



CCC Quality Manual

QM-001-U

October • 2006

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COMPRESSOR CONTROLS CORPORATION

Quality Manual

Letter	Revision Record	Approval	Date
J	Revision	D. Perkins	1/97
K	Revision	D. Perkins	1/98
L	Revision	D. Perkins	10/00
M	Revision	S. Taylor	11/01
N	Revision	S. Taylor	4/03
O	Revision	S. Taylor	6/03
P	Revision	S. Taylor	6/03
Q	Revision	S. Taylor	5/04
R	Revision	H. Krishnamurthy	4/05
S	Revision	H. Krishnamurthy	11/05
T	Revision	H. Krishnamurthy	5/06
U	Revision	H. Krishnamurthy	10/06

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CO #	REVISION DATE	REVISION LEVEL
NA	9/92	A
900/9211/003	6/93	B
010/9308/002	12/93	C
900/9403/007	3/94	D
900/9501/003	2/95	E
900/9506/013	9/95	F
900/9601/009	3/96	G
900/9604/002	5/96	H
900/9607/006	7/96	I
900/9611/001	1/97	J
900/9706/005	1/98	K
900/9812/012	10/00	L
050/0110/001	11/01	M
900/0304/005	4/03	N
900/0306/004	6/03	O
900/0306/009	6/03	P
900/0405/002	5/04	Q
900/0503/001	4/05	R
2618	11/05	S
2715	5/06	T
19	10/06	U



INTRODUCTION

Compressor Controls Corporation (CCC) designs, manufactures, and supplies an extensive range of products, systems, and services for the turbomachinery control market.

CCC developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers, and to improve the overall management of the company.

The Quality Management System of CCC meets the requirements of the international standard ISO-9001: 2000. This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of ISO 9001 - 2000. Each section begins with a policy statement expressing CCC's obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual is supported by documented quality procedures established and maintained by each affected department. The quality procedures provide specifications, standard practices, test and inspection methods, and other operational and manufacturing requirements that affect the quality of CCC products and services.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.



CORPORATE QUALITY POLICY

It is the policy of Compressor Controls Corporation to provide reliable products that fulfill our customers' ongoing needs and expectations; and to foster a work place environment that will facilitate the achievement of this objective.

To assure complete customer satisfaction, we will strive to anticipate their needs. To assure consistent quality, work will be performed according to established procedure. To assure continual improvement, procedures will be revised to reflect improvements in process, products, and technology.

Every employee is expected and encouraged to find ways to improve the quality of our products and services, with the full support and assistance from all levels of management.

A handwritten signature in black ink, appearing to read 'Paul Fisher'.

Paul Fisher
President, Compressor Controls Corporation



SECTION 1: SCOPE

1.1 General

This manual describes the quality system requirements for the design, manufacture, and supply of CCC products and services. The system is structured to comply with the conditions set forth in the International Standard ISO 9001:2000 and operates in all areas of the Company's Des Moines Facility.

Some older or obsolete products no longer marketed by CCC are not specifically included within the scope of the Quality Management System; however, they are produced and supplied using processes that generally meet the intent of this system.

1.2 Application

Compressor Controls Corporation has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

- There are no exclusions to be made.



SECTION 2: NORMATIVE REFERENCE

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- **ISO9000** Quality Management Systems-Fundamentals and vocabulary
- **ISO9001** Quality Management Systems-Requirements
- **ISO9004** Quality Management Systems-Guidelines for Performance Improvement
- **MIL-Q-9858A** Quality Program Requirements



SECTION 3: DEFINITIONS

3.0 Quality Management System Definitions

The following CCC-specific definitions are used within this manual.

- ASL-Approved Supplier List
- Assembly-An interim stage of manufacture, comprised of one or more partially or fully completed printed circuit boards and related hardware, uniquely identified for purposes of test, inspection, stocking, and/or traceability.

