

Quality Policy Manual

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CHANGE RECORD

Reference: 4.01.AA, Revision J2; Owner: P. Harris

Title: Quality Policy Manual
 Originator: S. Kelley
 Owner: P. Harris

Approved By: _____
 P. Harris

REV	DATE	CHANGE	RESPONSIBLE PERSON
A1	8-16-96	Release	S. Kelley
B1	10-30-96	ECO-940 Change org chart and misc corrections	S. Kelley
C1	11-20-96	ECO-967 Add Company Overview and misc corrections	S. Kelley
D1	01-10-97	ECO-992 Change Org. chart and misc corrections	R. A. Berry Jr.
E1	06-23-97	ECO-1089 Multiple changes to all pages in Manual.	S. Buturlia
F1	06-30-97	ECO-1114 Add items to BOM (4.03-4.20).	S. Buturlia
G1	10-08-97	ECO-1180 Multiple changes to pages in Manual.	S. Buturlia
H1	1/9/98	ECO-1241 Multiple changes to pages in Manual.	S. Buturlia
H2	4/27/98	ECO-1305 Multiple changes to pages in Manual. See Eco.	S. Buturlia
H3	1/7/99	ECO-1424 Multiple changes to pages in Manual See ECO	R.A. Berry
H4	6/1/99	ECO-1530 Multiple changes, organizational changes, new Processes, released	Mary Coles
H5	11/16/99	ECO-1673 Multiple Changes	Mary Coles
H6	3/29/00	ECO-1786 Multiple Changes	Mary Coles
H7	11/03/00	ECO-1916 Multiple changes to pages in Manual	R.A. Berry
I1	12-11-00	ECO-1928 Revise Revisions of all pages to be the same	R.A. Berry
I2	5/30/01	ECO – 2008 Changes in Manual	R. Caley
I3	10-16-02	Update org chart	R. A. Berry Jr
I4	12-16-02	Update org chart – Customer Service not listed	R. A. Berry Jr
I5	6/17/03	Eco # 2094 -Multiple Changes to Update to ISO 9001:2000	R Caley
I6	7/8/04	Updated per ECO #2278	R. A. Berry Jr.
J1	4/04/04	Update Per ECO 2326 QMS and ISO issues	N Johnson
J2	07/14/06	Update per ECO 2413 QMS and ISO Issues	R. Stonehouse
J3	07/14/06	Update per ECO 2431 QMS and ISO Issues	R. Stonehouse
J4	01-05-07	Update per ECO 2455 QMS and ISO Issues	N Johnson

TABLE OF CONTENTS

Reference: 4.01.A04, Revision J2; Owner: P. Harris

ISO REF.	Rev.	POLICY TITLE	POLICY OWNER ¹
4.01AA	J1	Change Record	President
4.01.A04	J1	Table of Contents	President
4.01.A01	J4	Mission Statement	President
4.01.A02	J4	Quality Policy	President
4.01.A03	J1	Foreword	President
4.01.A06	J1	Correspondence to ISO 9001:1994 and 9001:2000	President
4.01.A07	J4	Process Inter-actions Map	President
4.01	J1	Management Responsibility	President
4.01.A05	J4	Organization Chart	President
4.02	J4	Quality System	President
4.03	J4	Contract Review	President
4.05	J4	Document and Data Control	President
4.06	J4	Purchasing	President
4.07	J1	Customer Supplied Product	President
4.08	J1	Product Identification and Traceability	President
4.09	J4	Process Control	President
4.10	J4	Inspection and Testing	President
4.11	J1	Control of Inspection, Measuring, and Test Equipment	President
4.12	J1	Inspection and Test Status	President
4.13	J1	Control of Non-conforming Material	President
4.14	J4	Corrective and Preventative Action	President
4.15	J1	Handling, Storage, Packaging, Preservation and Delivery	President
4.16	J1	Control of Quality Records	President
4.17	J1	Internal Quality Assessments	President
4.18	J1	Training	President
4.19	J1	Servicing	President
4.20	J1	Statistical Techniques	President

¹ Process owners are responsible for ensuring that process implementation, training and performance measurements in their area of responsibility are effective and in accordance with specific requirements noted in the ISO 9001:2000 standard.

MISSION STATEMENT

Reference: 4.01.A01, Revision J1; Owner: P. Harris

QuadTech's Mission is to "Make the Customer Successful".

Our primary responsibility is to our: A) Employees B) Customers and C) Strategic Partners.

Our first responsibility is to our Employees. *We recognize that our success, and the success of our customers, depends upon the attitudes and performance of our employees. They provide the fundamental strength and reputation of the Company. It's up to each of us to help provide a stimulating and rewarding work environment, to treat each other with respect, to foster open and honest communications, and to encourage each other to continue to develop valuable skills and to achieve our career aspirations.*

Our second responsibility is to our customers. When our customers succeed, we succeed. Whether our job is at the point of sale or far removed, we realize our actions will in some way affect our customers. We will continually strive to improve the sense of common purpose and mutual trust we share with our customers.

Our third responsibility is to our strategic partners. We will treat our representatives, distributors, suppliers, and business partners as we treat each other, as members of our team.

QUALITY POLICY

Reference: 4.01.A02, Revision J2; Owner: P. Harris

Quality Policy

QuadTech is committed to meeting requirements of ISO9001-2000 and continually improving its process's in order to provide customer satisfaction with Quality products and services delivered on a timely basis through empowered QuadTech employees.

Accomplishment of Quality Policy

This Policy shall be accomplished by the determination of Quality Objectives throughout the company, including but not limited to:

Delivery Time and Performance: Promised Ship Date equal to or less than Actual Ship Date for 95% of shipments in any given period. – (reported monthly)

Customer Satisfaction: Returned surveys from Active Customers with Satisfaction Rating equal to or greater than 90%. Satisfaction rating is the sum total of columns 4 and 5 compared to total respondents. – (tallied quarterly)

Warranty Returns: Number of units returned for warranty issues shall be equal to or less than 2% of the total number of same product type units shipped in the previous 12 months. – (reported monthly)

Re-repairs: Number of units returned for re-repair issues shall be less than 2% of the total number of repairs done in the previous quarter plus 1 month.. - (reported monthly)

Employee Satisfaction: Employee satisfaction shall be equal to or greater than 88% Satisfaction rating is the sum total of columns 4 and 5 compared to total respondents. – (surveyed quarterly)

This Policy shall be accomplished through the designation of “Process Owners” who are responsible for ensuring that training and performance measurements in their area of responsibility are effective in this regard.

This Policy shall be accomplished through a formal review of these Quality Objectives at the Management Review meeting, and by directing any Preventative / Corrective Actions through these meetings.

This Policy shall be accomplished through the open publication of our Quality Performance, and use of these results as a basis for Continuous Improvement activities within QuadTech.

FOREWORD

Reference: 4.01.A03, Revision J1; Owner: P. Harris

Scope

This manual is published to describe the quality management system used by QuadTech. This manual and the systems and processes it describes conform to the ISO 9001:2000 Quality System Standard. QuadTech's Quality Management System excludes clause 7.3 Design Control. New products at QuadTech are PFR.

Foreword

QuadTech developed and implemented a quality management system to better satisfy its customers and to improve management of the company.

Controlled copies of this manual are distributed and maintained. Complimentary uncontrolled copies are available upon request for use by our suppliers, customers and prospective customers.

Company Overview

QuadTech was founded in 1991 with the acquisition of the GenRad Precision Instrument Product Line. QuadTech is a leading company in the T&M industry providing instruments and complete integrated testing solutions with a primary focus on Medical Device Manufacturers.

Our customers are successful because of our test instruments, software, knowledge and complete integrated systems combined with our unbeatable customer support and service.

QuadTech's facility is located at 5 Clock Tower Place Maynard, Massachusetts.

