



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 1 OF 40

DATE 2/4/10

REVISION M

# QUALITY OPERATING PROCEDURE

**Note:** The revision level of this document and any referenced documents must be verified for latest issue before use

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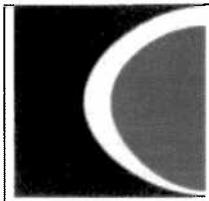
## QOP-00-02

TITLE

# QUALITY ASSURANCE SYSTEM MANUAL

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	APPROVALS	DATE	REVISIONS (SEE SHEET 2)
WRITER	DH	12/21/94	<del> </del>
APPROVED	DH	12/21/94	
ENGR	N/A		
QA	N/A		



**CURTIS INSTRUMENTS INC.**  
**200 KISCO AVE**  
**MOUNT KISCO, NY 10549 USA**

**OPERATING PROCEDURE**

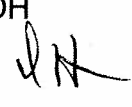
NO. QOP-00-02

PAGE 2 OF 40

DATE 2/4/10

REVISION M

**REVISION HISTORY**

REVISION	ECN	DESCRIPTION	DATE	APPROVAL
A	None	Original Issue	12/21/94	DH
B	None	March , 1997 update QA department controlled	3/15/97	DH
C	9200	Release to Engineering documentation control, procedural updates	12/18/00	DH
D	9261	Added section 2.2, Quality Planning, adjusted paragraph numbering; Added section 3.6, Customer Service reps., adjusted paragraph numbering; section 6.2.3 deleted text; section 8 adjusted paragraph numbering; added section 9.5, Special Processes; added 11.7, regarding measuring & testing equipment, added section 11.9, regarding measuring & testing equipment; renumbered paragraphs; section 14.1 changed "may" to "will"; added the word "legible" in section 16.2.	1/16/01	DH
E	10588	Major update to ISO 9001-2000 version Quality Management System	5/27/03	DH
F	10874	Minor updates and corrections for continual compliance for ISO 9001-2000.	2/11/04	DH
G	10907	Revised pg. 4 (5.4.1), pg. 9 (1, 4), pg. 10 (5), pg. 18 (5.4.1), pg. 19 (5.4.1), pg. 21 (org. chart) pg. 22 (org chart), pg. 23 (5.5.1.1).	3/1/04	DH
H	10955	Removed existing exclusion	3/11/04	DH
J	11158	Revised pg. 3, Controlled Copy #10 title, pg. 6 section 8.5.2 and 8.5.3 removed references to QOP-14-01 and 1.16 (PR) and replaced with COP-01-07 and COP-01-08.	9/29/04	DH
K	11789	Revised sections 1.0, and 5.6.1, updated pg. 3 controlled copies, updated org. charts (pg. 20 & 21) added California Livermore org. chart (pg. 22). Reference to Curtis PMC changed to Curtis Livermore.	3/3/06	DH
L	13696	Removed 1 <sup>st</sup> paragraph of section 7.4.1 Purchasing Process.	2/12/07	DH
M	15838	Updated references to ISO 9001:2000 to reflect current ISO 9001:2008, updated sec. 7.4.1 adding outsourcing process control, and corrected wording in 1st sentence of sec. 7.3.1. Pg.16 reviewed & signatures updated.	2/4/10	DH 



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02  
PAGE 3 OF 40  
DATE 2/4/10  
REVISION M

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**Controlled** copies are copies that are automatically updated at each revision. Persons who request a copy of the Quality System Manual will receive an **uncontrolled** version. This is a copy that will not automatically be updated at each revision, but only by request. A listing of the people who have received controlled copies of this manual will be noted on this and the next page. This manual shall be formally reviewed on an annual basis to ensure that any changes to systems have been documented.

### CONTROLLED COPIES GIVEN TO:

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<u>VP Quality</u>	<u>2</u>	<u>Curtis, Mt. Kisco</u>
<u>VP Engineering</u>	<u>3</u>	<u>Curtis, Mt. Kisco</u>
<u>VP Manufacturing</u>	<u>4</u>	<u>Curtis, Mt. Kisco</u>
<u>VP Sales</u>	<u>5</u>	<u>Curtis, Mt. Kisco</u>
<u>VP Human Resources</u>	<u>6</u>	<u>Curtis, Mt. Kisco</u>
<u>CFO</u>	<u>7</u>	<u>Curtis, Mt. Kisco</u>
<u>VP&amp; General Manager</u>	<u>8</u>	<u>Curtis, Puerto Rico</u>
<u>QA Manager</u>	<u>9</u>	<u>Curtis, Puerto Rico</u>
<u>VP &amp; Exec. Director</u>	<u>10</u>	<u>Curtis, Livermore</u>
<u>ISO Registrar</u>	<u>11</u>	<u>Curtis MT. Kisco</u>
<u>Management Rep.</u>	<u>12</u>	<u>Curtis Livermore</u>

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**CURTIS INSTRUMENTS INC.**  
**200 KISCO AVE**  
**MOUNT KISCO, NY 10549 USA**

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 4 OF 40

DATE 2/4/10

REVISION M

**Table of Content and Procedure Cross Reference**

SECTION	CONTENT	Process / Procedure	Process / Procedure	Process / Procedure	Process / Procedure	Process / Procedure
	Title Page	QOP-00-02				
	Revision History	QOP-00-02				
	Distribution	QOP-00-02				
	Introduction	QOP-00-02				
1	Activities, scope and permissible exclusions	QOP-00-02				
2	Normative reference	QOP-00-02				
3	Terms and definitions	QOP-00-02				
4	Quality management system	QOP-00-02				
4.1	General Quality Management Requirements	QOP-00-02	QOP-01-01	QOP-02-01		
4.2	Documentation requirements	QOP-00-02				
4.2.1	General Documentation Requirements	QOP-00-02	EOP-05-01	QOP-02-01	2.10 (PR)	
4.2.2	Quality Manual*	QOP-00-02				
4.2.3	Control of Documents*	QOP-00-02	QOP-05-02	2.10 (PR)	MOP-09-01	
4.2.4	Control of Records*	QOP-00-02	QOP-16-01	1.17 (PR)		
5	Management responsibility	QOP-00-02				
5.1	Management commitment	QOP-00-02	QOP-01-01	1.1 (PR)		
5.2	Customer Focus	QOP-00-02				
5.3	Quality Policy	QOP-00-02				
5.3.1	Role of Policy	QOP-00-02				
5.3.2	Communication	QOP-00-02				
5.3.3	Review	QOP-00-02				
5.4	Planning	QOP-00-02				
5.4.1	Quality Objectives	QOP-00-02	QOP-01-01			
5.4.2	Quality Management system Planning	QOP-00-02	QOP-02-01	EOP-04-01	MOP-09-03	
5.5	Responsibility, Authority and Communication	QOP-00-02				
5.5.1	Responsibility and Authority	QOP-00-02	Org Chart			
5.5.1.1	Top Management	QOP-00-02	Org Chart			
5.5.1.2	Engineering	QOP-00-02	Org Chart			
5.5.1.3	Production Control	QOP-00-02	Org Chart			
5.5.1.4	Production	QOP-00-02	Org Chart			
5.5.1.5	Purchasing	QOP-00-02	Org Chart			
5.5.1.6	Receiving	QOP-00-02	Org Chart			



