



QUALITY MANAGEMENT SYSTEM

1. PURPOSE

1.1. AQUATEC QUALITY MANAGEMENT SYSTEM (QMS)

DESCRIPTION

- 1.1.1. Implements top-level company-wide quality system documentation.
- 1.1.2. Mandates additional policies to implement the QMS.
- 1.1.3. Documents procedure for quality manual, quality policy, and quality objectives, per ISO 9001:2000.

2. SCOPE

2.1. APPLICATIONS OF THIS CODE-OF-CONDUCT, POLICY, AND PROCEDURE

- 2.1.1. Executive Committee.
- 2.1.2. Supervisors and Managers.
- 2.1.3. Any employee working with salable products and services.

2.2. QMS IMPACT

- 2.2.1. Company Customers.
- 2.2.2. Company suppliers of products and services.
- 2.2.3. Corporation stakeholders.

2.3. EXCLUSIONS TO ISO 9001:2000

- 2.3.1. There are no declared exclusions to International Standard ISO 9001:2000.

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3. POLICY

3.1. QUALITY MANAGEMENT SYSTEM (QMS)

3.1.1. General requirements

3.1.1.1. Aquatec establishes, documents, implements and maintains a QMS and continually improves its effectiveness in accordance with the requirements of ISO 9001:2000.

3.1.1.2. Aquatec performs the following functions:

3.1.1.2.1. Identifies the processes needed for the QMS and their application throughout Aquatec.

3.1.1.2.2. Determines the sequence and interaction of these processes.

3.1.1.2.3. Determines criteria and methods needed to ensure that both the operation and control of these processes are effective.

3.1.1.2.4. Ensures the availability of resources and information necessary to support the operation and monitoring of these processes.

3.1.1.2.5. Monitors, measures and analyzes these processes.

3.1.1.2.6. Implements actions necessary to achieve planned results and continual improvement of these processes.

3.1.1.3. These processes are managed by Aquatec in accordance with the requirements of ISO 9001:2000.

3.1.1.4. Aquatec ensures control over outsourced processes that affect product conformity with requirements.

3.1.1.5. Control of such outsourced processes are identified within the QMS.

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3.1.1.6. Processes needed for the QMS include processes for management activities, provision of resources, product realization and measurement.

3.1.2. Documentation requirements

3.1.2.1. General

3.1.2.1.1. The QMS documentation includes:

3.1.2.1.1.1. Documented statements of a quality policy and quality objectives, included herein.

3.1.2.1.1.2. A quality manual.

3.1.2.1.1.3. Documented (formally released) procedures required by ISO 9001:2000.

3.1.2.1.1.4. Documents needed by Aquatec to ensure the effective planning, operation and control of its processes.

3.1.2.1.1.5. Records required by ISO 9001:2000.

3.1.2.2. Quality manual

3.1.2.2.1. Aquatec maintains a quality manual that includes:

3.1.2.2.1.1. The scope of the QMS, including details of and justification for any exclusions.

3.1.2.2.1.2. The documented (formally released) procedures established for the QMS, or reference to them.

3.1.2.2.1.3. A description of the interaction between the processes of the QMS.

3.1.2.3. Control of documents

3.1.2.3.1. Documents required by the QMS are controlled.

3.1.2.3.2. Records are a special type of document and are controlled according to the requirements.

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- 3.1.2.3.3. A documented (formally released) procedure, QMS002, defines the controls needed:
- 3.1.2.3.3.1. To approve documents for adequacy prior to issue.
 - 3.1.2.3.3.2. To review and update as necessary and re-approve documents.
 - 3.1.2.3.3.3. To ensure that changes and the current revision status of documents are identified.
 - 3.1.2.3.3.4. To ensure that relevant versions of applicable documents are available at points of use.
 - 3.1.2.3.3.5. To ensure that documents remain legible and readily identifiable.
 - 3.1.2.3.3.6. To ensure that documents of external origin are identified and their distribution controlled.
 - 3.1.2.3.3.7. To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

3.1.2.4. Control of records

- 3.1.2.4.1. Records maintain evidence of conformity to requirements and of the effective operation of the QMS.
- 3.1.2.4.2. Records are legible, readily identifiable and retrievable.
- 3.1.2.4.3. A documented (formally released) procedure, QMS002, defines the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