CORRESPONDENCE BETWEEN ISO 9001:2000 AND 9001:1994

Reference: 4.01.A06, Revision J1; Owner: P. Harris; Page 1 of 2

<u>ISO 9001:1994</u>	<u>ISO 9001:2000</u>
1 Scope	1
2 Normative Reference	2
3 Definitions	3
4 Quality System Requirements [title only]	
4.1 Management Responsibility [title only]	
4.1.1 Quality Policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization [title only]	
4.1.2.1 Responsibility and Authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management Representative	5.5.2
4.1.3 Management Review	5.6.1 + 8.5.1
4.2 Quality System [title only]	
4.2.1 General	4.1 + 4.2.2
4.2.2 Quality System Procedures	4.2.1
4.2.3 Quality Planning	5.4.2 + 7.1
4.3 Contract Review [title only]	
4.3.1 General	
4.3.2 Review	5.2 + 7.2.1 + 7.2.2 + 7.2.3
4.3.3 Amendment to a Contract	7.2.2
4.3.4 Records	7.2.2
4.5 Documentation and Data Control [title only]	
4.5.1 General	4.2.3
4.5.2 Documentation and Data Approval and Issue	4.2.3
4.5.3 Document and Data Changes	4.2.3
4.6 Purchasing [title only]	
4.6.1 General	
4.6.2 Evaluation of Subcontractors	7.4.1
4.6.3 Purchasing Data	7.4.2
4.6.4 Verification of Purchased Product	7.4.3
4.7 Control of Customer-Supplied Product	7.5.4

CORRESPONDENCE BETWEEN ISO 9001:2000 AND 9001:1994

Reference: 4.01.A06, Revision J1; Owner: P. Harris; Page 2 of 2

ISO 9001:1994	ISO 9001:2000
4.8 Product Identification and Traceability	7.5.3
4.9 Process Control	6.3 + 7.5.1 + 7.5.2
4.10 Inspection and Testing [title only]	
4.10.1 General	7.1 + 8.1
4.10.2 Receiving Inspection and Testing	7.4.3, 8.2.4
4.10.3 In-Process Inspection and Testing	8.2.4
4.10.4 Final Inspection and Testing	8.2.4
4.10.5 Inspection and Test Records	7.5.3 + 8.2.4
4.11 Control of Inspection, Measuring and Test Equipment [title only]	
4.11.1 General	7.6
4.11.2 Control Procedure	7.6
4.12 Inspection and Test Status	7.5.3
4.13 Control of Non-Conformance [title only]	
4.13.1 General	8.3
4.13.2 Review and Disposition of Nonconforming Product	8.3
4.14 Corrective and Preventive Action [title only]	
4.14.1 General	8.5.2 + 8.5.3
4.14.2 Corrective Action	8.5.2
4.14.3 Preventive Action	8.5.3
4.15 Handling, Storage, Packaging, Preservation & Delivery [title only]	
4.15.1 General	
4.15.2 Handling	7.5.5
4.15.3 Storage	7.5.5
4.15.4 Packaging	7.5.5
4.15.5 Preservation	7.5.5
4.15.6 Delivery	7.5.1
4.16 Control of Quality Records	4.2.4
4.17 Internal Quality Audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
4.19 Servicing	7.5.1
4.20 Statistical Techniques [title only]	
4.20.1 Identification of Need	8.1 + 8.2.3 + 8.2.4 + 8.4
4.20.2 Procedures	8.1 + 8.2.3 + 8.2.4 + 8.4

CORRESPONDENCE BETWEEN ISO 9001:1994 AND 9001:2000

Reference: 4.01.A06, Revision J1; Owner: P. Harris; Page 1 of 2

<u>ISO 9001:2000</u>	<u>ISO 9001:1994</u>
1 Scope	1
1.1 General	
1.2 Application	
2 Normative Reference	2
3 Definitions	3
4 Quality System Requirements [title only]	
4.1 General Requirements	4.2.1
4.2 Documentation Requirements [title only]	
4.2.1 General	4.2.2
4.2.2 Quality Manual	4.2.1
4.2.3 Control of Documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of Records	4.16
5 Management Responsibility [title only]	
5.1 Management Commitment	4.1.1
5.2 Customer Focus	4.3.2
5.3 Quality Policy	4.1.1
5.4 Planning [title only]	
5.4.1 Quality Objectives	4.1.1
5.4.2 Quality Management System Planning	4.2.3
5.5 Responsibility, Authority and Communication [title only]	
5.5.1 Responsibility and Authority	4.1.2.1
5.5.2 Management Representative	4.1.2.3
5.5.3 Internal Communication	
5.6 Management Review [title only]	
5.6.1 General	4.1.3
5.6.2 Review Input	
5.6.3 Review Output	
6 Resource Management [title only]	
6.1 Provision of Resources [title only]	4.1.2.2
6.2 Human Resources [title only]	
6.2.1 General	4.1.2.2
6.2.2 Competence, Awareness and Training	4.18
6.3 Infrastructure	4.9
6.4 Work Environment	4.9
7 Product Realization [title only]	
7.1 Planning of Production Realization	4.2.3 + 4.10.1
7.2 Customer-Related Processes [title only]	
7.2.1 Determination of Requirements Related to the Product	4.3.2 + 4.4.4
7.2.2 Review of Requirements Relates to the Product	4.3.2 + 4.3.3 + 4.3.4
7.2.3 Customer Communication	4.3.2

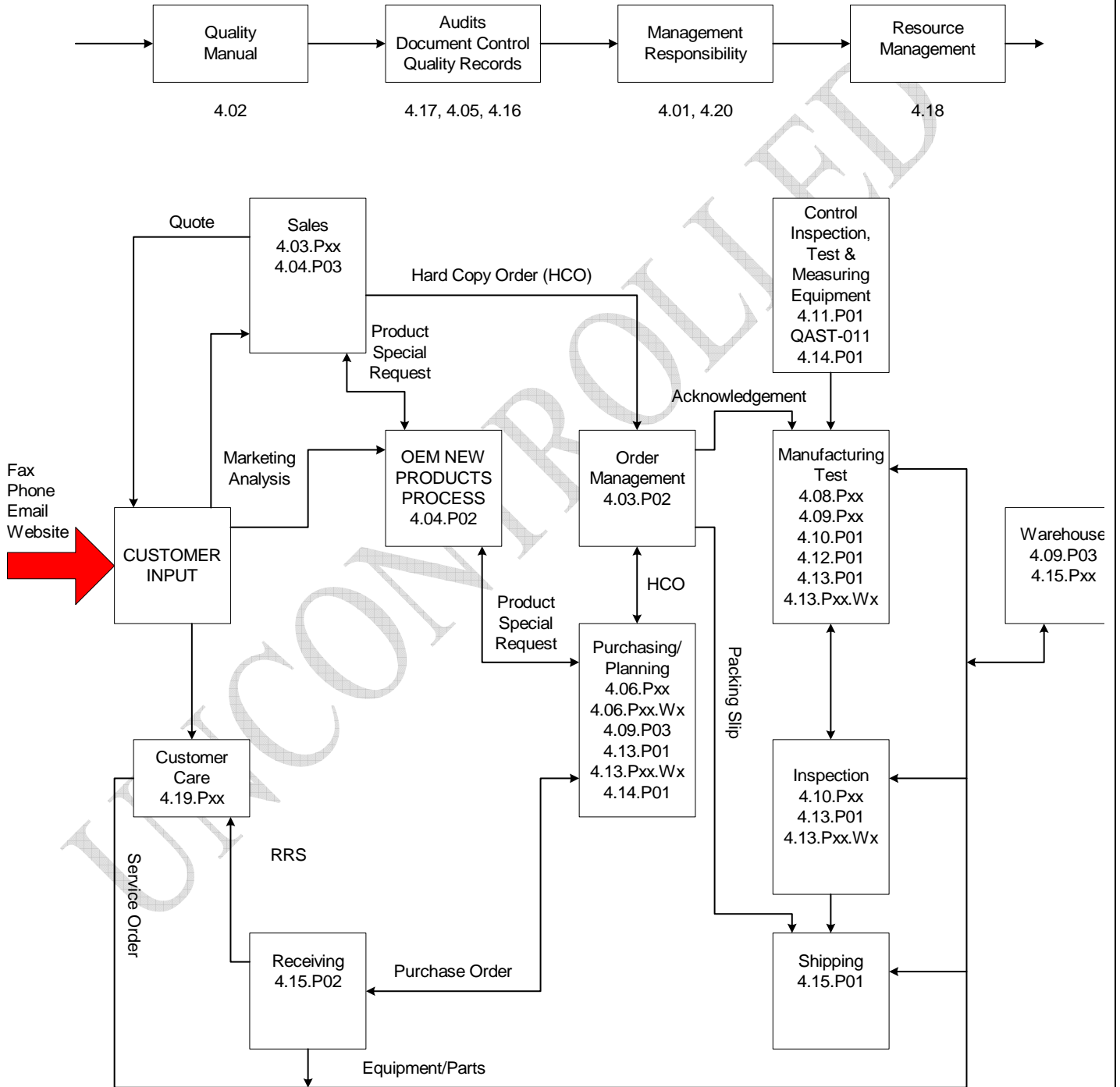
CORRESPONDENCE BETWEEN ISO 9001:1994 AND 9001:2000