Also, for design and engineering purposes, a uniquely identified part of a larger unit, usually defined by a single printed circuit board, and sometimes including related hardware.
- CCC-Compressor Controls Corporation
- Commissioning-Start up services for a CCC product as installed at the customer site; typically Engineering provides this service.
- Controller Products-An identified, usually standard level of construction consisting of one or more units and related hardware and software sold and shipped to CCC customers.
- CQC-Corporate Quality Committee
- DCS-Document Control Supervisor
- Executive Staff-A group of the company's top level managers lead by the Executive Vice President
- Management-Refers to all levels of management (group, departmental, and executive)
- Material-Used generically to mean all material, components, and non-CCC built products purchased and received by CCC for use in manufacturing products and systems.
- MR-Management Representative
- Panel Products-A type of CCC manufactured product which may incorporate various CCC controller product, electromechanical hardware, indicators, wiring, mounting hardware, and/or enclosures, sold and shipped as a fully integrated product. Panel products are typically custom designed per customer specifications and usually receive dedicated engineering and manufacturing resources within the Company.
- QAP-Quality Assurance Procedure
- Quality Management System-The quality system that states the requirements for the design, manufacture, and supply of CCC products and services.



- Record-Documented results of business or quality related operations or activities
- Subcontractor-Any supplier providing CCC with material or product designed and/or manufactured to CCC specifications per established contract requirements.
- Supplier-Any supplier or vendors from whom CCC purchases material for use in products or systems supplied to customers.
- Systems-In the field, a combination of CCC manufactured and/or purchased products, related hardware and software, customer-supplied materials, control system elements, and CCC supplied engineering services, which result in an operational control system.
- Unit-The lowest constructed level of functional product manufactured, sold, and shipped to CCC customers.



SECTION 4: GENERAL REQUIREMENTS

4.1 General requirements

CCC has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2000. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

To design and implement the QMS CCC has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- Determined criteria and methods needed to ensure that the operation and control of the processes are effective, documented, maintained, and continuously operated in accordance with this manual and all other quality documents and procedures.
- Evaluated and monitored outsourced processes to assure conformity to customer requirements
- Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes
- Established systems to monitor, measure and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records



4.2.2 Quality Manual

This Quality Manual has been prepared to describe CCC's QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Process Flow Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.



4.2.2 Business Processes

CCC has defined the following business processes, which are critical to achieving its objectives and goals. Key Performance Indicators (KPIs) for each of these processes are defined, measured and improved by respective process owners. Management reviews these KPIs on a monthly and quarterly basis.