**CURTIS INSTRUMENTS INC.**  
**200 KISCO AVE**  
**MOUNT KISCO, NY 10549 USA**

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 5 OF 40

DATE 2/4/10

REVISION M

**\* Mandatory Procedure Required by ISO 9001: 2008**

**Table of Content and Procedure Cross Reference**

SECTION	CONTENT	Process / Procedure	Process / Procedure	Process / Procedure	Process / Procedure	Process / Procedure
5.5.1.7	Shipping	QOP-00-02	Org Chart			
5.5.1.8	Warranty	QOP-00-02	Org Chart			
5.5.1.9	Sales/Marketing Services	QOP-00-02	Org Chart			
5.5.1.10	Product Management	QOP-00-02	Org Chart			
5.5.1.11	Customer Service	QOP-00-02	Org Chart			
5.5.1.12	Human Resources	QOP-00-02	Org Chart			
5.5.1.13	QA	QOP-00-02	Org Chart			
5.5.2	Management Representative	QOP-00-02	QOP-01-01			
5.5.3	Internal communication	QOP-00-02	QOP-02-01			
5.6.1	Management Review	QOP-00-02	QOP-01-01	1.1 (PR)		
5.6.2	Review Input	QOP-00-02	QOP-01-01			
5.6.3	Review Output	QOP-00-02	QOP-01-01			
6	Resource management	QOP-00-02				
6.1	Provision of resources	QOP-00-02				
6.2	Human resources	QOP-00-02				
6.2.1	Assignment of Personnel	QOP-00-02				
6.2.2	Competence, Awareness, and Training	QOP-00-02	HOP-18-01	MOP-09-18	QOP-18-01	6.1 (PR)
6.3	Infrastructure	QOP-00-02				
6.4	Work environment	QOP-00-02				
7	Product realization	QOP-00-02				
7.1	Planning of product realization	QOP-00-02	EOP-04-01			
7.2	Customer-related processes	QOP-00-02				
7.2.1	Determination of Requirements Relating To The Product	QOP-00-02	EOP-04-01	SOP-03-01		
7.2.2	Review of Requirements Related To The Product	QOP-00-02	EOP-04-01	SOP-03-01		
7.2.3	Customer Communications	QOP-00-02	SOP-72-01	COP-07-02	SOP-03-04	
7.3	Design and development	QOP-00-02				
7.3.1	Design and Development Planning	QOP-00-02	EOP-04-01			
7.3.2	Design and Development Inputs	QOP-00-02	EOP-04-01			
7.3.3	Design and Development Outputs	QOP-00-02	EOP-04-01			
7.3.4	Design and Review	QOP-00-02	EOP-04-01			



**CURTIS INSTRUMENTS INC.**  
 200 KISCO AVE  
 MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 6 OF 40

DATE 2/4/10

REVISION M

**\* Mandatory Procedure Required by ISO 9001: 2008**  
**Table of Content and Procedure Cross Reference**

SECTION	CONTENT	Process / Procedure	Process / Procedure	Process / Procedure	Process / Procedure	Process / Procedure
7.3.5	Design and Development Verification	QOP-00-02	EOP-04-01			
7.3.6	Design and Development Validation	QOP-00-02	EOP-04-01			
7.3.7	Control of Design and Development Changes	QOP-00-02	EOP-05-01	2.10 (PR)		
7.4	Purchasing	QOP-00-02				
7.4.1	Purchasing Process	QOP-00-02	POP-06-01			
7.4.2	Purchasing Information	QOP-00-02	POP-06-02			
7.4.3	Verification of Purchased Product	QOP-00-02	QOP10-01	1.7 (PR)		
7.5	Production provision	QOP-00-02				
7.5.1	Control of Production Provision	QOP-00-02	MOP-09-04			
7.5.2	Validation of Processes for Production Provision	QOP-00-02	EOP-04-01			
7.5.3	Identification and Traceability	QOP-00-02	1.13 (PR)			
7.5.4	Customer Property	QOP-00-02	QOP-07-01			
7.5.5	Preservation of Product	QOP-00-02	MOP-15-01	3.6(PR)		
7.6	Control of monitoring and measuring devices	QOP-00-02	COP-01-06	2.7(PR)		
8	Measurement, analysis and improvement	QOP-00-02				
8.1	Measurement, Analysis and Improvement General	QOP-00-02				
8.2	Monitoring and measurement	QOP-00-02				
8.2.1	Monitoring and measurement of Customer Satisfaction	QOP-00-02	QOP-82-01			
8.2.2	Internal Audit*	QOP-00-02	QOP-17-01	1.21 (PR)		
8.2.3	Monitoring and Measurement of Processes	QOP-00-02				
8.2.4	Monitoring and Measurement of Product	QOP-00-02	QOP-10-03			
8.3	Control of non-conforming product*	QOP-00-02	QOP-13-01	1.14 (PR)		
8.4	Analysis of data	QOP-00-02				
8.5	Improvement	QOP-00-02				
8.5.1	Continual Improvement	QOP-00-02				
8.5.2	Corrective Action*	QOP-00-02	COP-01-07			
8.5.3	Preventive Action*	QOP-00-02	COP-01-08			

**\* Mandatory Procedure Required by ISO 9001: 2008**



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 7 OF 40

DATE 2/4/10

REVISION M

## INTRODUCTION

This quality Management System promotes the adoption of a process approach when developing, implementing and improving the effectiveness of the quality management system, to enhance customer satisfaction by meeting customer requirements.

To function effectively the organization has identified and manages numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, are considered as a process. Often the output from one process directly forms the input into the next.

The application of a system of processes within the organization, together with the identification and interactions of these processes, and their management, are referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within the quality management system, such an approach emphasises the importance of:

- Understanding and meeting requirements
- The need to consider processes in terms of added value
- Obtaining results of process performance and effectiveness
- Continual improvement of processes based on objective measurement.