3.2. MANAGEMENT RESPONSIBILITY

3.2.1. Management commitment

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- 3.2.1.1. The Executive Committee consists of persons with ultimate company responsibility, authority and accountability:
- 3.2.1.1.1. Sami Levi, Chief Executive Officer and Chief Financial Officer
 - 3.2.1.1.2. Bryan Hausner, President; Vice President, Marketing
 - 3.2.1.1.3. Vasko Rizof, Manager, OEM Sales
 - 3.2.1.1.4. Isak Kucuklevi, Manager, Operations
 - 3.2.1.1.5. Ivar Schoenmeyr, Chief Technology Officer
 - 3.2.1.1.6. D. Paul Singh, Manager, Quality Assurance and Regulatory Affairs
 - 3.2.1.1.7. Bob LaTouche, Manager, Quality Systems
- 3.2.1.2. The Executive Committee provides evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness by:
- 3.2.1.2.1. Communicating to Aquatec the importance of meeting Customer as well as statutory and regulatory requirements.
 - 3.2.1.2.2. Establishing the quality policy.
 - 3.2.1.2.3. Ensuring that quality objectives are established.
 - 3.2.1.2.4. Conducting management reviews.
 - 3.2.1.2.5. Ensuring the availability of resources.
- 3.2.2. Customer focus
- 3.2.2.1. The Executive Committee ensures that Customer requirements are determined and are met with the aim of enhancing Customer satisfaction.

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3.2.3. Quality policy

- 3.2.3.1. Aquatec Water Systems is committed to becoming the preeminent provider of customized positive displacement pumps and related flow control devices to our global Customers.**
- 3.2.3.2. We realize this must be achieved with our continually improving quality system, the trust and respect of our Customers, the dedication of our employees recognized by management, and the support of our suppliers.**
- 3.2.3.3. Aquatec Water Systems will design and manufacture quality products, in compliance to requirements, within an ethical and fair environment for everyone.**
- 3.2.3.4. The Executive Committee ensures that the quality policy:

- 3.2.3.4.1. Is appropriate to the purpose of Aquatec.
- 3.2.3.4.2. Includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.
- 3.2.3.4.3. Provides a framework for establishing and reviewing quality objectives.
- 3.2.3.4.4. Is communicated and understood within Aquatec.
- 3.2.3.4.5. Is reviewed for continuing suitability.

3.2.4. Planning and quality objectives

3.2.4.1. Quality objectives

3.2.4.1.1. Salable product-specific objectives

- 3.2.4.1.1.1. Pumps meet all specified flow and pressure performance requirements.

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- 3.2.4.1.1.2. Pumps meet all specified sealing and fluid compatibility requirements.
- 3.2.4.1.1.3. Pumps meet all specified noise requirements.
- 3.2.4.1.1.4. Pumps meet all specified efficiency and life requirements, based on their operating environment.
- 3.2.4.1.1.5. Pumps meet all specified regulatory requirements.
- 3.2.4.1.2. Service-specific objectives
 - 3.2.4.1.2.1. Product warranty is determined specifically for each product model and its intended application.
 - 3.2.4.1.2.2. Product warranty service is completed in ten business days, or less, after receipt of product.
 - 3.2.4.1.2.3. Sales and Customer support inquiries are responded to within two business days.
- 3.2.4.1.3. The Executive Committee ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within Aquatec.
- 3.2.4.1.4. The quality objectives are measurable and consistent with the quality policy.
- 3.2.4.2. The policy and objectives are distributed in English and Spanish to company workers.
- 3.2.4.3. Quality management system planning
 - 3.2.4.3.1. The Executive Committee ensures that:
 - 3.2.4.3.1.1. The planning of the QMS is carried out in order to meet the requirements given and the quality objectives.

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3.2.4.3.1.2. The integrity of the QMS is maintained when changes to the QMS are planned and implemented.

3.2.5. Responsibility, authority and communication

3.2.5.1. Responsibility and authority

3.2.5.1.1. The Executive Committee ensures that responsibilities and authorities are defined and communicated within Aquatec.