Reference: 4.01.A06, Revision J1; Owner: P. Harris; Page 2 of 2

ISO 9001:2000	ISO 9001:1994
7.4 Purchasing [title only]	
7.4.1 Purchasing Process	4.6.2
7.4.2 Purchasing Information	4.6.3
7.4.3 Verification of Purchased Product	4.6.4 + 4.10.2
7.5 Production and Service Provision [title only]	
7.5.1 Control of Production and Service Provision	4.9 + 4.15.6 + 4.19
7.5.2 Validation of Processes for Production and Service Provision	4.9
7.5.3 Identification and Traceability	4.8 + 4.10.5 + 4.12
7.5.4 Customer Property	4.7
7.5.5 Preservation of Product	4.15.2 + 4.15.3 + 4.15.4 + 4.15.5
7.6 Control of Monitoring and Measuring Devices	4.11.1 + 4.11.2
8 Measurement, Analysis and Improvement [title only]	
8.1 General	4.10.1 + 4.20.1 + 4.20.2
8.2 Monitoring and Measurement [title only]	
8.2.1 Customer Satisfaction	
8.2.2 Internal Audit	4.17
8.2.3 Monitoring and Measurement of Processes	4.17 + 4.20.1 + 4.20.2
8.2.4 Monitoring and Measurement of Product	4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2
8.3 Control of Non-Conforming Product	4.13.1 + 4.13.2
8.4 Analysis of Data	4.20.1 + 4.20.2
8.5 Improvement [title only]	
8.5.1 Continual Improvement	4.1.3
8.5.2 Corrective Action	4.14.1 + 4.14.2
8.5.3 Preventive Action	4.14.1 + 4.14.3

QUADTECH INTERACTIONS MAP

Reference: 4.01.A07, Revision J1; Owner: P. Harris



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MANAGEMENT RESPONSIBILITY

Reference: 4.01, Revision J1; Owner: P. Harris; Page 1 of 3

5.1 Management commitment

QuadTech's top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) Establishing the quality policy,
- c) Ensuring that quality objectives are established,
- d) Conducting management reviews, and
- e) Ensuring the availability of resources.

5.3 Quality policy

QuadTech's top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

5.4.1 Quality objectives

QuadTech's top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.5.1 Responsibility and authority

QuadTech's top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

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

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained.

MANAGEMENT RESPONSIBILITY

Reference: 4.01, Revision J1; Owner: P. Harris; Page 2 of 3

5.6.1 General

QuadTech's top management shall review the organization'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.

Records from management reviews shall be maintained per 4.16.P01.

6.1 Provision of resources

QuadTech shall determine and provide the resources needed:

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

6.2.1 General

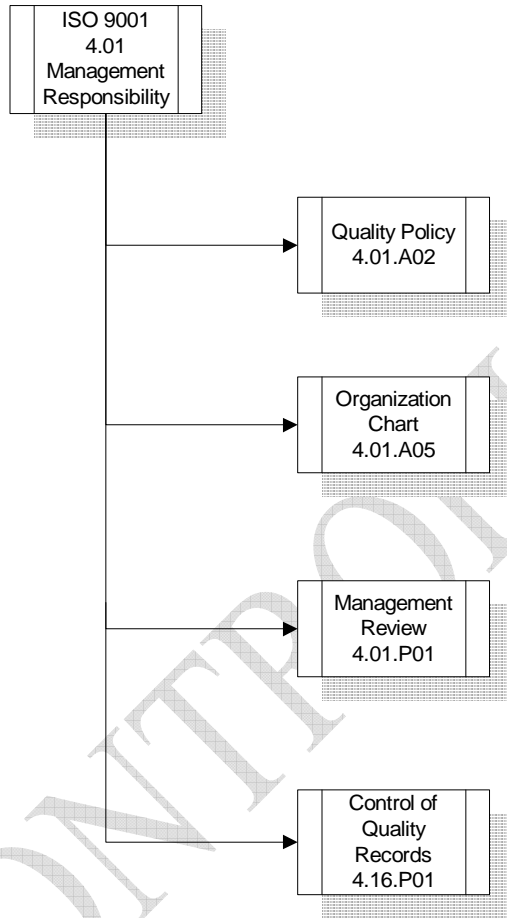
QuadTech personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

8.5.1 Continual improvement

QuadTech 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.

MANAGEMENT RESPONSIBILITY

Reference: 4.01, Revision J1; Owner: P. Harris; Page 3 of 3



QUALITY SYSTEM

Reference: 4.02, Revision J1; Owner: P. Harris; Page 1 of 4

4.1 General requirements

QuadTech shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of ISO 9001:2000 International Standard.

QuadTech shall:

- a) identify the processes needed for the quality management system and their application throughout the organization,
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure and analyze these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by QuadTech in accordance with the requirements of ISO 9001:2000 International Standard.

Where QuadTech chooses to outsource any process that affects product conformity with requirements, QuadTech shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

4.2.1 General

QuadTech's quality management system documentation shall include:

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures required by the ISO 9001:2000 International Standard,
- d) documents needed by QuadTech to ensure the effective planning, operation and control of its processes, and
- e) records required by ISO 9001:2000 International Standard per 4.16.P01.

QUALITY SYSTEM

Reference: 4.02, Revision J1; Owner: P. Harris; Page 2 of 4

4.2.2 Quality manual

QuadTech shall establish and maintain a quality manual that includes

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

5.4.2 Quality management system planning

QuadTech's top management shall ensure that

- a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1 of the ISO 9001:2000 International Standard, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

7.1 Planning of product realization

QuadTech 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.

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

- a) quality objectives and requirements for the product;
- b) the need to establish processes, documents, and provide resources specific to the product;
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements per 4.16.P01.

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

All of the above shall be reviewed at Management Review.

