



Quality Technology, Inc.



Quality Assurance Manual

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QuTech Policy Statement

The objective of Quality Technology, Inc. is to supply quality services that meet or exceed the standards required by our customers and by law. We are committed to the efficient delivery of safe and reliable systems within our scope of operations. The purpose of this Quality System Manual is to implement and continuously maintain our commitment to these objectives through a dynamic Quality System based on the international ISO 9001:2008 standard.

There are no exceptions to this commitment. Each and every employee operating under the guidance of this Quality System Manual, including management, is expected to understand and work towards our quality commitment. Success means satisfied customers. This Quality System reflects the corporation's total commitment to achieving the goal of meeting the needs of our customers efficiently and safely. In addition to meeting contract requirements and quality objectives, it is our commitment to continue improving our processes and offering increased value to our customers. We have established measurable quality objectives and performance standards as it relates to the current operating environment. Each year, we also identify continuous improvements initiatives that will be implemented throughout the year to address any emerging requirements, changes in the environment, new customer objectives, and general improvements to increase customer satisfaction. In each of our Quality System Processes, we have defined quality/performance objectives and standards, methods for measuring the results, and as applicable, any continuous improvement initiatives associated with a given process.

Renee Parker, CEO
Quality Technology, Inc.

QuTech Quality Policy

Quality Technology, Inc. ensures that our Employees are committed to Customer Satisfaction and Continuous Improvement with a goal of meeting or exceeding customer requirements and delivering products/services on time.

Our Quality Policy ensures we are:

- Customer Focused
- Quality Driven
- Performance Based

1 Quality Assurance at QuTech

This Quality Manual has been issued on the authority of the CEO of Quality Technology, Inc. (QuTech) for the use of all staff, subcontractors, clients or regulatory bodies to whom Quality Technology, Inc. may be required to provide such information.

This Quality Manual defines:

- the overall quality policy adopted by QuTech;
- QuTech that has been developed to implement this quality policy;
- the documentation (i.e. Quality Processes, Quality Procedures & Work Instructions) that has been designed to enable QuTech to carry out that policy.

Changes in the organization of QuTech or the environment, in which it operates, may necessitate modifications, amendments, insertions and/or deletions to the overall quality management adopted by QuTech and its associated documentation (e.g. Quality Processes and Quality Procedures). The contents of this Quality Manual may, therefore, be altered on an as required basis. Changes shall be deemed operational following approval by the authorized person(s) and published as updated sections of the Quality Manual.

1.1 Company Profile

Quality Technology, Inc. (QuTech) is a small business established in 1989 to provide technical support services and business solutions to government and commercial organizations. QuTech provides, as core offerings, a broad spectrum of services to State and Federal Government organizations, with Practice Areas in Systems Engineering and Information Technology (IT) Acquisition Support, Systems Operations and Management, and Enterprise Architecture, with Geographic Information Systems (GIS) support as a specialized area of expertise. With our corporate offices located in Largo, Maryland, we provide services to five states.

As a small business, we are able to be agile and flexible and respond quickly to our customers' requirements, while providing the depth and breadth of capabilities of a large company. Furthermore, as a small company, we retain the value that every customer is important and ensure that every project has visibility at the highest level of our executive staff.

QuTech controls and conducts its business by means of a formalized system of modern quality management which is in accordance with the quality system requirements and recommendations specified in the ISO 9001:2008.