The methodology known as “Plan-Do-Check-Act” can be applied to all processes and can be briefly described as follows:

- Plan: establish the objectives and processes necessary to deliver results in Accordance with customer requirements and the organization’s policies
- Do: implement the processes
- Check: monitor and measure processes and service against policies, objectives and requirements for the service and report the results
- Act: take actions to continually improve process performance.
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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 8 OF 40

DATE 2/4/10

REVISION M

## **1.0 ACTIVITIES, SCOPE AND PERMISSIBLE EXCLUSIONS**

**Curtis Instruments Inc.** headquartered at 200 Kisco Ave, Mt Kisco, New York is a leading global engineering, manufacturing and marketing company. Its primary focus is integrated systems consisting of instrumentation, power conversion products and controls for the global electric vehicle (EV) industry and for vehicles powered by internal combustion engines (primarily for off-road applications). We are the dominant or major producer in most of the industries we serve.

Curtis Instruments' North American design centers are located at 200 Kisco Avenue, Mt Kisco, NY and Curtis Livermore 235 Airway Blvd, Livermore, CA.

Curtis Instruments' North American manufacturing facility is located at Infantry Road, Carolina, Puerto Rico.

The success and reputation of the company may be measured by the high standing of its customers. A policy of continuous self-appraisal and attention to detail has ensured the expansion of its customer base

The company has implemented a quality management system to demonstrate its ability to provide a consistent service that meets customer and applicable statutory and regulatory requirements.

This will enable the company to address and achieve customer satisfaction through the effective application of the system, including processes for continual improvement and the prevention of nonconformity.

The scope of the quality management system applies the designing and manufacturing of instrumentation, power conversion products and controls. Any exclusion taken is documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

Exclusions are listed on the next page. If exclusions are taken they do not affect the organization's ability, or responsibility to provide services that meet customer and applicable statutory and regulatory requirements.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 9 OF 40

DATE 2/4/10

REVISION M

## **Exclusions**

1) No Exclusion Claimed:

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 10 OF 40

DATE 2/4/10

REVISION M

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 11 OF 40

DATE 2/4/10

REVISION M

## 2.0 NORMATIVE REFERENCE

This quality manual defines the policies and principles applied against each of the requirements of ISO 9001: 2008 and relates to all activities carried out in the organization that determine quality, and lays down guidelines within which the organization can operate.

Each section of the manual is related to an identified section of ISO 9001:2008.

### DISTRIBUTION

The Quality Representative is responsible for the controlled distribution of numbered copies of this manual, and changes thereto to senior management personnel. All other personnel can obtain the latest released version through the Mt Kisco Documentation Control Group.

### UNCONTROLLED MANUALS

Uncontrolled manuals are up-to-date at issue and are only issued to outside organizations, customers, etc. Such uncontrolled manuals are clearly marked "**UNCONTROLLED DOCUMENT**". Uncontrolled manuals are not updated. Nor will any log or register of recipients maintained.

## 3.0 TERMS AND DEFINITIONS

The following terms and definitions are provided to assure a uniform understanding of selected terms as they are used in these requirements.

ORGANIZATION means Curtis Instruments, Inc.

SUPPLIER means the party to whom an order has been placed by the organization for the purchase of supplies, or the execution of a specific part of a particular order used in the manufacture of products delivered to our customers.

CUSTOMER means firm or person having a contractual agreement with, or the recipient of a product from the organization.

PRODUCT means the result of a process, which is the combination of some of the four generic product categories, hardware, software, services and processed materials.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 12 OF 40

DATE 2/4/10

REVISION M

## **4.0 QUALITY MANAGEMENT SYSTEM REQUIREMENT**

### **4.1 GENERAL QUALITY MANAGEMENT SYSTEM REQUIREMENTS**

The organization has established, documented and implemented a quality management system which is maintained and continually improved in accordance with the requirements of this International Standard ISO 9001:2008. To implement the quality management system, the organization has:

- Identified the processes needed for the quality management system and their application throughout the organization
- Determined the sequence and interaction of these processes
- Determined criteria and methods required to ensure the effective operation and control of these processes
- Ensured the availability of information necessary to support the operation and monitoring of these processes
- Put procedures in place to manage, monitor, measure, and analyze these processes
- Implemented action necessary to achieve planned results and continual improvement
- Ensured any processes where outsourced, are identified and controlled. Control of such outsourced processes are identified within the quality management system
- QOP-02-01 delineates these actions in flow chart form

### **4.2 DOCUMENTATION REQUIREMENTS**

#### **4.2.1 GENERAL DOCUMENTATION REQUIREMENTS**

The quality management system based on the requirements of ISO 9001:2008 describes how the organization's program is designed to ensure that customer's requirements are recognized and that consistent and uniform control of these requirements are adequately maintained. This manual describes how effective control is established by the use of formal written procedures.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 13 OF 40

DATE 2/4/10

REVISION M

The quality management system documentation includes:

- Documented procedures and records required in this International Standard including a quality manual, quality policy and quality objectives
- Documents required by the organization to ensure the effective planning, operation and control of its processes in the form of written or visual reference standards of acceptability and verification methods at various stages of the process which may arise from:
- Contractual requirements from the customer or other interested parties
- International, national, regional and industry sector standards
- Relevant standards, statutory and regulatory requirements
- Decisions by the organization.

The following four levels of documentation are utilized and maintained to meet the requirements of ISO9001: 2008 and to ensure adequate control:

Level 1: Quality Manual

Level 2: Quality Procedures

Level 3: Work Instructions

Level 4: Records and Forms

## **4.2.2 QUALITY MANUAL**

This quality manual has been established which includes the scope of the quality management system, including details of and justification for any exclusions, with documented procedures describing the sequence and interaction of the processes included in the quality management system.

Management has defined the documentation needed to support the needs of the organization and the quality management system. The defined documentation provides for implementation, maintenance and improvement of the system and includes:

- Policy documentation
- Documentation for control of processes
- Work instructions where required for defined tasks
- Standard formats for collection and reporting of data
- Quality records.

The primary purpose of quality documentation is to express the quality policy and to describe the quality management system. This documentation serves as a basis for the implementation, effective operation and maintenance of the system.

The quality manual is under the control of the Quality Representative.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 14 OF 40

DATE 2/4/10

REVISION M

## 4.2.3 CONTROL OF DOCUMENTS

Sufficient records are maintained to demonstrate conformance to requirements and verify effective operation and provide knowledge for maintenance and improvement of the quality management system.