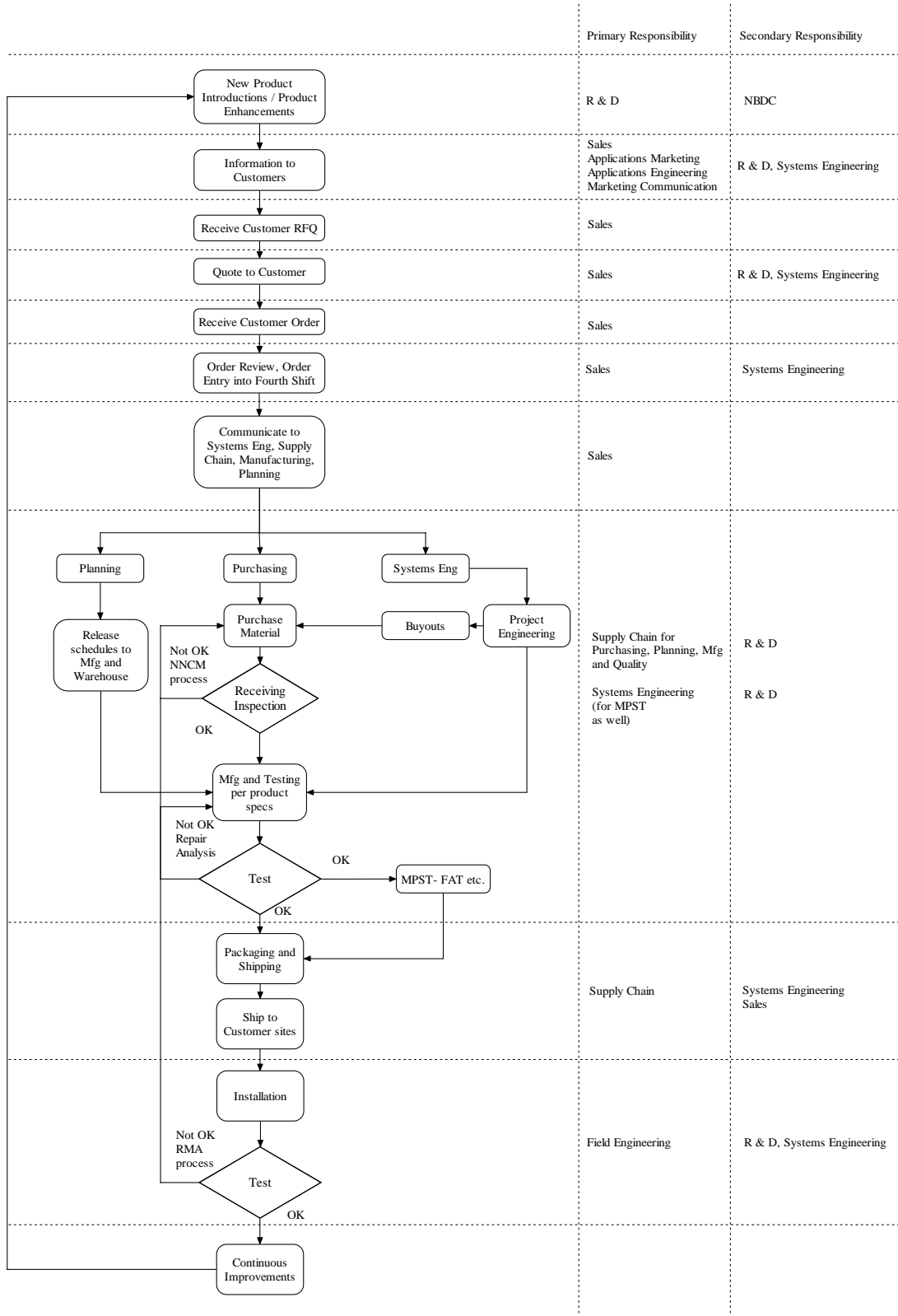
Process	Input	Activity	Resources	Primary Responsibility	Secondary Responsibility	Output
Product Development	Customer requirements, Statutory & Regulatory requirements, Marketing team, Major Corrective actions and improvements	Design and Develop new products to meet customer requirements and Sustaining Engineering of existing products	Human Software External resources Equipment	Director, Product Design	Marketing, Sales, NBDC, Manufacturing, Product Support, Quality	New products / Enhanced products for Customers / Manufacturing
Customer Support	Customer requirements, CCC Design, Field Engineering input, Project Engineering input	New Product Validation and Release, Project Special Software validation and Release, Product status review, Recommendation for product use, and improvement process in collaboration with R&D; Project problem investigation, Support for project and field engineers, Product Training, Pilot project engineering	Human Hardware Software Test Equipment	Director, Product Support	Product Design, Project Engineering, Field Engineering, Quality, Manufacturing	New product releases, Special software releases per projects, Problem resolution and root cause analysis, Product Defect reports and enhancement requests; Product training presentation
Sales Operations	Customer requirements, RFQ, Accepted Customer Order	Review of Customer requirements (Tender / Proposal Review, Contract Review), Order Entry	Human Software	Director, Sales Operations	R & D, Project Engineering, Manufacturing, Supply Chain	Requirements communicated effectively to Manufacturing for product realization



Process	Input	Activity	Resources	Primary Responsibility	Secondary Responsibility	Output
Purchasing and Warehouse	Customer requirements, Accepted Customer Order, Product Specifications	Purchase of items and services for fulfilling customer orders	Human Software External resources - Suppliers	Operations Manager	Quality, Manufacturing	Right Parts / Services for Manufacturing, Systems Engineering at right cost and time
Project Engineering	Customer requirements, Accepted Customer Order, Product Specifications	Engineer product / system to suit individual project / customer requirements	Human Software Equipment	VP – Project Engineering	R & D, Sales, Manufacturing	Engineered solution meeting or exceeding customer expectations at right cost and time
Manufacturing (Panel Shop, Final Assembly and Test)	Customer requirements, Accepted Customer Order, Product Specifications	Manufacturing / verification of products & services per customer requirements, Calibration of measuring & monitoring devices	Human Software Equipment Measuring & Monitoring devices	Operations Manager	Quality, R & D, Systems Engineering, Sales	Right product, services to next customer at right time and right cost
Field Engineering	Products delivered to customers	Field installation of CCC products at customer sites	Human, Equipment, Software	VP – Field Engineering	Project Engineering, R&D, Manufacturing, Quality	Products installed and working, meeting or exceeding customer requirements
Customer Training	CCC Product Information, Individual Customer Projects	Provide training to Customers on CCC products and applications	Human Software	Customer Training Manager	VP - Field Engineering	Customers trained to use CCC products effectively
Quality	Products & Services, Measuring & Monitoring devices, Quality Management system	Effective Functioning of QMS, coordinate internal / external auditing, implementation of corrective / preventive action process, drive companywide continuous improvement processes	Human, Software, Measuring & Monitoring devices	Quality Manager, All functions	None	Effective Quality system with continuous improvements