1.2 Quality Technology, Inc. - Organizational chart

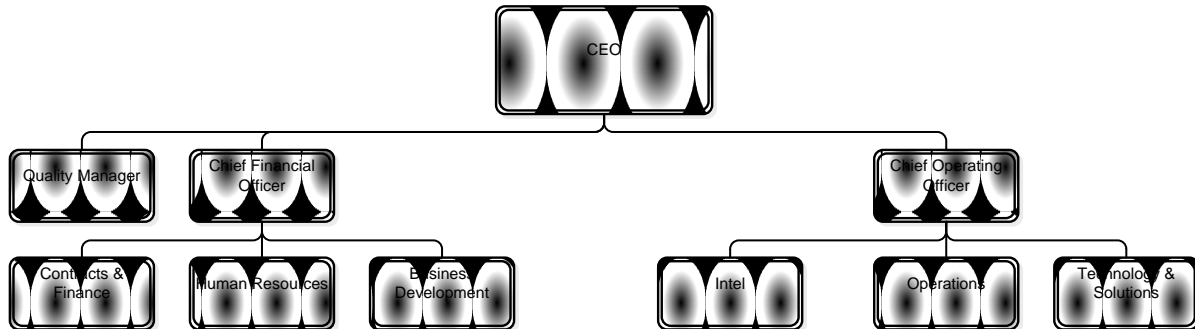


Figure 1: Quality Technology, Inc. - Organizational chart

1.3 Quality policy and objectives

1.3.1 Policy

As stated earlier, Our Quality Policy ensures we are Customer Focused, Quality Driven, and Performance Based. To that end, QuTech shall define and manage the processes necessary to ensure that all products conform to customer requirements. As a means of achieving continuous improvement in performance, QuTech has established a QMS covering the requirements of ISO 9001:2008, This QMS shall be implemented, maintained, continually improved and have the full support of Executive Management.

QuTech shall prepare procedures that describe the processes required to implement the QMS. These shall include:

- Core Business Processes and Supporting Processes;
- Quality Procedures that describe the methods adopted to manage the Core Business Process and Supporting Processes;

1.3.2 Objectives

The main objective of the QuTech QMS is to ensure that company activities, whether they are organizational (e.g. management and infrastructure) or technical (e.g. specification work, testing and simulation) comply with the Quality Assurance Manual and its associated quality documents.

In cases of non-compliance (e.g. if work is not carried out in accordance with the QMS) a problem solving process shall be executed by the functional area manager. This process shall include the location of root causes, remedial action, review of QuTech procedures and, if necessary, their adjustment and modification.

The Quality Manager plays an important part in this process. His/her role shall be to suggest alternative solutions and help the functional area manager take the necessary remedial action. If no effective corrective action is taken, the Quality Manager has the duty to inform Executive Management.

Summarized, the QMS shall include:

- clear responsibilities for each activity and task;

- confirmation that each activity is defined and controlled by a Quality Procedure;
- confirmation that staff are trained to the requirements listed in the Quality Assurance Manual and Project;
- confirmation that compliance with the processes and procedures detailed in the Quality Assurance Manual are audited;
- confirmation that remedial action is taken whenever appropriate;
- confirmation that the Quality Processes and Quality Procedures referenced in the Quality Assurance Manual are regularly reviewed.

1.4 Implementation

Quality management at QuTech is based on the Quality Management System described in ISO 9001:2008. The purpose of the QuTech QMS is to define the policy, organization and responsibilities for the management of quality within QuTech.

The most important aspects of QuTech's QMS are to be found in the QuTech Quality Assurance Manual (i.e. this document) which describes, in detail, how the main elements of ISO 9001:2008 are carried out. The Quality Assurance Manual is then supported by individual Quality Processes and Quality Procedures.

All QuTech personnel shall have access to a copy of this Quality Assurance Manual (see Section 3.9.1 page 21) and as part of personnel induction training, the objectives of the manual shall be explained to them by the QuTech Human Resources Manager.

1.4.1 Overall responsibility

The responsibility of ensuring that QuTech has a quality policy and for ensuring that an organization with the necessary resources is in place to implement the policy lies with Executive Management.

1.4.2 Responsibility for quality system

The CEO has appointed the Quality Manager to have overall responsibility for implementing and maintaining the QuTech quality system. The Quality Manager has the responsibility and the authority to ensure that adequate processes, procedures, plans and instructions are drawn up so as to provide a common approach to quality assurance throughout QuTech and to ensure that the quality system is continuously monitored and improved by means of internal audits and management reviews.