ISO 9001
4.02
Quality System



System Scope
4.02.P02



- 4.01.A01 Mission Statement (in 4.01)
- 4.01.A02 Quality Policy (in 4.01)
- 4.01.A03 Forward (in 4.01)
- 4.01.A04 Table of Contents (in 4.01)
- 4.01.A05 Organization Chart (in 4.0)
- 4.01.AA Change Record (in 4.01)
- 4.01.P01 Management Review
 - 150149 Form, ISO Management Review
- 4.02 Quality System(in 4.01)
 - 4.02.P02 System Scope Map (in 4.01)
- 4.03 Contract Review(in 4.01)
 - 4.03.P01 Quotation, Contract Review
 - 4.03.P02 Incoming Order Process
- 4.04.P03 Customer Special Product R
- 4.05 Doc. and Data Control (in 4)
 - 4.05.P02 ECO Document Control
 - QAST-001 Document Control
- 4.06 Purchasing(in 4.01)
 - 4.04.P02 OEM New Product Process
 - 4.06.P01 PURCHASING
 - 4.06.P05 Supplier Qualification
 - 4.06.P06 Supplier Disqualification
- 4.07 Purchaser Suppld Prod(in 4.
 - 4.07.P01 Customer Supplied Product
- 4.08 Prod I.D. & Tracking (in 4)
 - 4.08.P01 Product Identification
 - 4.08.P02 Traceability
- 4.09 Process Control (in 4.01)
 - 4.09.P03 Planning Workorder Product
 - 4.09.P05 OEM / Sub Contract Mfg.
 - 4.09.P23 Certification

- 4.10 Inspctn and Test (in 4.01)
 - 4.10.P01 Inspection and Test
 - 4.10.P03 INCOMING INSPECTION
 - 4.13.P01 Non-Conforming
- 4.11 Ctrl of Insp,Measure+Test
 - 4.11.P01 Calibration
- 4.12 Inspctn & Test Status(in 4)
 - 4.12.P01 Inspection and Test Status
 - 4.13.P01 Non-Conforming
- 4.13 Non-Conforming Mtrl(in 4.0)
 - 4.13.P01 Non-Conforming
- 4.14 Corr/Prev Action (in 4.01)
 - 4.14.P01 Corrective Action
 - 4.14.P02 Customer Concerns
- 4.15 Handling/Storage/Preserve/
 - 4.15.P01 SHIPPING
 - 4.15.P02 RECEIVING
 - 4.15.P03 STOCKROOM MATERIAL ISSUING
- 4.16 Control of Qual Rcrds(in 4)
 - 4.16.P01 Control of Quality Records
- 4.17 Internal Qual Audit (in 4.
 - 4.17.P01 Internal Audit
- 4.18 Training (in 4.01)
 - 4.18.P01 New Hire Training
 - 4.18.P02 Needs Assesment
 - 4.18.P03 Training Procedure
- 4.19 Servicing (in 4.01)
 - 4.19.P01 Customer Service
- 4.20 Stat Techniques (in 4.01)
 - 4.20.P01 Statistical Techniques

CONTRACT REVIEW

Reference: 4.03, Revision J1; Owner: P. Harris; Page 1 of 2

5.2 Customer focus

QuadTech's top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

7.2.1 Determination of requirements related to the product

QuadTech shall determine

- 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 specified or intended use, where known,
- c) statutory and regulatory requirements related to the product, and
- d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

QuadTech shall review the requirements related to the product. This review shall be conducted prior to QuadTech's commitment to supply a product to the customer and shall ensure that

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) QuadTech has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained per 4.16.P01.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by QuadTech before acceptance.

Where product requirements are changed, QuadTech shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer communication

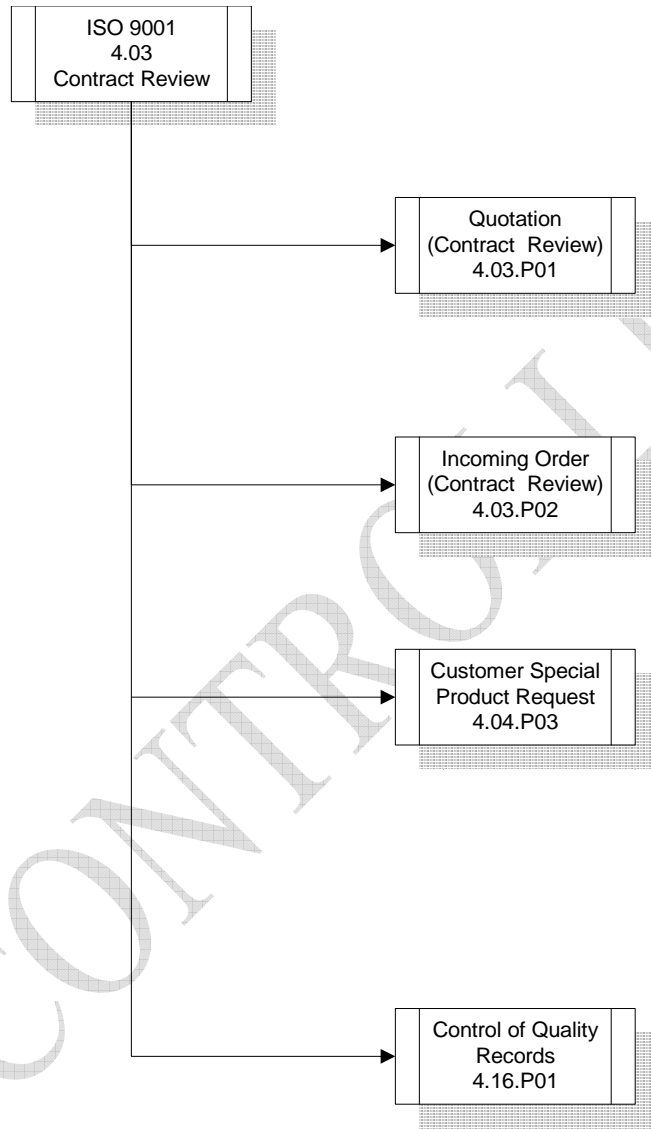
QuadTech shall determine and implement effective arrangements for communicating with customers in relation to

- a) product information,
- b) inquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints per 4.14.P02.

UNCONTROLLED

CONTRACT REVIEW

Reference: 4.03, Revision J1; Owner: P. Harris; Page 2 of 2



DOCUMENTATION AND DATA CONTROL

Reference: 4.05, Revision J1; Owner: P. Harris; Page 1 of 2

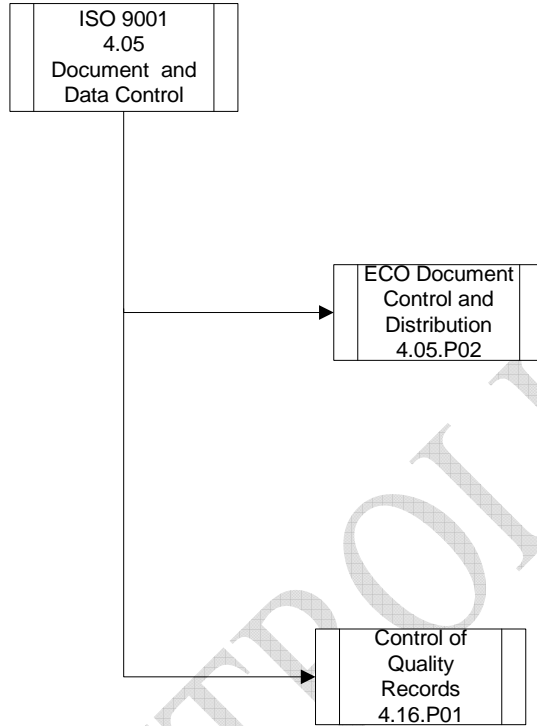
4.2.3 Control of documents

QuadTech's documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to 4.16.P01.

QuadTech's documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

DOCUMENTATION AND DATA CONTROL
Reference: 4.05, Revision J1; Owner: P. Harris; Page 2 of 2



PURCHASING

Reference: 4.06, Revision J1; Owner: P. Harris; Page 1 of 2

7.4.1 Purchasing process

QuadTech 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.

QuadTech shall evaluate and select suppliers based on their ability to supply product in accordance with QuadTech'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 per 4.16.P01.