4.2.2 Business Process Flow Chart





4.2.3 Control of documents

All of the QMS documents are controlled according to the *Document Control Practices* (TQAP003). This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified and their distribution controlled, and
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose
- Assigning overall supervision and responsibility for Document Control to the DCS.

4.2.4 Control of quality records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the *CCC Quality Records Procedure* (TREF008). This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

Related Documents

TQAP003 - *Document Control Practices*

TQAP010- *Control of Quality Records*

TREF008 - *CCC Quality Records*



Section 5: Management Responsibility

5.1 Management commitment

The Executive Staff has been actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following as detailed in *Quality Management Review* (AQAP003).

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Ensure that the quality system operates continuously within CCC
- Direct the improvement efforts of the quality system at CCC
- Establish overall reliability and quality objectives
- Establish the quality policy.
- Conduct management reviews.
- Ensure the availability of resources.
- Select the Management Representative (MR)

5.2 Customer focus

CCC strives to identify current and future customer needs, meet customer requirements, and exceed customer expectations.

The Executive Staff ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization per *Systems Engineering Document Control Procedure* (TQAP227).

5.3 Quality policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee (Quality Awareness) training and training on the QMS. It is posted in the facility, is part of the Quality Manual, and can be viewed by all employees through the public drive of the computer network.

Management reviews the quality policy during the monthly management review meeting to determine the policy's continuing suitability for our organization.



5.4 Planning

5.4.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Objectives have been established, and the CQC members are responsible for reporting on these objectives monthly. These objectives involve department quality objectives. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

The quality objectives have been documented through the management review process. This is stated in Section 5.1 Management Commitment in the Quality Manual.

5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001 standard. Quality planning takes place as changes that affect the quality system are planned and implemented. Quality Planning for CCC is covered in the procedure *Quality Planning* (TREF001) and in *CCC Quality Planning* (AQAP008).

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by management for adequacy. These documents are available through the Human Resources Department to help employees understand their responsibilities and authorities.

5.5.2 Management representative

The Executive Staff normally appoints the Quality Systems Manager, to serve as the Management Representative. However, nothing precludes assigning this role to any appropriate individual. As Management Representative, they have the following responsibility and authority:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.



- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.
- Works with all departments to assess quality needs and objectives.
- Ensure that internal quality audits are conducted on a regular basis throughout the company.

5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, quarterly company luncheons, reviews of audits both internal and external, and other routine business communication.

5.6 Management Review

5.6.1 General

Top management reviews the QMS monthly at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

5.6.2 Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs may include, but are not limited to the following:

- Results of audits
- Customer feedback and customer complaint forms (CCFs)
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement
- Minutes from the monthly CQC meeting and the SPC charts produced by the CQC group



5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

Related Documents

AQAP003 - *Quality Management Review*

AQAP008 - *CCC Quality Planning*

TQAP227 - *Systems Engineering Document Control Procedure*

TREF001 - *Quality Planning*

Management Review Quality Manual, Section 5.1



SECTION 6: RESOURCE MANAGEMENT

6.1 Provision of resources

CCC has implemented a Quality Management System that complies with the ISO 9000: 2000 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain, continually improve the system, and ensure customer satisfaction, management will determine and provide the necessary resources.

6.2 Human resources

6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure. *Employee Job Requirements, Evaluation, Training, and Records (AQAP001)*.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

Records of education, training, skills, and experience will be maintained in the employee's file.