1.5 Registrations and approvals held

QuTech is a Registered Organization certified by an Accredited Certification Body and verified as having quality documentation and effective practices in operation which are in accordance with the requirements of the international Quality System ISO 9001:2008.

2 QuTech's Management System

2.1 Requirements

QuTech's QMS is the organized structure of responsibilities, activities, resources and events that together provide procedures and methods of implementation to ensure the capability of QuTech to meet the quality requirements of our customers.

Within QuTech, an effective QMS ensures that all activities are fully understood, controlled and documented and that everyone knows exactly what they are supposed to be doing and how they should be doing it. The most important element making up the QuTech QMS is the one which demands that **everyone** shall be involved in quality in order for it to succeed and that it **must** be management led and that there **must** be a commitment to quality - **at the highest level**. Within QuTech we have this commitment and it manifests itself throughout QuTech's management, at all levels.

2.2 Organizational goals

The primary goal of QuTech shall, at all times, be the quality of the end product (human capital) and service. To succeed, QuTech must be able to offer products and services that:

- Satisfy the customer's requirements and expectations;
- Comply with applicable quality standards and specifications.

In order to meet these objectives, QuTech shall organize itself in such a way that the technical, administrative and human factors affecting the quality of QuTech's human capital and services are always under quality control.

It is **imperative** that this control is orientated to the reduction, elimination and - of paramount importance - the prevention of quality deficiencies. The QuTech QMS, therefore, has to be developed and implemented for the purpose of accomplishing the QuTech's Quality objectives.

Above all (and to achieve maximum effectiveness) it is essential that the QuTech QMS is designed so that it is appropriate to the type of product (human capital) and services being offered by QuTech.

Demonstration of the continued success of the QMS shall be achieved via regular audits and reviews.

2.3 Purpose

The purpose of a QMS is to ensure that QuTech's human capital conforms to the customer's contractual requirements.

QuTech's QMS, therefore, involves all QuTech functions, wherever and however instigated (e.g. Executive Management level, Functional Manager level, etc.) that directly, or indirectly, affect QuTech products and services.

In essence, QuTech's QMS essentially consists of the documented rules, procedures and instructions prepared in accordance with ISO 9001:2008. These are stated in the Quality Assurance Manual (QM) as well as the associated Quality Procedures (QPs) and Work Instructions (WIs). The QuTech audit team (consisting of the Quality Manager and Internal Auditor) plus Functional Area Manager may decide if additional documents are required for individual functions. In these cases, the requirement for an additional document shall be clearly stated and rules developed. The following section of the manual describes QuTech's quality policy for meeting the requirements of ISO 9001:2008.

3 Adherence to Standards

QuTech's Quality Manual is based on the requirements of ISO 9001:2008. If there are any discrepancies between QuTech's Quality Assurance Manual and the ISO 9001:2008 standard, the requirements of QuTech's Quality Assurance Manual shall prevail.

4 Quality Management System (ISO 9001:2008 - 4)

Subsequent sections of this QM are modelled on ISO 9001:2008 and describe the arrangements or systems that have been established to meet the specified requirements of this standard. As far as possible, the following sections (i.e. 4-8) have been structured in a similar manner to those in ISO 9001:2008 (i.e. each section, sub-section, etc. directly corresponds in terms of number and content with the ISO equivalent number). The correspondence between the Quality Manual and the requirements of ISO 9001:2008 is shown at Appendix B.

Conformance with ISO 9001:2008

Other than the permissible exclusions shown in the relevant parts of the text, QuTech's QMS conforms to the requirements specified in ISO 9001:2008.

Quality Manual administration

The Quality Manager shall review the effectiveness and suitability of the Quality Manual at least twice a year. Where the system is found to be ineffective as a result of changed requirements, amendments shall be made to the QM.

Confidentiality

This QM is the intellectual property of QuTech and may not be copied in whole or part, or transmitted to any third party without the express written permission of the CEO.

4.1 General requirements (ISO 9001:2008 - 4.1)

QuTech shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of the International Standard.