3.2.5.1.2. Principle functional leadership and channels-of-communication are defined in the Aquatec Organization Chart.

3.2.5.2. Management representative

3.2.5.2.1. The Executive Committee appoints a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:

3.2.5.2.1.1. Ensuring that processes needed for the QMS are established, implemented and maintained.

3.2.5.2.1.2. Reporting to the Executive Committee on the performance of the QMS and any need for improvement.

3.2.5.2.1.3. Ensuring the promotion of awareness of Customer requirements throughout Aquatec.

3.2.5.2.2. The responsibility of a management representative includes liaison with external parties on matters relating to the QMS.

3.2.5.2.3. The Manager of Quality Systems is designated as Management Representative.

3.2.5.3. Internal communication

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3.2.5.3.1. The Executive Committee ensures that appropriate communication processes are established within Aquatec and that communication takes place regarding the effectiveness of the QMS.

3.2.6. Management review

3.2.6.1. General

3.2.6.1.1. The Executive Committee reviews Aquatec's QMS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

3.2.6.1.2. This review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.

3.2.6.1.3. Records from management reviews are maintained.

3.2.6.2. Review input

3.2.6.2.1. The input to management review includes information on:

3.2.6.2.1.1. Results of audits.

3.2.6.2.1.2. Customer feedback.

3.2.6.2.1.3. Process performance and product conformity.

3.2.6.2.1.4. Status of preventive and corrective actions.

3.2.6.2.1.5. Follow-up actions from previous management reviews.

3.2.6.2.1.6. Changes that could affect the QMS.

3.2.6.2.1.7. Recommendations for improvement.

3.2.6.3. Review output

3.2.6.3.1. The output from the management review includes any decisions and actions related to:

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3.2.6.3.1.1. Improvement of the effectiveness of the QMS and its processes.

3.2.6.3.1.2. Improvement of product related to Customer requirements.

3.2.6.3.1.3. Resource needs.

3.3. RESOURCE MANAGEMENT

3.3.1. Provision of resources

3.3.1.1.1. Aquatec determines and provides the resources needed:

3.3.1.1.1.1. To implement and maintain the QMS and continually improve its effectiveness.

3.3.1.1.1.2. To enhance Customer satisfaction by meeting Customer requirements.

3.3.2. Human resources

3.3.2.1. General

3.3.2.1.1. Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

3.3.2.2. Competence, awareness and training

3.3.2.2.1. Aquatec performs the following functions:

3.3.2.2.1.1. Determines the necessary competence for personnel performing work affecting product quality.

3.3.2.2.1.2. Provides training or take other actions to satisfy these needs.

3.3.2.2.1.3. Evaluates the effectiveness of the actions taken.

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3.3.2.2.1.4. Ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

3.3.2.2.1.5. Maintains appropriate records of education, training, skills and experience.

3.3.2.3. The Manager of Finance is responsible for the control of documents and records related to human resources.

3.3.2.4. Each employee's supervisor is responsible for recording that the employee meets the job criteria.

3.3.3. Infrastructure

3.3.3.1. Aquatec determines, provides and maintains the infrastructure needed to achieve conformity to product requirements.

3.3.3.2. Infrastructure includes, as applicable:

3.3.3.2.1. Buildings, workspace and associated utilities.

3.3.3.2.2. Process equipment (both hardware and software).

3.3.3.2.3. Supporting services (such as transport or communication).

3.3.3.3. The Manager of Operations is responsible for sufficient production environments.

3.3.4. Work environment

3.3.4.1. Aquatec determines and manages the work environment needed to achieve conformity to product requirements.

3.4. PRODUCT REALIZATION

3.4.1. Planning of product realization

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- 3.4.1.1. Aquatec plans and develops the processes needed for product realization.
 - 3.4.1.2. Planning of product realization is consistent with the requirements of the other processes of the QMS.
 - 3.4.1.3. In planning product realization, Aquatec determines the following, as appropriate:
 - 3.4.1.3.1. Quality objectives and requirements for the product.
 - 3.4.1.3.2. The need to establish processes, documents, and provide resources specific to the product.
 - 3.4.1.3.3. Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
 - 3.4.1.3.4. Records needed to provide evidence that the realization processes and resulting product meet requirements.
 - 3.4.1.4. The output of this planning is in a form suitable for Aquatec's method of operations.
 - 3.4.1.5. Documents specifying the processes of the QMS (including the product realization processes) and the resources to be applied to a specific product, project or contract, are designated "quality plan."
 - 3.4.1.6. Aquatec's product realization *processes* are developed similarly to *product designs*.
 - 3.4.1.7. The Manager of Engineering is responsible for product development planning.
- 3.4.2. Customer-related processes
- 3.4.2.1. Determination of requirements related to the product
 - 3.4.2.1.1. Aquatec determines:

