 8.5.3 Property belonging to customers or external providers.

Fluidtrol Process Technologies shall exercise care with property belonging to customers or external providers while it is under Fluidtrol Process Technologies' control or being used by Fluidtrol Process Technologies. Fluidtrol Process Technologies shall identify, verify, protect and safeguard customer's or external provider's property provided for use or incorporated into the products and services. When the property of the customer or external provider is lost, damaged or otherwise found to be unsuitable for use, Fluidtrol Process Technologies shall report this to the customer or external provider and retain documented information on what has occurred. A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property or personal data.

### 8.5.4 Preservation.

Fluidtrol Process Technologies preserves the outputs during production and service provision, to the extent necessary to ensure conformity of requirements. Preservation can include identification, handling, containment, control, packaging, storage, transmission or transportation, and protection.

### 8.5.5 Post-delivery activities.

Fluidtrol Process Technologies shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, Fluidtrol Process Technologies considers statutory and regulatory requirements; the potential undesired consequences associated with its products and services; the nature, use and intended lifetime of its products and services; customer requirements; and customer feedback. Post delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

### 8.5.6 Control of changes.

Fluidtrol Process Technologies reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. Fluidtrol Process Technologies retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

### 8.6 Release of products and services.

Fluidtrol Process Technologies implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

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Fluidtrol Process Technologies retains documented information on the release of products and services. The documented information shall include evidence of conformity with the acceptance criteria and traceability to the person(s) authorizing the release.

### 8.7 Control of nonconforming output.

**8.7.1** Fluidtrol Process Technologies ensures that outputs that do not conform to the requirements are identified and controlled to prevent their unintended use or delivery. Fluidtrol Process Technologies shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

Fluidtrol Process Technologies deals with nonconforming outputs in one or more of the following ways:

- a) Correction.
- b) Segregation, containment, return or suspension of provision of products and services.
- c) Informing the customer.
- d) Obtaining authorization for acceptance under concession.

**8.7.2** Fluidtrol Process Technologies retains documented information that describes the nonconformity, describes the actions taken, describes any concessions obtained, and identifies the authority deciding the action in respect of the nonconformity.

### 9.0 Performance evaluation.

#### 9.1 Monitoring, measurement, analysis and evaluation.

##### 9.1.1 General.

Fluidtrol Process Technologies shall determine what needs to be measured; the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; when the monitoring and measuring shall be performed; and when the results from monitoring and measuring shall be performed. Fluidtrol Process Technologies shall evaluate the performance and the effectiveness of the QMS and retain appropriate documented information as evidence of the results.

##### 9.1.2 Customer satisfaction.

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Fluidtrol Process Technologies shall monitor customer's perception of the degree to which their needs and expectations have been fulfilled. Fluidtrol Process Technologies shall determine the methods for obtaining, monitoring and reviewing information. Monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, customer score cards, warranty claims and dealer reports.

### **9.1.3 Analysis and evaluation.**

Fluidtrol Process Technologies analysis's and evaluates appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate conformity of products and services; the degree of customer satisfaction; the performance and effectiveness of the QMS; if planning has been implemented effectively; the effectiveness of actions taken to address risk and opportunities; the performance of external providers and the need for improvements to the QMS. Methods to analysis data can include statistical techniques.

## **9.2 Internal Audit.**

**9.2.1** Fluidtrol Process Technologies conducts internal audits at planned intervals to provide information on whether the QMS conforms to Fluidtrol Process Technologies' own requirements for its QMS and the requirements of ISO 9001:2015 to verify that the QMS is effectively implemented and maintained.

**9.2.2** Fluidtrol Process Technologies has:

- a) Planned, established, implemented and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, taking into consideration the importance of the processes concerned, changes affecting Fluidtrol Process Technologies, and the results of previous audits.
- b) Defined the audit criteria and scope for each audit.
- c) Selected auditors and conduct audits to ensure objectivity and the impartiality of the audit process.
- d) Ensures the results of the audits are reported to relevant management.
- e) Takes appropriate correction and corrective actions without undue delay.
- f) Retains documented information as evidence of the implementation of the audit program and the audit results.

## **9.3 Management Review.**

### **9.3.1 General.**

Top management reviews Fluidtrol Process Technologies' QMS, at planned intervals, to ensure continuing suitability, adequacy, effectiveness and alignment with the strategic direction of Fluidtrol Process Technologies.

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### 9.3.2 Management Review Inputs.

The Management Review is planned and carried out taking into consideration:

- a) The status of actions from previous management reviews.
- b) Changes in external and internal issues that are relevant to the QMS.
- c) Information on the performance and effectiveness of the QMS, including trends in customer satisfaction and feedback from relevant interested parties; the extent to which quality objectives have been met; process performance and conformity of products and services; nonconformities and corrective actions; monitoring and measurement results; audit results and the performance of external providers.
- d) The adequacy of resources.
- e) The effectiveness of actions taken to address risk and opportunities (Ref: FPT-SOP-6.1).
- f) Opportunities for improvement.