QuTech shall:

- determine the processes needed for the quality management system and their application throughout QuTech (see 1.2),
- determine the sequence and interaction of these processes,
- determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- monitor, measure where applicable, and analyse these processes, and
- implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by QuTech in accordance with the requirements of the International Standard.

Where QuTech chooses to outsource any process that affects product conformity to requirements, QuTech shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

4.2 Documentation requirements (ISO 9001:2008 - 4.2)

4.2.1 General (ISO 9001:2008 - 4.2.1)

QuTech QMS documentation shall include:

- documented statements of a quality policy and quality objectives,
- a quality manual,
- documented procedures and records required by the International Standard, and
- documents, including records, determined by QuTech to be necessary to ensure the effective planning, operation and control of its processes.

4.2.2 Quality Manual (ISO 9001:2008 - 4.2.2)

a. QuTech policy and objectives

QuTech shall establish and maintain a quality manual that includes:

- the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- the documented procedures established for the quality management system, or reference to them, and
- a description of the interaction between the processes of the quality management system.

b. Responsibilities

The Quality Manager is responsible for overseeing the operation of the QMS; for ensuring that the QMS is fully and effectively implemented and for coordinating the writing as well as the availability of the necessary processes, procedures and instructions.

c. Implementation

QMS-OP-0011 – Management Review Procedure

QMS-OP-0004 – Document and Records Control Procedure

4.2.3 Control of documents (ISO 9001:2008 - 4.2.3)

a. QuTech policy and objectives

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed:

- documents are approved for adequacy prior to issue,
- documents are reviewed and updated as necessary and re-approved,
- changes and the current revision status of documents are identified,
- relevant versions of applicable documents are available at points of use,
- documents remain legible and readily identifiable,
- documents of external origin determined by QuTech to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- the unintended use of obsolete documents is prevented, and the suitable identification to them if they are retained for any purpose are applied.

b. Responsibilities

The Quality Manager is responsible for the overall planning of document control procedures throughout QuTech.

c. Implementation

QMS-OP-0004 - Document and Records Control Procedure

4.2.4 Control of quality records (ISO 9001:2008 - 4.2.4)

a. QuTech policy and objectives

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

QuTech shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

b. Responsibilities

The Quality Manager is responsible for maintaining quality records demonstrating conformance to the requirements and the effective operation of the QMS.

c. Implementation

QMS-OP-0004 - Document and Records Control Procedure

5 Management Responsibility (ISO 9001:2008 - 5)

5.1 Management commitment (ISO 9001:2008 - 5.1)

a. QuTech policy and objectives

QuTech Executive Management (CEO, COO, Vice Presidents and Quality Manager) shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- communicating to QuTech the importance of meeting customer as well as statutory and regulatory requirements,
- establishing the quality policy,
- ensuring that quality objectives are established,
- conducting management reviews, and
- ensuring the availability of resources.

b. Responsibilities

Executive Management is responsible for demonstrating commitment to quality and providing the necessary support for this QMS.

c. Implementation

QMS-P2-QP001 - Quality Assurance Manual

5.2 Customer focus (ISO 9001:2008 - 5.2)

a. QuTech policy and objectives

QuTech shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

b. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-P2-QP001 - Quality Assurance Manual

5.3 Quality policy (ISO 9001:2008 - 5.3)

a. QuTech policy and objectives

QuTech shall ensure that the quality policy:

- is appropriate for the needs of QuTech and its customers;
- includes a commitment to meeting requirements and continual improvement;
- provides a framework for establishing and reviewing quality objectives;
- is communicated, understood and implemented throughout QuTech ;
- is regularly reviewed for continuing suitability.

b. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

5.4 Planning (ISO 9001:2008 - 5.4)

5.4.1 Quality objectives (ISO 9001:2008 - 5.4.1)

1. QuTech policy and objectives

QuTech shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a], are established at relevant functions and levels within the QuTech organization. The quality objectives shall be measurable and consistent with the quality policy..

2. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0004 - Document and Records Control Procedure

5.4.2 Quality Management System planning (ISO 9001:2008 - 5.4.2)

a. QuTech policy and objectives

QuTech shall ensure that:

- the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Planning shall ensure that organizational change is conducted in a controlled manner and that the QMS is maintained during this change.

b. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0004 - Document and Records Control Procedure

5.5 Responsibility, Authority and Communication (ISO 9001:2008 - 5.5)

5.5.1 Responsibility and authority (ISO 9001:2008 - 5.5.1)

1. QuTech policy and objectives

QuTech shall ensure that responsibilities and authorities are defined and communicated within QuTech.

2. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

Duties and responsibilities are defined by Executive Management in A “Functional Responsibilities” memo that is sent to all staff when changes in corporate staff occur.

5.5.2 Management Representative (ISO 9001:2008 - 5.5.2)

a. QuTech policy and objectives

The CEO shall appoint a member of QuTech's management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- ensuring that processes needed for the quality management system are established, implemented and maintained,
- reporting to CEO on the performance of the quality management system and any need for improvement, and
- ensuring the promotion of awareness of customer requirements throughout QuTech.

b. Implementation

Details of the Quality Manager's duties and responsibilities are posted on the QuTech corporate portal.

5.5.3 Internal communication (ISO 9001:2008 - 5.5.3)

a. QuTech policy and objectives

Executive Management shall ensure that appropriate communication processes are established within QuTech and that communication takes place regarding the effectiveness of the quality management system.

b. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-P2-QP001- Quality Assurance Manual

5.6 Management Review (ISO 9001:2008 - 5.6)

5.6.1 General (ISO 9001:2008 - 5.6.1)

a. QuTech policy and objectives

QuTech shall review QuTech's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

b. Responsibilities

Executive Management has the overall responsibility to ensure that Management Reviews are conducted at least once a year.

The Quality Manager is responsible for ensuring that quality records are maintained in a systematic and presentable form.

All staff is responsible for ensuring that they provide the necessary records as required from their involvement in implementing the QMS.

c. Implementation

QMS-OP-0011 - Management Review Procedure

QMS-OP-0004 – Document and Records Control Procedure

5.6.2 Review input (ISO 9001:2008 - 5.6.2)

a. QuTech policy and objectives

The input to management review shall include information on:

- results of audits,
- customer feedback,
- process performance and product conformity,
- status of preventive and corrective actions,
- follow-up actions from previous management reviews,
- changes that could affect the quality management system, and
- recommendations for improvement.

b. Responsibilities

Executive Management has the overall responsibility to ensure that Management Reviews are conducted at least once a year.

The Quality Manager is responsible for ensuring that quality records are maintained in a systematic and presentable form.

All staff are responsible for ensuring that they provide the necessary records as required from their involvement in implementing the quality systems.

c. Implementation

QMS-OP-0011 – Management Review Procedure

QMS-OP-0004 – Document and Records Control Procedure

5.6.3 Review output (ISO 9001:2008 - 5.6.3)

a. QuTech policy and objectives

The output from the management review shall include any decisions and actions related to:

- improvement of the effectiveness of the quality management system and its processes,
- improvement of product related to customer requirements, and
- resource needs.

Results of management reviews shall be recorded. (see Section 4.2.4).

b. Responsibilities

The Quality Manager is responsible for ensuring that quality records are maintained in a systematic and presentable form.

All staff are responsible for ensuring that they provide the necessary records as required from their involvement in implementing the quality systems.

c. Implementation

QMS-OP-0011 - Management Review Procedure

6 Resource Management (ISO 9001:2008 - 6)

6.1 Provision of Resources (ISO 9001:2008 - 6.1)

a. QuTech policy and objectives

QuTech shall determine and provide the resources needed:

- to implement and maintain the quality management system and continually improve its effectiveness, and
- to enhance customer satisfaction by meeting customer requirements.

b. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0010 - Quality Training Procedure