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- 3.4.2.1.1.1. Requirements specified by the Customer, including the requirements for delivery and post-delivery activities.
- 3.4.2.1.1.2. Requirements not stated by the Customer but necessary for specified or intended use, where known.
- 3.4.2.1.1.3. Statutory and regulatory requirements related to the product.
- 3.4.2.1.1.4. Any additional requirements determined by Aquatec.
- 3.4.2.2. Review of requirements related to the product
 - 3.4.2.2.1. Aquatec reviews the requirements related to the product.
 - 3.4.2.2.2. These reviews are conducted prior to Aquatec's commitment to supply a product to the Customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that:
 - 3.4.2.2.2.1. Product requirements are defined.
 - 3.4.2.2.2.2. Contract or order requirements differing from those previously expressed are resolved.
 - 3.4.2.2.2.3. Aquatec has the ability to meet the defined requirements.
 - 3.4.2.2.3. Records of the results of the review and actions arising from the review are maintained.
 - 3.4.2.2.4. Where the Customer provides no documented statement of requirement, the Customer requirements are confirmed by Aquatec before acceptance.

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3.4.2.2.5. Where product requirements are changed, Aquatec ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

3.4.2.2.6. When formal review is impractical for each order, the review will cover relevant product information such as catalogs or advertising material.

3.4.2.3. Customer communication

3.4.2.3.1. Aquatec determines and implements effective arrangements for communicating with Customers in relation to:

3.4.2.3.1.1. Product information.

3.4.2.3.1.2. Inquiries, contracts or order handling, including amendments.

3.4.2.3.1.3. Customer feedback, including Customer complaints.

3.4.2.4. The company President is responsible for contract or order review processes, and appropriate communications with Customers.

3.4.3. Design and development

3.4.3.1. Design and development planning

3.4.3.1.1. Aquatec plans and controls the design and development of product.

3.4.3.1.2. During the design and development planning, Aquatec determines:

3.4.3.1.2.1. The design and development stages.

3.4.3.1.2.2. The review, verification and validation that are appropriate to each design and development stage.

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- 3.4.3.1.2.3. The responsibilities and authorities for design and development.
- 3.4.3.1.3. Aquatec manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
- 3.4.3.1.4. Planning outputs are updated, as appropriate, as the design and development progresses.
- 3.4.3.2. Design and development inputs
 - 3.4.3.2.1. Inputs relating to product requirements are determined and records maintained.
 - 3.4.3.2.2. These inputs include:
 - 3.4.3.2.2.1. Functional and performance requirements.
 - 3.4.3.2.2.2. Applicable statutory and regulatory requirements.
 - 3.4.3.2.2.3. Where applicable, information derived from previous similar designs.
 - 3.4.3.2.2.4. Other requirements essential for design and development.
 - 3.4.3.2.3. These inputs are reviewed for adequacy.
 - 3.4.3.2.4. Requirements are complete, unambiguous and not in conflict with each other.
- 3.4.3.3. Design and development outputs
 - 3.4.3.3.1. The outputs of design and development are provided in a form that enables verification against the design and development input and are approved prior to release.
 - 3.4.3.3.2. Design and development outputs:

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- 3.4.3.3.2.1. Meet the input requirements for design and development.
- 3.4.3.3.2.2. Provide appropriate information for purchasing, production and for service provision.
- 3.4.3.3.2.3. Contain or reference product acceptance criteria.
- 3.4.3.3.2.4. Specify the characteristics of the product that are essential for its safe and proper use.

3.4.3.4. Design and development review

- 3.4.3.4.1. At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements:
 - 3.4.3.4.1.1. To evaluate the ability of the results of design and development to meet requirements.
 - 3.4.3.4.1.2. To identify any problems and propose necessary actions.
- 3.4.3.4.2. Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed.
- 3.4.3.4.3. Records of the results of the reviews and any necessary actions are maintained.

3.4.3.5. Design and development verification

- 3.4.3.5.1. Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.
- 3.4.3.5.2. Records of the results of the verification and any necessary actions are maintained.