7.4.2 Purchasing information

QuadTech's purchasing information shall describe the product to be purchased, including where appropriate:

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

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

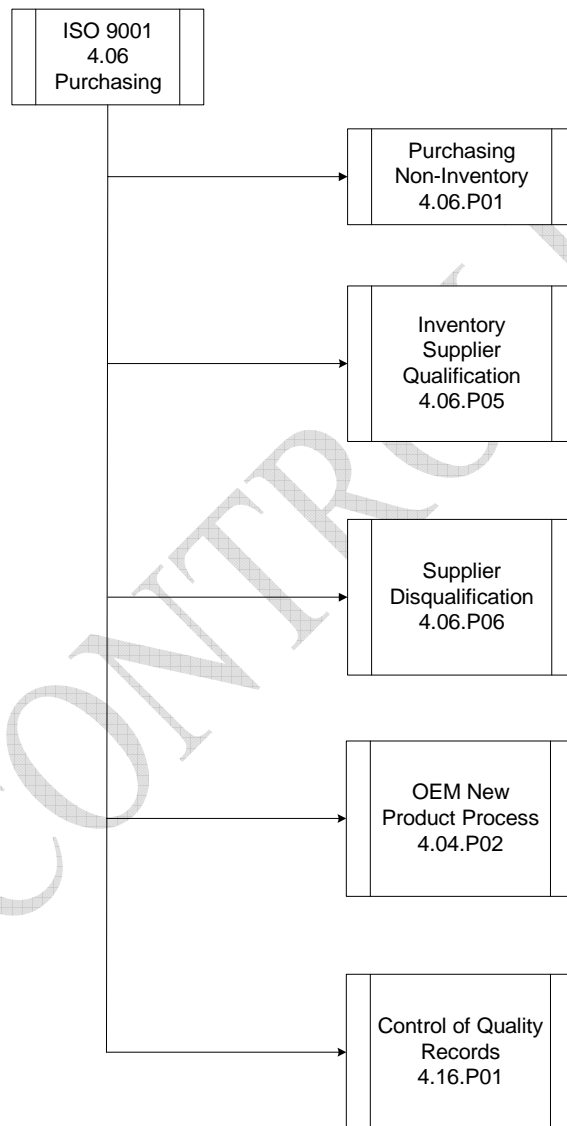
7.4.3 Verification of purchased product

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

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

PURCHASING

Reference: 4.06, Revision J1; Owner: P. Harris; Page 2 of



7.5.4 Customer property

QuadTech shall exercise care with customer property while it is under the organization's control or being used by the organization. QuadTech 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, this shall be reported to the customer and records maintained per 4.16.P01.

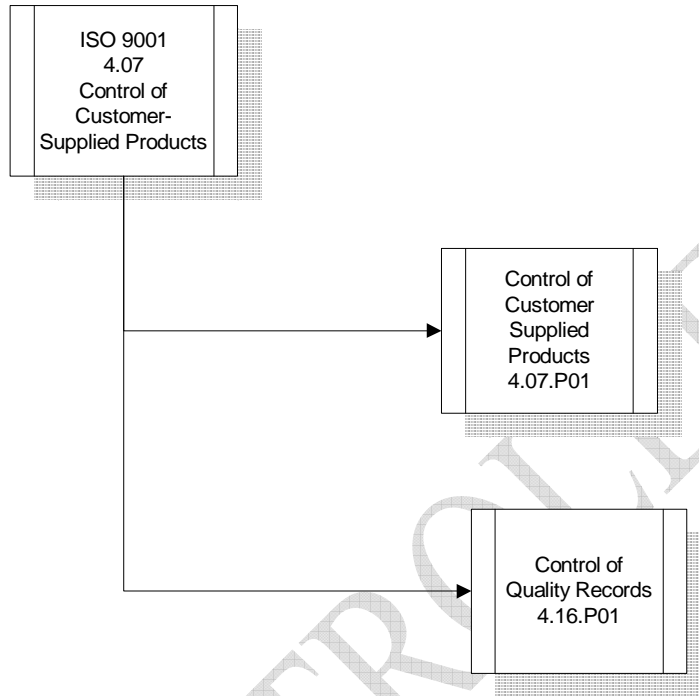
NOTE Customer property can include intellectual property.*

* Customer Supplied intellectual property will be handled in the same manor as stated in QAST-001, section 7.3 in Documentation Control.

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CUSTOMER SUPPLIED PRODUCT

Reference: 4.07, Revision J1; Owner: P. Harris; Page 2 of 2



PRODUCT IDENTIFICATION AND TRACEABILITY

Reference: 4.08, Revision J1; Owner: P. Harris; Page 1 of 2

7.5.3 Identification and traceability

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

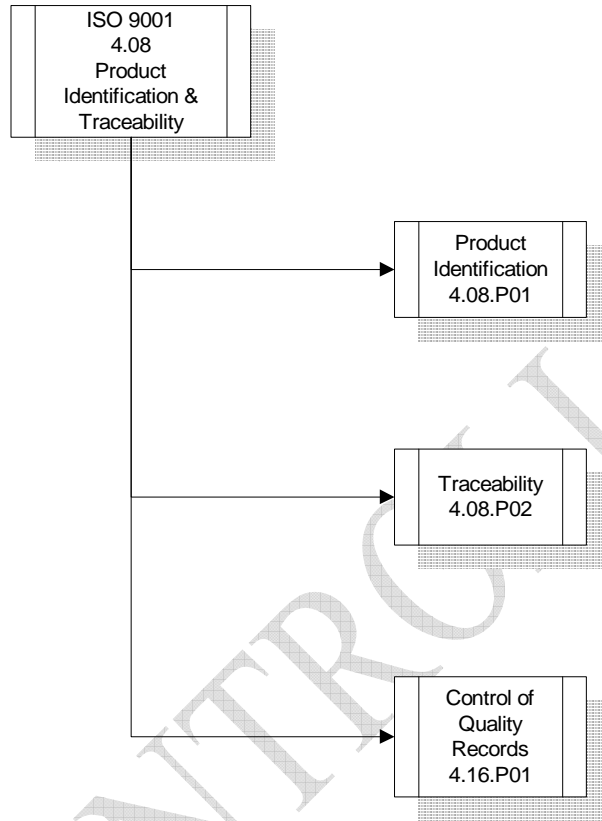
QuadTech shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, QuadTech shall control and record the unique identification of the product per 4.08.P02.

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PRODUCT IDENTIFICATION AND TRACEABILITY

Reference: 4.08, Revision J1; Owner: P. Harris; Page 2 of 2



PROCESS CONTROL

Reference: 4.09, Revision J1; Owner: P. Harris; Page 1 of 2

6.3 Infrastructure

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

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

6.4 Work environment

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

7.5.1 Control of production and service provision

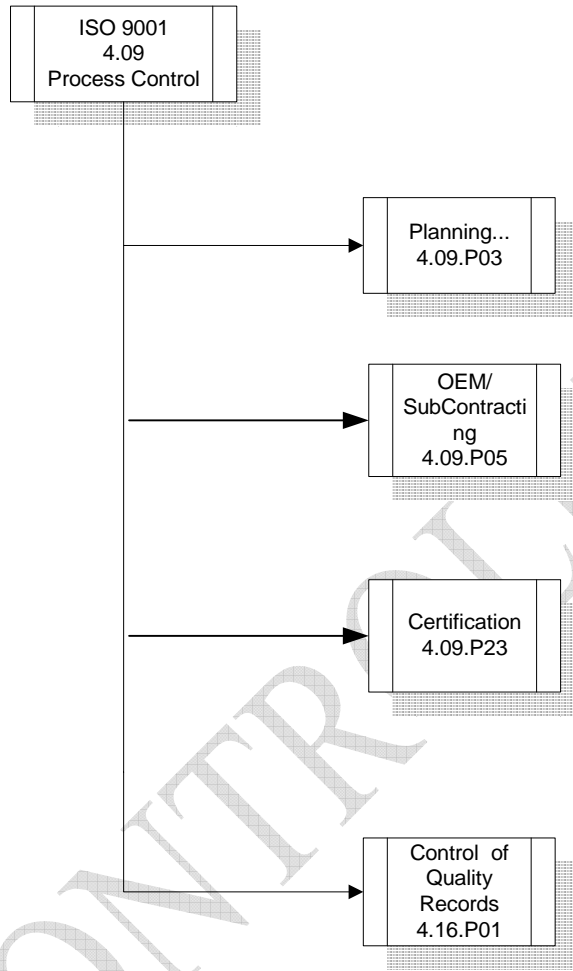
QuadTech shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

EXCEPTION: QuadTech does not presently employ any processes for production or services where the resulting output cannot be verified by subsequent monitoring or measurement. Should this status change, QuadTech will revise its QMS to meet the requirements of ISO 9001:2000 7.5.2.