QMS-OP-0002 – Outsourcing Procedure

6.2 Human Resources (ISO 9001:2008 - 6.2)

6.2.1 General (ISO 9001:2008 - 6.2.1)

a. QuTech policy and objectives

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

b. Responsibilities

Human Resources has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0010 - Quality Training Procedure

QMS-OP-0002 – Outsourcing Procedure

6.2.2 Competence, awareness and training (ISO 9001:2008 - 6.2.2)

a. QuTech policy and objectives

QuTech shall:

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provide training or take other actions to achieve the necessary competence,
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

b. Responsibilities

Managers are responsible for ensuring that this activity is carried out.

c. Implementation

QMS-OP-0002 – Outsourcing Procedure

QMS-OP-0010 - Quality Training Procedure

6.3 Infrastructure (ISO 9001:2008 - 6.3)

a. QuTech policy and objectives

QuTech shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

- buildings, workspace and associated utilities,
- process equipment (both hardware and software), and
- supporting services (such as transport, communication or information systems).

b. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0009 – Purchasing Procedure

QMS-OP-0011 – Management Review Procedure

6.4 Work environment (ISO 9001:2008 - 6.4)

a. QuTech policy and objectives

QuTech shall determine and manage the work environment needed to achieve conformity to product requirements.

b. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

Federal and State regulatory documents.

7 Product Realization (ISO 9001:2008 - 7)

7.1 Planning of realization processes (ISO 9000:2008 - 7.1)

a. QuTech policy and objectives

QuTech shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, QuTech shall determine the following, as appropriate:

- quality objectives and requirements for the product;
- the need to establish processes and documents, and to provide resources specific to the product;
- required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

- records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for QuTech's method of operations.

b. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0001 Computer Solutions Procedure

QMS-OP-0002 Outsourcing Solutions Procedure

7.2 Customer-Related Processes (ISO 9000:2008 - 7.2)

7.2.1 Determination of requirements related to the product (ISO 9001:2008 - 7.2.1)

a. QuTech policy and objectives

QuTech shall establish determine:

- requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- requirements not stated by the customer but necessary for specified or intended use, where known,
- statutory and regulatory requirements applicable to the product, and
- any additional requirements considered necessary by QuTech.

b. Responsibilities

The Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0001 Computer Solutions Procedure

QMS-OP-0002 Outsourcing Solutions Procedure

QMS-OP-0013 Customer Survey and Communication Procedure

7.2.2 Review of requirements related to the product (ISO 9000:2008 - 7.2.2)

a. QuTech policy and objectives

QuTech shall review the requirements related to the product. This review shall be conducted prior to QuTech'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 shall ensure that:

- product requirements are defined,
- contract or order requirements differing from those previously expressed are resolved, and
- QuTech has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by QuTech before acceptance. Where product requirements are changed, QuTech shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

b. Responsibilities

The Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0001 Computer Solutions Procedure

QMS-OP-0002 Outsourcing Solutions Procedure

QMS-OP-0008 Contract Review, Setup and Modification Procedure

QMS-OP-0004 Document and Records Control Procedure

7.2.3 Customer communication (ISO 9000:2008 - 7.2.3)

a. QuTech policy and objectives

QuTech shall determine and implement effective arrangements for communicating with customers in relation to:

- a) product information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

b. Responsibilities

The Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

c. Implementation

QMS-OP-0013 – Customer Survey and Communication Procedure

7.3 Design and Development (ISO 9000:2008 - 7.3)

QuTech is not a service design-responsible vendor. Due to the nature of QuTech and its product, QuTech is excluded from compliance to the service design and development requirements of ISO 9001:2008, clause 7.3, but only as 7.3 relates to service design and development.

This exclusion does not affect the ability or responsibility of QuTech to provide service that meets customer and applicable regulatory requirements

7.4 Purchasing (ISO 9001:2008 - 7.4)

7.4.1 Purchasing process (ISO 9001:2008 - 7.4.1)

1. QuTech policy and objectives

QuTech shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be

dependent upon the effect of the purchased product on subsequent product realization or the final product.