Documentation control has been defined and implemented to ensure that correct documents are used. All documents are required to be checked for the latest revision to the master list before use. This is established to assure that all obsolete documents are promptly removed from all points of issue, therefore prevented from unintended use. Documents to be retained, and records of quality performance, are controlled, maintained and protected.

Controls are imposed to ensure that the latest copies of all documentation relevant to the accomplishment of work are available at the time and place of work to ensure effective functioning of the organization's quality management system. Quality records are analyzed to provide inputs for corrective and preventive action, improvements to process control and the quality management system.

Documents defined as quality records are controlled. A documented procedure has been established to:

- Approve documents for adequacy prior to use
- To review, update as necessary and re-approve documents
- Identify the current revision status of documents
- Ensure that relevant versions of applicable documents are available at point of use
- Ensure that documents remain legible, readily identifiable and retrievable
- Ensure that documents of external origin are identified and their distribution controlled
- Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
- Individual business units will maintain their own documents



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 15 OF 40

DATE 2/4/10

REVISION M

## **4.2.4 CONTROL OF RECORDS**

Records required for the quality management system are controlled and maintained to provide evidence of conformance to requirements and of effective operation of the quality management system.

Records shall remain legible, readily identifiable and retrievable. A documented procedure has been established to define the controls needed for identification, storage, protection, retrieval, retention time and disposition of records. Documentation and records may be in any form or type of medium suitable for the needs of the organization. All information held on computer is controlled by means of password protection.

## **5.0 MANAGEMENT RESPONSIBILITY**

### **5.1 MANAGEMENT COMMITMENT**

The President and senior management has provided evidence of their commitment to the development and improvement of the quality management system by:

- Communicating to the staff the importance of meeting customer as well as statutory and regulatory requirements
- Establishing the quality policy and quality objectives
- Conducting management reviews
- Ensuring the availability of necessary resources.

### **5.2 CUSTOMER FOCUS**

The President and senior management has ensured that customer needs and expectations are determined, converted into requirements and fulfilled with the aim of achieving customer satisfaction. Obligations related to service including statutory and regulatory requirements are considered when determining these needs and expectations.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 16 OF 40

DATE 2/4/10

REVISION M

## 5.3 QUALITY POLICY

### CURTIS CORPORATE QUALITY POLICY

**It is the policy of Curtis to meet customer requirements and increasing customer satisfaction through continual improvement of its products, services, and the quality management system. Curtis' endeavor is to supply only one level of quality: the highest. Quality performance is the responsibility of all departments. Their endeavors are to provide the highest level of products and service to our customers.**

The above policy for quality, conforming to the requirements of ISO 9001:2008 has been established. The guidelines used to ensure compliance follow below:

Curtis Instruments Quality Policy:

- Is appropriate to the purpose of the organization, the expected level of customer satisfaction and the needs of other interested parties
- Includes a commitment to meeting requirements and to continual improvement
- Has the resources needed and the contribution of suppliers and partners
- Provides a framework for establishing and reviewing quality objectives
- Demonstrates top management commitment and ensures the quality objectives are communicated, understood and implemented at appropriate levels of the organization
- Is regularly reviewed at the management review meeting for suitability and effectiveness addressing continual improvement and client satisfaction.

Stuart Marwell                      Signature on File                      Date:      February 4, 2010

\_\_\_\_\_  
President

Dennis Houghton                      Signature on File                      Date:      February 4, 2010

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Management Representative

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 17 OF 40

DATE 2/4/10

REVISION M

### **5.3.1 ROLE OF THE POLICY**

- The main role of the quality policy is to communicate the company's commitments and aspirations with regard to quality, and to define principal objectives for the quality management system.
- The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort.
- The use of quality policy in setting quality objectives is addressed in this manual in Section 5.4, Quality Planning.

### **5.3.2 COMMUNICATION**

- The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees.
- The quality policy is also communicated to customers, consumers and other interested parties.

### **5.3.3 REVIEW**

The quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in Operational Procedure Management Review.

## **5.4 PLANNING**

### **5.4.1 PLANNING QUALITY OBJECTIVES**

The President and top management have ensured that quality objectives needed to meet requirements for the product which are measurable and consistent with the quality policy including the commitment to continual improvement have been established and maintained at relevant functions and levels within the organization.

Objectives include, but not limited to:

- To achieve the quality policy;
  - To ensure and demonstrate our ability to provide consistently product that meets customer and regulatory requirements;
-



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 18 OF 40

DATE 2/4/10

REVISION M

- To ensure high level of customer satisfaction;
- To facilitate continual improvement; and
- To comply with requirements of ISO 9001 standard.

Specific quality objectives are added to or deleted from a listing of objectives developed by top management and reviewed as management review meetings.

The quality management system is described in a series of procedures and specifies the management objectives, policies and organizations that have been developed to ensure compliance with ISO 9001:2008. When any inconsistency exists between the requirements of a particular customer specified in a contract/order and those called for in the above standard, the higher standard will prevail.

The quality manual provides a general outline of the quality management system with respect to the requirements of ISO 9001:2008. Detailed responsibilities of management and organization have been set out in this manual. This manual is controlled and the current version is always available for reference to all employees through the established document control system.

The quality system is detailed and targeted to achieve the organization quality policy and objectives documented in this manual. The quality system is maintained to provide assurance to our customers that the organization has the ability and resources to give constant service to a defined standard of quality.

## **5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING**

Quality planning is an integral part of the quality management system and the President and top management have identified, planned and provided the resources needed to achieve the quality objectives and ensure continual improvement of the system.

The organization applies quality planning to all their work resources and consider the implementation of the contents of this quality manual to meet ISO 9001:2008 to be their primary quality plan.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 19 OF 40

DATE 2/4/10

REVISION M

## **5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION**

### **5.5.1 RESPONSIBILITY AND AUTHORITY**

The responsibilities, authority and the interrelation of all personnel who manage, perform and verify work affecting quality are defined and communicated in order to facilitate effective management.

All people have been given authorities and responsibilities to enable them to assist in the achievement of the quality objectives. This assignment of authority and responsibility helps to establish involvement and commitment of people throughout the organization.

The responsibility of personnel is given. An individual may be appointed with a dual role, in such cases he/she is responsible for fulfilling the tasks assigned to both roles.

Written job descriptions are maintained with the personnel records and copies issued to employees during each performance appraisal.