PROCESS CONTROL



INSPECTION AND TEST

Reference: 4.10, Revision J1; Owner: P. Harris; Page 1 of 3

7.1 Planning of product realization

QuadTech 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.

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

- a) quality objectives and requirements for the product per 4.04;
- b) the need to establish processes, documents, and provide resources specific to the product per 4.04;
- c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements per 4.16.P01.

QuadTech's output of this planning shall be in a form suitable for the organization's method of operations.

7.4.3 Verification of purchased product

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

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

7.5.3 Identification and traceability

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

QuadTech shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, QuadTech shall control and record the unique identification of the product per 4.16.P01.

INSPECTION AND TEST

Reference: 4.10, Revision J1; Owner: P. Harris; Page 2 of 3

8.1 General

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

- a) to demonstrate conformity of the product,
- b) to ensure conformity of the quality management system, and
- c) 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.

8.2.4 Monitoring and measurement of product

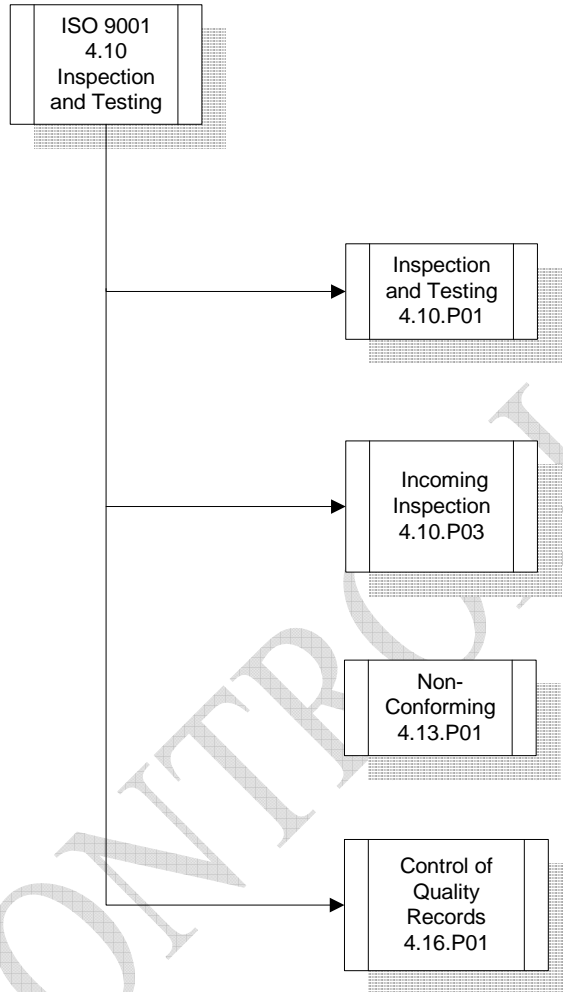
QuadTech shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product per 4.16.P01.

QuadTech's product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

INSPECTION AND TEST

Reference: 4.10, Revision J1; Owner: P. Harris; Page 3 of 3



CONTROL OF INSPECTION MEASURING AND TEST EQUIPMENT

Reference: 4.11, Revision J1; Owner: P. Harris; Page 1 of 2

7.6 Control of monitoring and measuring devices

QuadTech shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

QuadTech shall establish 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.

QuadTech's measuring equipment, where necessary to ensure valid results, shall:

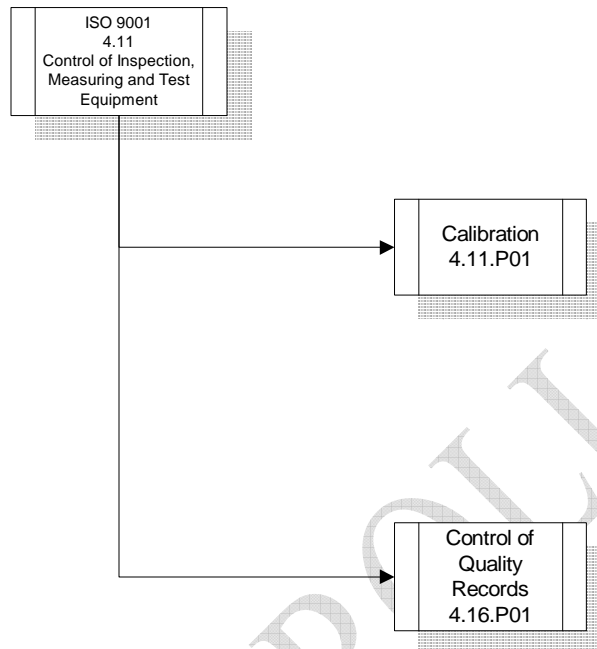
- a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to enable the calibration status to be determined;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, QuadTech shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. QuadTech shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained per 4.16.P01.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken by QuadTech prior to initial use and reconfirmed as necessary.

CONTROL OF INSPECTION MEASURING AND TEST EQUIPMENT

Reference: 4.11, Revision J1; Owner: P. Harris; Page 2 of 2



INSPECTION AND TEST STATUS

Reference: 4.12, Revision J1; Owner: P. Harris; Page 1 of 2

7.5.3 Identification and traceability

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

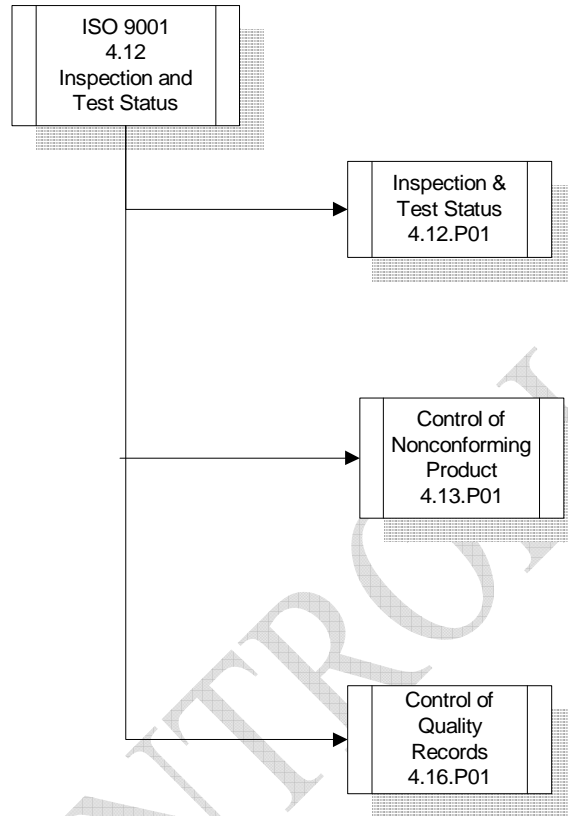
QuadTech shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product per 4.08.P02.