6.3 Infrastructure

To meet quality objectives and product requirements CCC has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment, and supporting services. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented in:

- Preventive maintenance plans



6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. The work environment is managed for continuing suitability. Data from the quality system is evaluated and reviewed to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Related Documents

AQAP001 - *Employee Job Requirements, Evaluation, Training, and Records*



SECTION 7: PRODUCT REALIZATION

7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the *Tender Review-Contract Review-Order Entry Procedure* (OQAP001) and or *Quality Management Procedure for Planning of Product Realization* (AQAP006). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, validation, monitoring, inspection and test requirements, and
- Criteria for product acceptance

The output of quality planning includes documented quality objectives, processes, procedures and design outputs. Records are available to verify that the realization process and resulting product meet customer requirements.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

CCC determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by CCC

Customer requirements are determined according to the *Tender Review-Contract Review-Order Entry Procedure* (OQAP001) and the *Project Execution Procedure* (TQAP201).



7.2.2 Review of requirements related to the product

CCC has a process in place for the review of requirements related to the product *Tender Review-Contract Review-Order Entry Procedure* (OQAP001). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- CCC has the ability to meet the defined requirements
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, CCC communicates changes to relevant personnel and amends relevant documents

7.2.3 Customer communication

CCC has implemented the *Contract Management* (TQAP224) for communicating with customers in relation to:

- Product Information
- Inquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints through the *Customer Satisfaction Survey Procedure* (TQAP602) and *Customer Complaint Form Procedure* (TQAP603)

7.3 Design and Development

7.3.1 Design and development planning

The *Design/Development Planning, Design Input, and Design Output Procedure* (TQAP110) outlines the process for controlling the design and development process. The R&D Department plans design and development according to this procedure. The design plan includes:

- Design and development stages
- Required design reviews



- Verification and validation methods appropriate to each design and development stage
- Responsibilities and authorities for design and development
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses

7.3.2 Design and development inputs

Inputs relating to product requirements are determined, documented, and maintained according to *Design/Development Planning, Design Input, and Design Output Procedure* (TQAP110). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous input. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development

7.3.3 Design and development outputs

Outputs of design and development are documented according to the *Design/Development Planning, Design Input, and Design Output Procedure* (TQAP110). They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

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



7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed

7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained.

7.3.7 Control of design and development changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.



7.4 Purchasing

7.4.1 Purchasing process

Purchasing P.O. Procedure (MQAP600) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in procedure *Supplier Selection and Approval Requirements* (MQAP603). Records of the evaluation and any necessary actions are maintained as quality records.

7.4.2 Purchasing information

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

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of purchased product

Warehouse Procedure (MQAP002) describes the process used to verify that purchased product meets specified purchase requirements. If CCC or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

CCC plans and carries out production and service provision under controlled conditions according to documented procedures. Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment



- The availability and use of monitoring and measuring devices
- The implementation of monitoring and measurement
- The implementation of release, delivery and post-delivery activities

7.5.2 Validation of processes for production and service provision

CCC validates any processes for production and service provision where subsequent monitoring or measurement cannot verify the resulting output. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

CCC has documented the process for validation including:

- 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
- Revalidation

7.5.3 Identification and traceability

CCC identifies the product throughout product realization according to the *Product Nonconformance, Inspection, and Test Status Procedure* (MQAP105) and the *Product Assembly, Test, and Serialization Requirements Procedure* (MQAP107). Product is identified with respect to monitoring and measurement requirements.

CCC controls and records the unique identification of the product wherever traceability is a specified requirement according to *Product Assembly, Test, and Serialization Requirements Procedure* (MQAP107).

7.5.4 Customer property

CCC exercises care with customer property while it is under the organization's control or being used. *Warehouse Procedure* (MQAP002) outlines the Identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.



7.5.5 Preservation of product

CCC preserves the conformity of product during internal processing and delivery to the intended destination per procedures *Handling of Electrostatic Sensitive Devices (ESD) Procedure* (MQAP001), *Product Nonconformance, Inspection, and Test Status Procedure* (MQAP105), and *Product Assembly, Test, and Serialization Requirements Procedure* (MQAP107).