Departments, groups and functions within the company, and their interrelations, are defined in the organizational chart enclosed at the end of this section.

All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.

Following specific responsibilities and authorities are assigned:



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

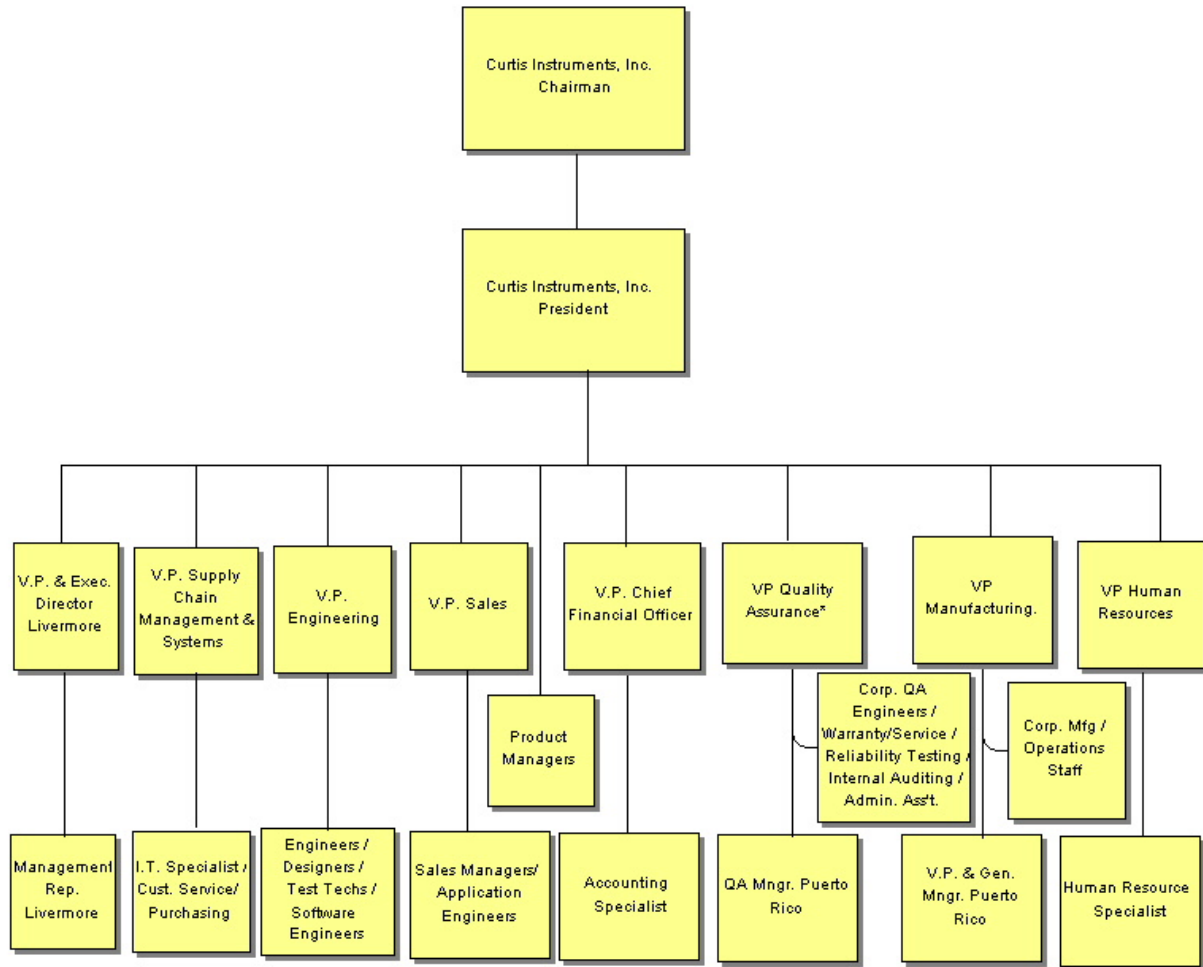
NO. QOP-00-02

PAGE 20 OF 40

DATE 2/4/10

REVISION M

### Curtis Instruments' Organizational Chart



\*VA QA serves as Management Representative

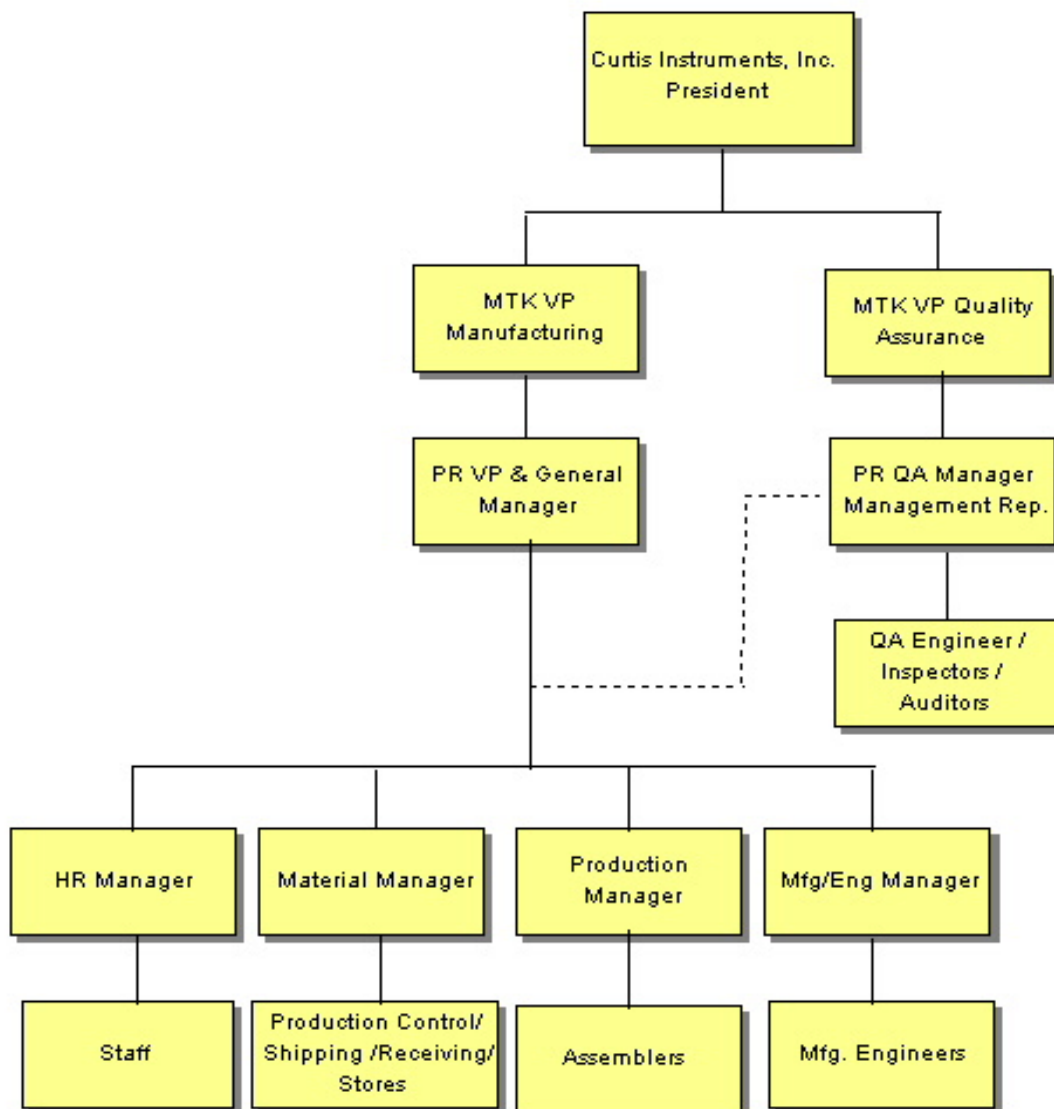


**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02  
PAGE 21 OF 40  
DATE 2/4/10  
REVISION M