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INSPECTION AND TEST STATUS

Reference: 4.12, Revision J1; Owner: P. Harris; Page 2 of 2



NON-CONFORMING MATERIAL

Reference: 4.13, Revision J1; Owner: P. Harris; Page 1 of 2

8.3 Control of nonconforming product

QuadTech shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

QuadTech shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application.

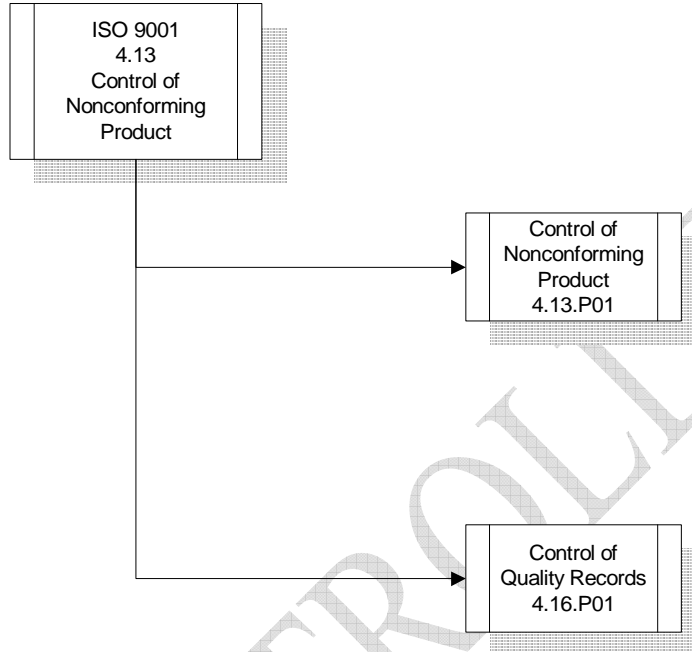
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained per 4.16.P01.

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

When nonconforming product is detected after delivery or use has started, QuadTech shall take action appropriate to the effects, or potential effects, of the nonconformity.

NON-CONFORMING MATERIAL

Reference: 4.13, Revision J1; Owner: P. Harris; Page 2 of 2



CORRECTIVE AND PREVENTIVE ACTION

Reference: 4.14, Revision J1; Owner: P. Harris; Page 1 of 2

8.5.2 Corrective action

QuadTech shall take action to eliminate the cause of nonconformities in order to prevent recurrence.

QuadTech's corrective actions shall be appropriate to the effects of the nonconformities encountered.

QuadTech's documented procedure shall be established to define requirements for:

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities ,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken per 4.16.P01, and
- f) reviewing corrective action taken.

8.5.3 Preventive action

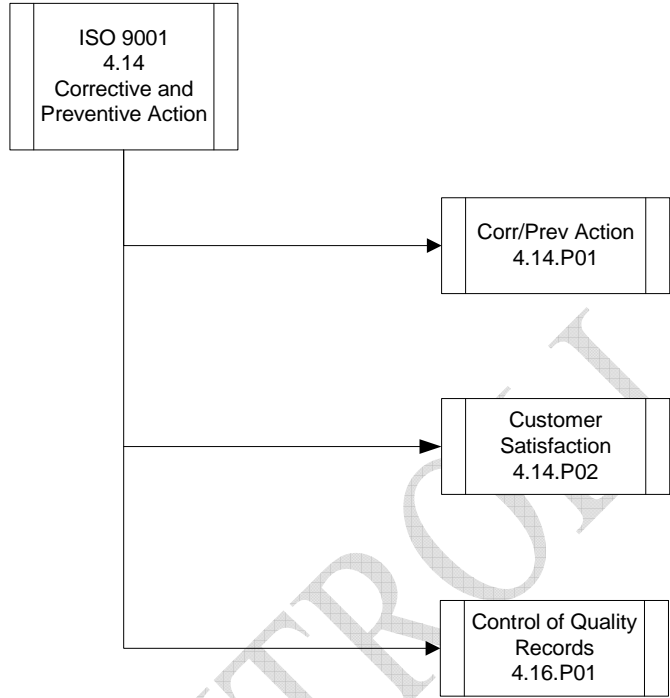
QuadTech shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

QuadTech's documented procedure shall be established to define requirements for:

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of results of action taken per 4.16.P01, and
- e) reviewing preventive action taken.

CORRECTIVE AND PREVENTIVE ACTION

Reference: 4.14, Revision J1; Owner: P. Harris; Page 2 of 2



HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

Reference: 4.15, Revision J1; Owner: P. Harris; Page 1 of 2

7.5.1 Control of production and service provision

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

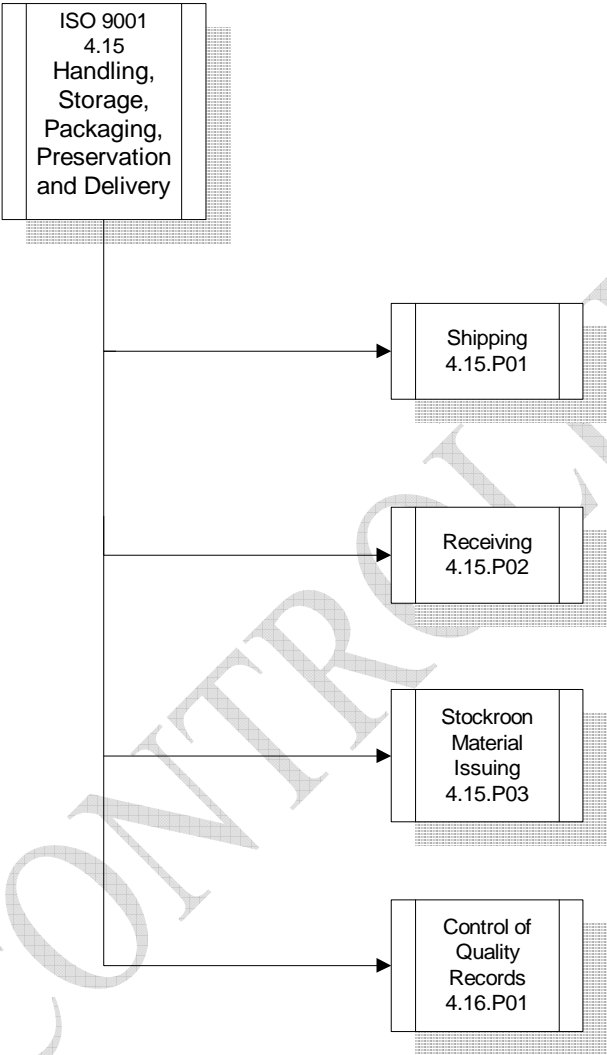
- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

7.5.5 Preservation of product

QuadTech shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY

Reference: 4.15, Revision J1; Owner: P. Harris; Page 2 of 2



CONTROL OF QUALITY RECORDS

Reference: 4.16, Revision J1; Owner: P. Harris; Page 1 of 2

4.2.4 Control of records

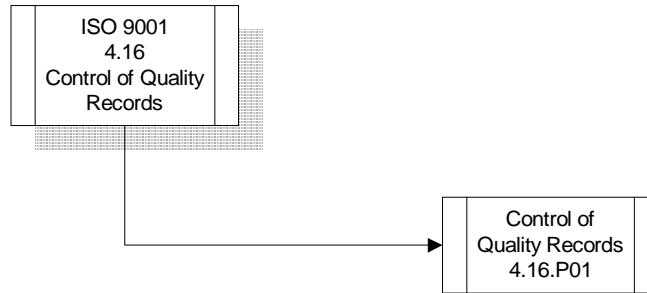
QuadTech's records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable.