3.4.3.6. Design and development validation

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- 3.4.3.6.1. Design and development validation are performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.
- 3.4.3.6.2. Wherever practicable, validation is completed prior to the delivery or implementation of the product.
- 3.4.3.6.3. Records of the results of validation and any necessary actions are maintained.
- 3.4.3.7. Control of design and development changes
 - 3.4.3.7.1. Design and development changes are identified and records maintained.
 - 3.4.3.7.2. The changes are reviewed, verified and validated, as appropriate, and approved before implementation.
 - 3.4.3.7.3. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered.
 - 3.4.3.7.4. Records of the results of the review of changes and any necessary actions are maintained.
- 3.4.3.8. The Chief Technical Officer is responsible for defining research, development, and product qualification programs.
- 3.4.3.9. The Manager of Engineering is responsible for qualifying salable products prior to production.
- 3.4.3.10. The Manager of Operations is responsible for product change controls.
- 3.4.4. Purchasing
 - 3.4.4.1. Purchasing process

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- 3.4.4.1.1. Aquatec ensures that purchased product conforms to specified purchase requirements.
 - 3.4.4.1.2. The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product.
 - 3.4.4.1.3. Aquatec evaluates and selects suppliers based on their ability to supply product in accordance with Aquatec's requirements.
 - 3.4.4.1.4. Criteria for selection, evaluation and re-evaluation are established.
 - 3.4.4.1.5. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.
- 3.4.4.2. Purchasing information
- 3.4.4.2.1. Purchasing information describes the product to be purchased, including where appropriate:
 - 3.4.4.2.1.1. Requirements for approval of product, procedures, processes and equipment.
 - 3.4.4.2.1.2. Requirements for qualification of personnel.
 - 3.4.4.2.1.3. Quality management system requirements.
 - 3.4.4.2.2. Aquatec ensures the adequacy of specified purchase requirements prior to their communication to the supplier.
- 3.4.4.3. Verification of purchased product
- 3.4.4.3.1. Aquatec establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

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- 3.4.4.3.2. Where Aquatec or its Customer intends to perform verification at the supplier's premises, Aquatec states the intended verification arrangements and method of product release in the purchasing information.
- 3.4.4.4. The Manager of Operations is responsible for control of procured inventory and equipment.
- 3.4.4.5. The Manager of Quality Assurance is responsible for verification of procured inventory.
- 3.4.5. Production and service provision
 - 3.4.5.1. Control of production and service provision
 - 3.4.5.1.1. Aquatec plans and carries out production and service provision under controlled conditions.
 - 3.4.5.1.2. Controlled conditions include, as applicable:
 - 3.4.5.1.2.1. The availability of information that describes the characteristics of the product.
 - 3.4.5.1.2.2. The availability of work instructions, as necessary.
 - 3.4.5.1.2.3. The use of suitable equipment.
 - 3.4.5.1.2.4. The availability and use of monitoring and measuring devices.
 - 3.4.5.1.2.5. The implementation of monitoring and measurement.
 - 3.4.5.1.2.6. The implementation of release, delivery and post-delivery activities.
 - 3.4.5.2. Validation of processes for production and service provision
 - 3.4.5.2.1. Aquatec validates any processes for production and service provision where the resulting output cannot

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be verified by subsequent monitoring or measurement.