## Curtis Puerto Rico Organizational Chart





**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

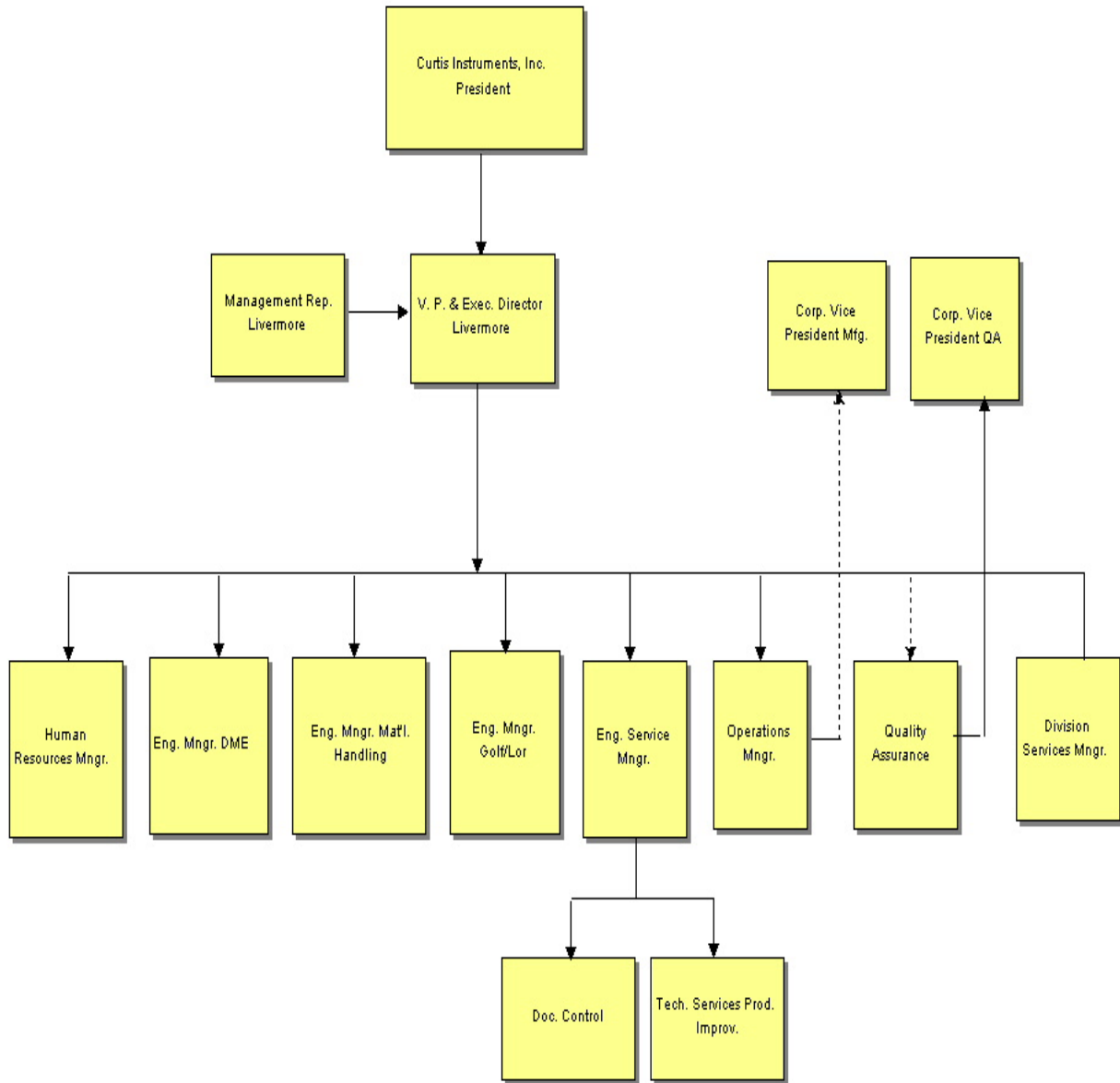
NO. QOP-00-02

PAGE 22 OF 40

DATE 2/4/10

REVISION M

### Curtis Livermore Organizational Chart





**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 23 OF 40

DATE 2/4/10

REVISION M

### **5.5.1.1 Top Management**

- Formulates the quality policy
- Provides resources necessary to maintain and improve the quality system
- Conducts management reviews of the quality system
- Establishes quality objectives

Throughout this manual, the term Top Management refers to a management team including the President and Officers responsible for operations, engineering, sales, finance, human resources, and quality assurance.