QuTech shall evaluate and select suppliers based on their ability to supply product in accordance with QuTech's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

2. Responsibilities

The Office Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0009 Purchasing Procedure

QMS-OP-0004 Document and Records Control Procedure

7.4.2 Purchasing information (ISO 9001:2008 - 7.4.2)

1. QuTech policy and objectives

Purchasing information shall describe the product to be purchased, including, where appropriate:

- requirements for approval of product, procedures, processes and equipment,
- requirements for qualification of personnel, and
- quality management system requirements.

QuTech shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

2. Responsibilities

The Office Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0009 Purchasing Procedure

7.4.3 Verification of purchased product (ISO 9001:2008 - 7.4.3)

1. QuTech policy and objectives

QuTech shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

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

2. Responsibilities

The Office Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0009 Purchasing Procedure

7.5 Production and Service Provision (ISO 9001:2008 - 7.5)

7.5.1 Control of production and service provision (ISO 9001:2008 - 7.5.1)

1. QuTech policy and objectives

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

- the availability of information that describes the characteristics of the product,
- the availability of work instructions, as necessary,
- the use of suitable equipment,
- the availability and use of monitoring and measuring equipment,
- the implementation of monitoring and measurement, and
- the implementation of product release, delivery and post-delivery activities.

2. Responsibilities

The Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

7.5.2 Validation of processes for production and service provision (ISO 9001:2008 - 7.5.2)

QuTech shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

QuTech shall establish arrangements for these processes including, as applicable,

- defined criteria for review and approval of the processes,
- approval of equipment and qualification of personnel,
- use of specific methods and procedures,
- requirements for records (see 4.2.4), and
- revalidation.

7.5.3 Identification and traceability (ISO 9001:2008 - 7.5.3)

1. QuTech policy and objectives

Where appropriate, QuTech shall identify the product by suitable means throughout product realization.

QuTech shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, QuTech shall control the unique identification of the product and maintain records (see 4.2.4).

2. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0001 – Computer Solutions

QMS-OP-0002- Outsourcing Procedure

QMS-OP-0004 – Document and Records Control Procedure

7.5.4 Customer property (ISO 9001:2008 - 7.5.4)

1. QuTech policy and objectives

QuTech shall exercise care with customer property while it is under QuTech's control or being used by QuTech. QuTech shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, QuTech shall report this to the customer and maintain records (see 4.2.4).

Program management/QA prepares, approves and maintains a list of customer property. Upon receipt of customer property; PM/QA inspects to verify count, part number, and obvious damage. A record of inspection is recorded on the Customer Property Receipt form QTI10-0010.



Note Customer property can include intellectual property and personal data.

2. Responsibilities

The Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0002 - Outsourcing Procedure

7.5.5 Preservation of product (ISO 9001:2008 - 7.5.5)

1. QuTech policy and objectives

QuTech shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

2. Responsibilities

Operations has overall responsibility for establishing, implementing and maintaining this activity.

7.6 Control of Monitoring and Measuring Equipment (ISO 9001:2008 - 7.6)

QuTech has no monitoring and measuring devices requiring calibration and control. Due to the nature of QuTech and its product, QuTech is excluded from compliance to the monitoring and measuring device calibration and control requirements of ISO 9001:2008, clause 7.6, but only as 7.6 relates to customer property.

This exclusion does not affect the ability or responsibility of QuTech to provide service that meets customer and applicable regulatory requirements.

8 Measurement, Analysis and Improvement (ISO 9001:2008 - 8)

8.1 General (ISO 9001:2008 - 8.1)

1. QuTech policy and objectives

QuTech shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- to demonstrate conformity to product requirements,
- to ensure conformity of the quality management system, and
- to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

2. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0005 Process/Product Measurements; Outsourcing Solutions Procedure
QMS-OP-0006 Process/Product Measurements; Computer Solutions Procedure
QMS-OP-0012 Internal Audit Procedure

8.2 Monitoring and Measurement (ISO 9001:2008 - 8.2)

8.2.1 Customer satisfaction (ISO 9001:2008 - 8.2.1)

1. QuTech policy and objectives

As one of the measurements of the performance of the quality management system, QuTech shall monitor information relating to customer perception as to whether QuTech has met customer requirements. The methods for obtaining and using this information shall be determined.