3.4.5.2.2. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

3.4.5.2.3. Validation demonstrates the ability of these processes to achieve planned results.

3.4.5.2.4. Aquatec establishes arrangements for these processes including, as applicable:

3.4.5.2.4.1. Defined criteria for review and approval of the processes.

3.4.5.2.4.2. Approval of equipment and qualification of personnel.

3.4.5.2.4.3. Use of specific methods and procedures.

3.4.5.2.4.4. Requirements for records.

3.4.5.2.4.5. Revalidation.

3.4.5.3. Identification and traceability

3.4.5.3.1. Where appropriate, Aquatec identifies the product by suitable means throughout product realization.

3.4.5.3.2. Aquatec identifies the product status with respect to monitoring and measurement requirements.

3.4.5.3.3. Where traceability is a requirement, Aquatec controls and records the unique identification of the product.

3.4.5.3.4. At Aquatec, configuration management supports product identification and traceability.

3.4.5.4. Customer property

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- 3.4.5.4.1. Aquatec exercises care with Customer property while it is under Aquatec's control or being used by Aquatec.
- 3.4.5.4.2. Aquatec identifies, verifies, protects and safeguards Customer property provided for use or incorporation into the product.
- 3.4.5.4.3. If any Customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the Customer and records maintained.
- 3.4.5.4.4. Customer property includes intellectual property.
- 3.4.5.5. Preservation of product
 - 3.4.5.5.1. Aquatec preserves the conformity of product during internal processing and delivery to the intended destination.
 - 3.4.5.5.2. This preservation includes identification, handling, packaging, storage and protection.
 - 3.4.5.5.3. Preservation also applies to the constituent parts of a product.
- 3.4.5.6. The Manager of Operations is responsible for production controls.
- 3.4.6. Control of monitoring and measuring devices
 - 3.4.6.1. Aquatec determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.
 - 3.4.6.2. Aquatec establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

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- 3.4.6.3. Where necessary to ensure valid results, measuring equipment is:
- 3.4.6.3.1. Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.
 - 3.4.6.3.1.1. Where no such standards exist, the basis used for calibration or verification is recorded.
 - 3.4.6.3.2. Adjusted or re-adjusted as necessary.
 - 3.4.6.3.3. Identified to enable the calibration status to be determined.
 - 3.4.6.3.4. Safeguarded from adjustments that would invalidate the measurement result.
 - 3.4.6.3.5. Protected from damage and deterioration during handling, maintenance and storage.
- 3.4.6.4. In addition, Aquatec assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements.
- 3.4.6.5. Aquatec takes appropriate action on the equipment and any product affected.
- 3.4.6.6. Records of the results of calibration and verification are maintained.
- 3.4.6.7. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed.
- 3.4.6.8. This is undertaken prior to initial use and reconfirmed as necessary.
- 3.4.6.9. *ISO 10012 - Measurement Management Systems - Requirements For Measurement Processes And*

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Measuring Equipment is applied to calibration processes.

3.4.6.10. The Manager of Quality Assurance is responsible for metrology systems.

3.5. MEASUREMENT, ANALYSIS AND IMPROVEMENT

3.5.1. General

3.5.1.1. Aquatec plans and implements the monitoring, measurement, analysis and improvement processes needed:

3.5.1.1.1. To demonstrate conformity of the product.

3.5.1.1.2. To ensure conformity of the QMS.

3.5.1.1.3. To continually improve the effectiveness of the QMS.

3.5.1.2. This includes determination of applicable methods, including statistical techniques, and the extent of their use.

3.5.1.3. The Manager of Operations is responsible for measuring and analyzing the conformity of salable products.

3.5.1.4. The Manager of Quality Systems is responsible for the design and effectiveness of the QMS.

3.5.2. Monitoring and measurement

3.5.2.1. Customer satisfaction

3.5.2.1.1. As one of the measurements of the performance of the QMS, Aquatec monitors information relating to Customer perception as to whether Aquatec has met Customer requirements.

3.5.2.1.2. The methods for obtaining and using this information are determined.

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3.5.2.1.3. The company President is responsible for measuring and monitoring Customer satisfaction.

3.5.2.2. Internal audit

3.5.2.2.1. Aquatec conducts internal audits at planned intervals to determine whether the QMS:

3.5.2.2.1.1. Conforms to the planned arrangements, to the requirements of ISO 9001:2000 and to the QMS requirements established by Aquatec.

3.5.2.2.1.2. Is effectively implemented and maintained.

3.5.2.2.2. An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.

3.5.2.2.3. The audit criteria, scope, frequency and methods are defined.

3.5.2.2.4. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process.

3.5.2.2.5. Auditors do not audit their own work.

3.5.2.2.6. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in a documented (formally released) procedure, QMS003.

3.5.2.2.7. The management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes.

3.5.2.2.8. Follow-up activities include the verification of the actions taken and the reporting of verification results.

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- 3.5.2.2.9. ISO 19011:2002 *Guidelines for quality and/or environmental management systems auditing* is applied to the auditing programs.
- 3.5.2.2.10. The Manager of Quality Systems is responsible for auditing programs.
- 3.5.2.3. Monitoring and measurement of processes
 - 3.5.2.3.1. Aquatec applies suitable methods for monitoring and, where applicable, measurement of the QMS processes.
 - 3.5.2.3.2. These methods demonstrate the ability of the processes to achieve planned results.
 - 3.5.2.3.3. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.
 - 3.5.2.3.4. The Manager of Quality Assurance is responsible for monitoring and measurement of processes.
- 3.5.2.4. Monitoring and measurement of product
 - 3.5.2.4.1. Aquatec monitors and measures the characteristics of the product to verify that product requirements have been met.
 - 3.5.2.4.2. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.
 - 3.5.2.4.3. Evidence of conformity with the acceptance criteria is maintained.
 - 3.5.2.4.4. Records indicate the person(s) authorizing release of product.
 - 3.5.2.4.5. Product release and service delivery does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved

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by a relevant authority and, where applicable, by the Customer.