### **5.5.1.2 Engineering**

- Prepares or reviews design input specifications
- Designs products and product improvements
- Conducts design reviews
- Verifies and tests designs
- Documents design outputs
- Assists in product realization and verification planning

### **5.5.1.3 PRODUCTION CONTROL**

- Schedules production
- Establishes production work orders

### **5.5.1.4 PRODUCTION**

- Plans production facilities, equipment, and processes
  - Develops production processes
  - Develops process operator and set-up instructions
  - Controls and monitors processes
  - Applies and maintains in-process product identification
  - Maintains production equipment
  - Provides training for its personnel
-



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 24 OF 40

DATE 2/4/10

REVISION M

### **5.5.1.5 PURCHASING**

- Selects qualified supplies and subcontractors
- Prepares and approves purchasing documents
- Monitors and evaluates supplier performance with input from QA

### **5.5.1.6 RECEIVING**

- Receives purchased products
- Performs first-stage receiving (paperwork) inspection

### **5.5.1.7 SHIPPING**

- Packages products (secondary packaging)
- Ships products to customers
- Operates the finished product stockroom

### **5.5.1.8 WARRANTY**

- Performs warranty functions
- Collects field performance and reliability data
- Provides training for its personnel

### **5.5.1.9 SALES/MARKETING SERVICES**

- Determines customer satisfaction in conjunction with QA
  - Advertises and promotes company's products
  - Carries out contract and order reviews
-





**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 25 OF 40

DATE 2/4/10

REVISION M

### **5.5.1.10 PRODUCT MANAGEMENT**

- Establishes specifications for new products (product briefs)
- Provide the liaison between engineering and sales with regards to customer notification of product changes or obsolescence.

### **5.5.1.11 CUSTOMER SERVICE**

- Provides customer liaison and service
- Provides product information
- Handles customer feedback and complaints in conjunction with QA.

### **5.5.1.12 HUMAN RESOURCES**

- Defines personnel qualification requirements
- Implements measures to motivate personnel
- Conducts company-wide training

### **5.5.1.13 QUALITY ASSURANCE AND QUALITY CONTROL**

- Establishes and maintains the quality management system
  - Audits implementation and effectiveness of the quality system
  - Identifies opportunities for improvement of the quality system
  - Develops quality plans and control plans
  - Initiates corrective and preventive actions
  - Maintains and calibrates measuring and test equipment
  - Carries out subcontractor quality surveys and audits
  - Performs inspections and testing
  - Identifies the need for the use of statistical techniques
  - Handles nonconforming products
-



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 26 OF 40

DATE 2/4/10

REVISION M

- Coordinates document control activities
- Maintains, or coordinates the maintenance of quality records
- Coordinates collection of quality performance data
- Provides required training for its personnel.
- Provide input and support to Sales and Customer Service with regards to Customer satisfaction and Customer Complaints.

## **5.5.2 MANAGEMENT REPRESENTATIVE**

Curtis Instruments Inc. has appointed as the management representative the VP of Quality Assurance. The Management representative has the authority and responsibility to:

- To appoint local management representatives in its remote sites to act in his behalf in the implementing of this Quality Management System.
- Ensure that the quality management system is implemented, maintained and continually improved;
- Promote awareness of customer requirements throughout the organization;
- Report to the top management on the performance of the quality system, including needs for improvement; and
- Coordinate communication with external parties on matters relating to the quality system and ISO 9001 registration.
- Assure Internal audits are performed to schedule.
- Corrective and Preventive Actions are closed out.

## **5.5.3 INTERNAL COMMUNICATION**

The President and top management have defined and implemented processes for the communication of quality requirements, objectives and accomplishments. The providing of this information becomes a resource for improvement and the involvement of people in achieving quality objectives. The information is communicated through manuals, work instructions, drawings, specifications, quality records, reports, etc.; and through training, on-the-job instruction, and meetings. Operational Procedures, Quality System Documentation, Control of Documents; and, Training and Awareness, regulate these activities.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 27 OF 40

DATE 2/4/10

REVISION M

## **5.6. MANAGEMENT REVIEW**

### **5.6.1 MANAGEMENT REVIEW GENERAL**

The President or the sites Senior VP, in conjunction with top management, Quality Representative and appropriate staff, review the quality management system at intervals of at least once a year to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the system and to verify that quality policy and objectives are being satisfied.

The management reviews the input and output process analyzing current activities that may require change and consider opportunities for improvement, including quality policy and quality objectives.

The meeting is arranged by the Local Management Representative and chaired by the President, Senior VP or General Manager. Present shall be management, supervisory and personnel having responsibility for the quality management system. Other personnel may attend where necessary to provide relevant input at the discretion and invitation.

The Management Representative or his assignee is responsible for minutes including observations, conclusions and recommendations issued as a result of such review. Minutes of the meeting are approved by the President and retained as a quality record with all agreed actions monitored and results recorded. Summary minutes are issued to all people as a way of internal communication.

### **5.6.2 REVIEW INPUT**

Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Results of audits,
  - Customer feedback and complaints,
  - Process performance and product conformance data,
  - Status of preventive and corrective actions,
  - Changes that could affect the quality system,
  - Follow-up actions from earlier management reviews, and
  - Recommendations for improvement.
-



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 28 OF 40

DATE 2/4/10

REVISION M

### **5.6.3 REVIEW OUTPUT**

- Management reviews are concluded with actions related to improvement of the quality management system, and improvement of processes and products to better meet customer requirements. The review also identifies resource needs to implement these actions.
- Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

## **6.0 RESOURCE MANAGEMENT**

### **6.1 PROVISION OF RESOURCES**

The resources needed to develop, implement and continually improve the processes of the quality management system and to address and enhance customer satisfaction have been determined and provided in a timely manner to ensure requirements are met.

### **6.2 HUMAN RESOURCES**

#### **6.2.1 ASSIGNMENT OF PERSONNEL**

Personnel who are assigned responsibilities defined in the quality management system are competent on the basis of applicable education, training, skills and experience.

#### **6.2.2 COMPETENCE, AWARENESS AND TRAINING**

It is policy to evaluate and determine minimum competencies required for each position performing activities affecting quality, provide training to satisfy those needs if determined to be necessary and assess the qualifications of incumbents and candidates against those criteria.

Effectiveness of training is evaluated using the following approaches:



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 29 OF 40

DATE 2/4/10

REVISION M

- **Follow-up evaluation of individual employees:**

Management (Supervisors, Managers, and Group Leaders) is responsible for continually assessing staff qualifications to meet requirements. Formal performance evaluations are conducted at least annually. This evaluation assesses whether the employee is sufficiently competent and/or skilled to perform the job function for which he or she was trained. The human resource department in individual employee files maintains results of this evaluation.

- **Correlation of training with nonconformities and system failures:**

Training and competency are always considered when investigating causes of product and process nonconformities and failures of the quality system. When inadequate training is the cause, the investigation goes further to determine specifically which particular training is at fault. This training is then reviewed and improved, by changing its scope, format, or frequency, as appropriate.