QuadTech's documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

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CONTROL OF QUALITY RECORDS

Reference: 4.16, Revision J1; Owner: P. Harris; Page 2 of 2



INTERNAL QUALITY ASSESSMENTS

Reference: 4.17, Revision J1; Owner: P. Harris; Page 1 of 2

8.2.2 Internal audit

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

- a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the QuadTech, and
- b) is effectively implemented and maintained.

QuadTech's 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. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process.

QuadTech auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records per 4.16.P01 shall be defined in a documented procedure.

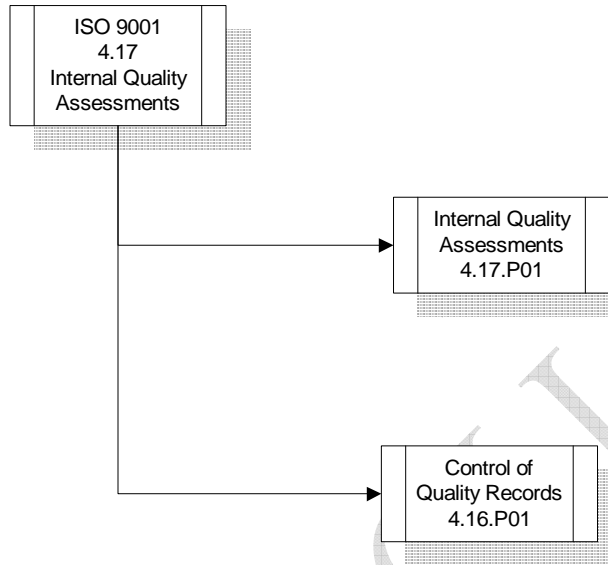
QuadTech's management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and measurement of processes

QuadTech 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, to ensure conformity of the product.

INTERNAL QUALITY ASSESSMENTS

Reference: 4.17, Revision J1; Owner: P. Harris; Page 2 of 2



TRAINING

Reference: 4.18, Revision J1; Owner: P. Harris; Page 1 of 2

6.2.1 General

QuadTech's personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

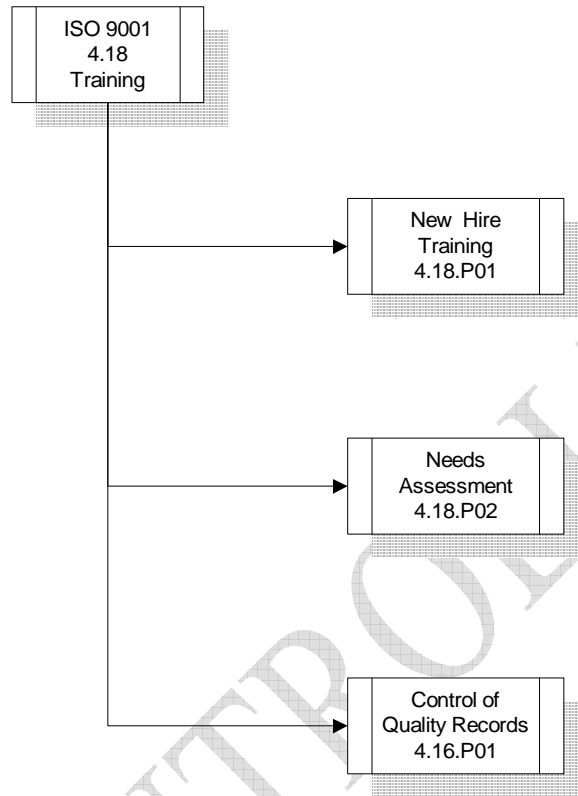
QuadTech shall:

- a) determine the necessary competence for personnel performing work affecting product quality,
- b) provide training or take other actions to satisfy these needs,
- 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 per 4.16.P01.

* The effectiveness of the training shall be reviewed at Management Review.

TRAINING

Reference: 4.18, Revision J1; Owner: P. Harris; Page 2 of 2



SERVICING

Reference: 4.19, Revision J1; Owner: P. Harris; Page 1 of 2

7.5.1 Control of production and service provision

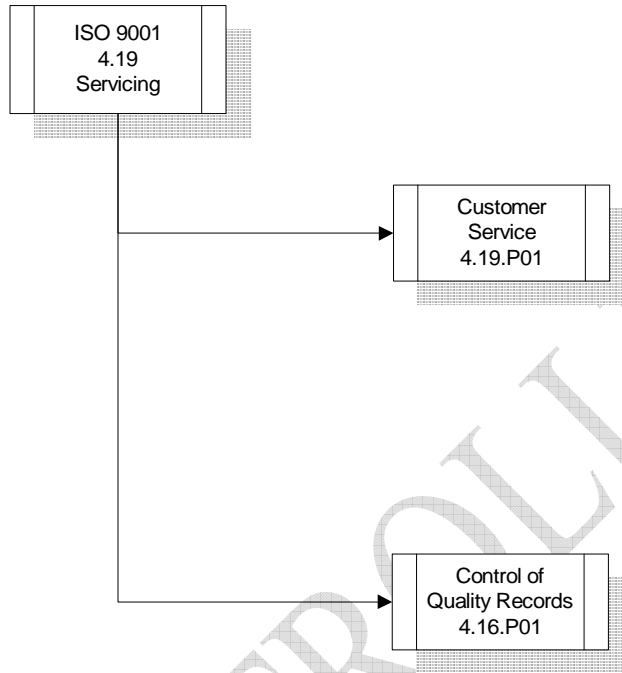
QuadTech shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

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SERVICING

Reference: 4.19, Revision J1; Owner: P. Harris; Page 2 of 2



STATISTICAL TECHNIQUES

Reference: 4.20, Revision J1; Owner: P. Harris; Page 1 of 3

5.5.3 Internal communication

QuadTech's top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6.2 Review input

QuadTech's input to management review shall include information on:

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

5.6.3 Review output

QuadTech's output from the management review shall include any decisions and actions related to

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

8.1 General

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

- a) to demonstrate conformity of the product,
- b) to ensure conformity of the quality management system, and
- c) to continually improve the effectiveness of the quality management system.

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

8.2.1 Customer satisfaction

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

STATISTICAL TECHNIQUES

Reference: 4.20, Revision J1; Owner: P. Harris; Page 2 of 3

8.2.3 Monitoring and measurement of processes

QuadTech 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, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

QuadTech 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.

QuadTech's evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product per 4.16.P01.

QuadTech's Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.4 Analysis of data

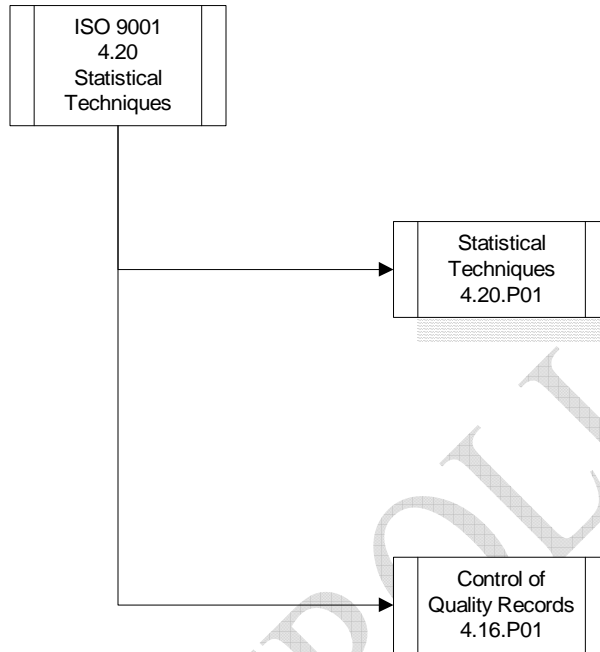
QuadTech shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:

- a) customer satisfaction,
- b) conformity to product requirements
- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

STATISTICAL TECHNIQUES

Reference: 4.20, Revision J1; Owner: P. Harris; Page 3 of 3



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