### 9.3.3 Management Review Outputs.

The outputs of the management review includes decisions and actions related to:

- a) Opportunities for improvement.
- b) Any need for changes for the QMS.
- c) Resources needed.

Fluidtrol Process Technologies retains documented information as evidence of the results of management review.

## 10.0 Improvement.

### 10.1 General.

Fluidtrol Process Technologies determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These opportunities shall include:

- a) Improving products and services to meet requirements as well as address future needs and expectations.
- b) Correcting, preventing or reducing undesired effects.

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- c) Improving the performance and effectiveness of the QMS.

## 10.2 Nonconformity and corrective action.

10.2.1 When a nonconformity occurs, including any arising from complaints, Fluidtrol Process Technologies will:

- a) React to the nonconformity and, as applicable, take action to control and correct it; and deal with the consequences.
- b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by reviewing and analyzing the nonconformity; determining the causes of the nonconformity; and determining if similar nonconformities exist, or could potentially occur.
- c) Implement any action needed.
- d) Review the effectiveness of any corrective action taken.
- e) Update risks and opportunities determined during planning, if necessary.
- f) Make changes to the QMS, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 Fluidtrol Process Technologies retains documented information as evidence of the nature of the nonconformities and any subsequent actions taken; and the results of any corrective action.

## 10.3 Continual Improvement.

Fluidtrol Process Technologies continually improves the suitability, adequacy and effectiveness of the QMS. Fluidtrol Process Technologies considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

## Annex A - Acronyms

ANAB	American National Accreditation Board
ANSI	American National Standards Institute
ASQ	American Society for Quality
CP	Customer Property
SOP	Standard Operating Procedure

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IRCA	International Register of Certified Auditors
FPT	Fluidtrol Process Technologies
NIST	National Institute for Standards and Technology
QMS	Quality Management System
SEQMS	Southeast Quality Management Systems, LLC

### Annex B - Definitions

Audit	A systematic and independent examination to determine whether quality activities and related results comply with documented procedures and whether these procedures are implemented effectively and are suitable to achieve objectives.
Auditor	A person who is qualified and authorized to perform audits
Corrective action	An action taken to eliminate the present and future causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence.
Customer-supplied equipment	Equipment provided to Fluidtrol Process Technologies by the customer for a special purpose, such as servicing of test equipment, and not for incorporation into the end item to be delivered to the customer.
Customer-supplied product	Product owned by the customer and furnished directly to Fluidtrol Process Technologies for use in meeting the requirements of contracts. Customer supplied product is to be incorporated into the end item to be delivered to the customer.

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Lead Auditor	An auditor who is certified to manage audits and review audit results.
Management Representative	A management appointee who has defined authority and responsibility for ensuring that the requirements of the Fluidtrol Process Technologies Quality Management System are implemented and maintained.
Policy	A published management statement establishing governing principles, direction and prime responsibility for achieving corporate and legal objectives.
Pre-award survey	An evaluation of a prospective supplier's capability to perform under the terms of a proposed contract, including quality requirements.
Preventive action	Action taken to eliminate potential causes of non-conformity, defect or other undesirable situation in order to prevent occurrence.
Procedure	A published document normally implementing policy by prescribing the methodology through which action is initiated and controlled, responsibility is assigned, interfaces are defined, authority is delegated and accountability is assigned.
Program Plan	A document that identifies the specific quality practices, resources and sequence of activities relevant to a particular service, contract or project.
Quality Manual	The Fluidtrol Process Technologies Quality Manual stating quality policies and describing the QMS.
Risk Management	Risk management is the process of identification, analysis and either acceptance or mitigation of uncertainty in investment decision-making.
Servicing	After-sale attention provided for Fluidtrol Process Technologies services, usually at the customer's site.
Special process	Service process which requires special skills in its operation or maintenance or the results of which cannot be easily or fully verified by subsequent inspection and test.
Third Party Survey	Audits performed of supplier's or potential supplier's quality systems by an independent accredited ISO 9001 registration company.
Validation	The process of evaluating services to ensure compliance with specified requirements.
Verification	The process of evaluating product at a given design phase to ensure correctness and consistency with respect to the products and standards provided as input to that phase.
Work Instruction	A published document that provides detailed guidance and direction. It normally implements in greater detail the procedure requirements within a functional organization and is in compliance with established guidelines prescribed in policy or procedure.

## **Annex C - Instructions for the Use of Certificates and Logos**

**OBJECTIVE**      The objective of this operating procedure (OP) is to define the general requirements for certification and the use of certification marks, as well as actions to be taken in the event of misuse of the certification mark by the certificate holder.

### **APPENDIX 1 TO MANAGEMENT SYSTEM CERTIFICATE**

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(Placeholder pending certification)