3.5.2.4.6. The Manager of Quality Assurance is responsible for monitoring and measurement of products.

3.5.3. Control of nonconforming product

3.5.3.1. Aquatec ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

3.5.3.2. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented (formally released) procedure, QMS004.

3.5.3.3. Aquatec deals with nonconforming product by one or more of the following ways:

3.5.3.3.1. By taking action to eliminate the detected nonconformity.

3.5.3.3.2. By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the Customer.

3.5.3.3.3. By taking action to preclude its original intended use or application.

3.5.3.4. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

3.5.3.5. When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements.

3.5.3.6. When nonconforming product is detected after delivery or use has started, Aquatec takes action appropriate to the effects, or potential effects, of the nonconformity.

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- 3.5.3.7. The Manager of Quality Assurance is responsible for identification and control of nonconforming materials.
- 3.5.4. Analysis of data
 - 3.5.4.1. Aquatec determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made.
 - 3.5.4.2. This includes data generated as a result of monitoring and measurement and from other relevant sources.
 - 3.5.4.3. The analysis of data provides information relating to:
 - 3.5.4.3.1. Customer satisfaction.
 - 3.5.4.3.2. Conformity to product requirements.
 - 3.5.4.3.3. Characteristics and trends of processes and products including opportunities for preventive action.
 - 3.5.4.3.4. Suppliers.
- 3.5.5. Improvement
 - 3.5.5.1. Continual improvement
 - 3.5.5.1.1. Aquatec continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
 - 3.5.5.2. Corrective action
 - 3.5.5.2.1. Aquatec takes action to eliminate the cause of nonconformities in order to prevent recurrence.
 - 3.5.5.2.2. Corrective actions are appropriate to the effects of the nonconformities encountered.

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- 3.5.5.2.3. A documented (formally released) procedure, QMS005, defines requirements for:
 - 3.5.5.2.3.1. Reviewing nonconformities (including Customer complaints).
 - 3.5.5.2.3.2. Determining the causes of nonconformities.
 - 3.5.5.2.3.3. Evaluating the need for action to ensure that nonconformities do not recur.
 - 3.5.5.2.3.4. Determining and implementing action needed.
 - 3.5.5.2.3.5. Records of the results of action taken.
 - 3.5.5.2.3.6. Reviewing corrective action taken.

3.5.5.3. Preventive action

- 3.5.5.3.1. Aquatec determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence.
- 3.5.5.3.2. Preventive actions are appropriate to the effects of the potential problems.
- 3.5.5.3.3. A documented (formally released) procedure, QMS005, defines requirements for:
 - 3.5.5.3.3.1. Determining potential nonconformities and their causes.
 - 3.5.5.3.3.2. Evaluating the need for action to prevent occurrence of nonconformities.
 - 3.5.5.3.3.3. Determining and implementing action needed.
 - 3.5.5.3.3.4. Records of results of action taken.
 - 3.5.5.3.3.5. Reviewing preventive action taken.

3.5.5.4. The Manager of Quality Systems is responsible for adequate Corrective and Preventive action programs.

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3.6. QUALITY SYSTEM DISTRIBUTION

3.6.1. External uses

3.6.1.1. The QMS001 QMS, or portions of it, can be provided to Customers, Suppliers, and Partners, whether potential or active, without authorization or notice.

3.6.1.2. Distribution of other documents and records from the quality system, for destinations external to Aquatec, must be approved in advance by a member of the Executive Committee.

4. PROCEDURE

4.1. QMS OPERATIONS

4.1.1. This policy mandates, and refers to, additional policies which include procedures to operate the QMS.

4.1.2. Refer to the Master List of documents for current information.

5. EXHIBITS

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