This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of monitoring and measuring devices

CCC has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. *Test, Measurement, and Diagnostic Equipment (TMDE) Maintenance and Application Procedure* (MQAP102) outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards
- Adjusted or re-adjusted as necessary;
- Identified to enable the calibration status to be determined;
- Safeguarded from adjustments that would invalidate the measurement result;
- Protected from damage and deterioration during handling, maintenance and storage.

In addition, Quality Assurance will assist Manufacturing in assessing the validity of the previous measuring results when the equipment is found not to conform to requirements. CCC takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

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



Related Documents

- AQAP006 - *Quality Management Procedure for Planning of Product Realization*
- MQAP001 - *Handling of Electrostatic Sensitive Devices (ESD) Procedure*
- MQAP002 - *Warehouse Procedure*
- MQAP102 - *Test, Measurement, and Diagnostic Equipment (TMDE) Maintenance and Application Procedure*
- MQAP105 - *Product Nonconformance, Inspection, and Test Status Procedure*
- MQAP107 - *Product Assembly, Test, and Serialization Requirements*
- MQAP417 - *Series 5 Calibration Structure Definition*
- MQAP418 - *Series 5 IO Accuracy Specification*
- MQAP419 - *Series 5 Manufacturing Data EEPROM Definition*
- MQAP420 - *Series 5 Software Configuration*
- MQAP600 - *Purchasing P.O. Procedure*
- MQAP603 - *Supplier Selection and Approval Requirements*
- OQAP001 - *Tender Review-Contract Review-Order Entry Procedure*
- TQAP110 - *Design/Development Planning, Design Input, and Design Output Procedure*
- TQAP201 - *Project Execution Procedure*
- TQAP224 - *Contract Management*
- TQAP603 - *Customer Complaint Form Procedure*



SECTION 8: MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

CCC has plans and implements the monitoring, measurement, analysis and improvement processes as needed

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

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, CCC monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the *Customer Satisfaction Survey Procedure* (TQAP602).

8.2.2 Internal Audit

CCC conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the *CCC Internal Audit Procedure* (TQAP901).

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected



nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and measurement of processes

CCC applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

CCC monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process. Procedures from the MQAP4xx series detail the process of measurement and acceptance.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.3 Control of Nonconforming Product

CCC ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls, maintenance of records, corrective action, related responsibilities, and authorities for dealing with nonconforming product and nonconformities are defined in the *Product Nonconformance, Inspection, and Test Status Procedure* (MQAP105), *Handling and Return of Nonconforming Materials Procedure* (MQAP601) and *Corrective and Preventive Action (CAPA) Procedure* (TQAP906).

8.4 Analysis of Data

CCC determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

- Customer satisfaction
- Conformance to product requirements



- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

8.5 Improvement

8.5.1 Continual improvement

CCC continually improves 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.

8.5.2 Corrective action

CCC takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

Corrective and Preventive Action (CAPA) Procedure (TQAP906) defines 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 corrective action taken.

8.5.3 Preventive action

CCC determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

Corrective and Preventive Action (CAPA) Procedure (TQAP906) defines 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
- Reviewing preventive action taken

Related Documents

MQAP105 - *Product Nonconformance, Inspection, and Test Status Procedure*
MQAP400 - *Series 3 Plus Test Software Procedure*
MQAP401 - *Series 3 Plus Controller Final Test Procedure*
MQAP402 - *Series 3 EAS Test Software Procedure*
MQAP403 - *Equipment Verification Procedure*
MQAP408 - *Series 3 EAS Final Test Procedure*
MQAP410 - *Controller Hardware Accessories Configuration and Final Test Procedure*
MQAP411 - *Series 4 Final Test and Documentation Procedure*
MQAP412 - *Continuity Analyzer Test Procedure*
MQAP413 - *Series 5 Final Test and Documentation Procedure*
MQAP415 - *Master Series 5 Test Procedure*
MQAP601 - *Handling and Return of Nonconforming Materials Procedure*
TQAP602 - *Customer Satisfaction Survey Procedure*
TQAP901 - *CCC Internal Audit Procedure*
TQAP906 - *Corrective and Preventive Action (CAPA) Procedure*
TQAP908 - *“CE” Testing Procedure*