2. Responsibilities

Operations has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0013 – Customer Survey and Communication Procedure
QMS-OP-0004 – Document and Records Control Procedure

8.2.2 Internal audit (ISO 9001:2008 - 8.2.2)

1. QuTech policy and objectives

QuTech shall conduct internal audits at planned intervals to determine whether the quality management system:

- conforms to the planned arrangements (see 7.1), to the requirements of the International Standard and to the quality management system requirements established by QuTech, and
- is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

2. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0004 – Document and Records Control Procedure

QMS-OP-0012 - Internal Audit Procedure

8.2.3 Monitoring and measurement of processes (ISO 9001:2008 - 8.2.3)

1. QuTech policy and objectives

QuTech shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

2. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0005 Process/Product Measurements; Outsourcing Solutions Procedure

QMS-OP-0006 Process/Product Measurements; Computer Solutions Procedure

8.2.4 Monitoring and measurement of product (ISO 9001:2008 - 8.2.4)

1. QuTech policy and objectives

QuTech shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

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

2. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0004 – Document and Records Control Procedure

QMS-OP-0005 Process/Product Measurements; Outsourcing Solutions Procedure

QMS-OP-0006 Process/Product Measurements; Computer Solutions Procedure

8.3 Control of non-conforming product (ISO 9001:2008 - 8.3)

1. QuTech policy and objectives

QuTech shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, QuTech shall deal with nonconforming product by one or more of the following ways:

- by taking action to eliminate the detected nonconformity;
- by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- by taking action to preclude its original intended use or application;
- by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

2. Responsibilities

The Quality Manager, assisted by the Section Managers, has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0003 Nonconforming Material System Procedure

8.4 Analysis of data (ISO 9001:2008 - 8.4)

1. QuTech policy and objectives

QuTech shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall

include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:

- customer satisfaction (see 8.2.1),
- conformity to product requirements (see 8.2.4),
- characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- suppliers (see 7.4).

2. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

8.5 Improvement (ISO 9001:2008 - 8.5)

8.5.1 Continual improvement (ISO 9001:2008 - 8.5.1)

1. QuTech policy and objectives

QuTech shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

2. Responsibilities

Executive Management has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0011 – Management Review Procedure

QMS-OP-0012 - Internal Audit Procedure

QMS-OP-0014 – Corrective and Preventive Action Procedure

8.5.2 Corrective action (ISO 9001:2008 - 8.5.2)

1. QuTech policy and objectives

QuTech shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for:

- reviewing nonconformities (including customer complaints),
- determining the causes of nonconformities,
- evaluating the need for action to ensure that nonconformities do not recur,
- determining and implementing action needed,
- records of the results of action taken (see 4.2.4), and
- reviewing the effectiveness of the corrective action taken.

2. Responsibilities

The Quality Manager has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0011 – Management Review Procedure

QMS-OP-0012 - Internal Audit Procedure

QMS-OP-0014 – Corrective and Preventive Action Procedure

8.5.3 Preventive action (ISO 9001:2008 - 8.5.3)

1. QuTech policy and objectives

QuTech shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for:

- determining potential nonconformities and their causes,
- evaluating the need for action to prevent occurrence of nonconformities,
- determining and implementing action needed,
- records of results of action taken (see 4.2.4), and
- reviewing the effectiveness of the preventive action taken.

2. Responsibilities

Executive Management, assisted by Section Managers, has overall responsibility for establishing, implementing and maintaining this activity.

3. Implementation

QMS-OP-0011 – Management Review Procedure

QMS-OP-0012 - Internal Audit Procedure

QMS-OP-0014 – Corrective and Preventive Action Procedure