A procedure exists for the induction of new employees in mandatory and quality system elements and for the training needs of existing staff in order to achieve its objectives.

Employees are given job descriptions and made aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives,

Records are maintained of education, experience, training and experience.

## **6.3 INFRASTRUCTURE**

The President has determined, provided and arranged maintenance for the infrastructure needed to achieve the conformity of the product requirements, including buildings, workspace and associated facilities, process equipment, computer hardware and software, communication media, transport and supporting services.

A maintenance program specifies the type and frequency of needed maintenance, the methods for maintenance and the verification of its completion.

## **6.4 WORK ENVIRONMENT**

It is ensured that the working environment in the factory, offices, and site areas is suitable at all times to achieve conformity to service requirements.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 30 OF 40

DATE 2/4/10

REVISION M

## **7.0 PRODUCT REALIZATION**

### **7.1 PLANNING OF PRODUCT REALIZATION**

Planning of product realization is that sequence of processes and sub-processes required achieving the required end product. Planning of the realization processes is consistent with the other requirements of the organization's quality management system. Documentation has been put in place to support and manage the processes including:

- Quality objectives and requirements for the product
- Activities within the processes, including documents and the provision of resources
- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for acceptance of the product
- Records are to provide evidence that the realization processes and resulting product meets requirements.

### **7.2 CUSTOMER-RELATED PROCESSES**

#### **7.2.1 DETERMINATION OF REQUIREMENTS RELATING TO THE PRODUCT**

Requirements including product requirements specified by the customer are determined. Particular consideration is given to:

- The extent to which customers have specified the requirements of the product
- Customer requirements, availability of collection, delivery and support
- Requirements not specified by the customer but necessary for fitness and purpose
- Obligations related to product including statutory and legal requirements
- Any additional requirements determined by the organization.

#### **7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT**

In order to establish and maintain customer satisfaction, a formal system is in place and maintained to ensure that each commitment to supply a service is formally reviewed and controlled. This review is conducted prior to the commitment to supply and shall ensure that:

- The requirements are adequately defined, documented and planned
-



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 31 OF 40

DATE 2/4/10

REVISION M

- Where the customer provides no written statement of requirement, the order Requirements are confirmed verbally before acceptance
- The requirements comply with the enquiry and any differing requirements are satisfactorily resolved
- The organization has the ability to meet those defined requirements

The results of the review and subsequent follow-up actions are recorded. Where product requirements are changed, and agreed with the customer or their representative the documentation is amended and all relevant personnel made aware of the changed requirements.

### **7.2.3 CUSTOMER COMMUNICATION**

Methods and procedures have been identified and implemented to communicate with customers on information about the product and service, to deal with inquiries, contracts or order handling, including amendments, customer feedback and complaints.

## **7.3 DESIGN AND DEVELOPMENT**

There is no requirement for design and development activities within the Curtis Instrument Puerto Rico facilities therefore this clause of the standard is a permissible exclusion for that facility only. This exclusion does not affect the organization's ability, or responsibility to provide services that meet customer and applicable statutory and regulatory requirements. This clause does apply to Curtis Instruments Inc. and Curtis Livermore.

### **7.3.1 DESIGN AND DEVELOPMENT PLANNING**

The organization plans and controls the design and development activities.

During the design and development process the organization determines;

- Design and development stages
- A review, verification and validation as appropriate of the design and development stage.
- Design and development responsibilities and authorities.

The organization also ensures effective management of communications between the different groups involved in the design and development as well as a clear assignment of responsibility.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 32 OF 40

DATE 2/4/10

REVISION M

## **7.3.2 DESIGN AND DEVELOPMENT INPUTS**

Inputs relating to product requirements are determined and include;

- Functional and performance requirements.
- Statutory and regulatory requirements where ever applicable.
- Information derived from similar historical designs if applicable.
- Any additional requirements essential for that design and development.

These inputs are reviewed for adequacy and are complete, unambiguous and do not conflict with each other and their records are maintained.

## **7.3.3 DESIGN AND DEVELOPMENT OUTPUTS**

Any output from the design and development is provided in such a form that enables the output to be verified against the design and development input that is approved prior to release.

All design and development outputs;

- agree with the input requirements for design and development
- supply adequate information for the requirements for purchasing, production as well as service provision

## **7.3.4 DESIGN AND REVIEW**

The organization reviews design and development in accordance with its planning reference 7.3.1 and evaluates the resulting design and development's ability to meet the requirements and to identify problems and propose any necessary actions.

Relevant individuals or groups that are concerned in the design and development are present at such reviews and the results of the reviews and their actions are recorded.

## **7.3.5 DESIGN AND DEVELOPMENT VERIFICATION**

All verification of the design and development are carried out as per the planned arrangements reference 7.3.1 ensuring that that the output meets the requirements of the input.

Records of the verification are maintained.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 33 OF 40

DATE 2/4/10

REVISION M

## **7.3.6 DESIGN AND DEVELOPMENT VALIDATION**

The design and development validation is carried out using and in accordance with the planned arrangements reference 7.3.1. The validation is completed where practicable prior to the delivery or implementation of the product. Records of the validation are maintained.

## **7.3.7 CONTROL OF DESIGN AND DEVELOPMENT CHANGES**

Any changes to the design and development are identified and recorded. Any such changes are reviewed, verified and validated where appropriate and approved before implementation.

Any review of design and development changes includes an evaluation on the effect of the changes to parts or product already delivered.

Records are maintained of the result of the review of changes.

## **7.4 PURCHASING**

### **7.4.1 PURCHASING PROCESS**

All purchasing processes are controlled to ensure purchased product or services conform to requirements. The type and extent of control is dependent upon the effect on subsequent realization processes and their output.

A system for the evaluation and selection of suppliers is operated, based on their ability to supply a product or service in accordance with the organization's requirements

Evaluation and selection criteria for suppliers is based on either:

- A supplier's previous and continuous record of providing product and/or services to satisfactory standards.
  - An evaluation of a supplier's quality management system, to determine their ability to satisfy the purchase requirements.
  - Outsourced processes and their respective suppliers are used in the event it is necessary to maintain the Curtis QMS. Suppliers of these processes are evaluated by a sourcing team comprised of appropriate Curtis personnel. Suppliers with an acceptable quality performance are not be surveyed, unless the process is new and untested.
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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 34 OF 40

DATE 2/4/10

REVISION M

An "Approved List" of those suppliers affecting the final product or service is maintained to show they have been evaluated and successfully selected.

## **7.4.2 PURCHASING INFORMATION**

Purchasing documents contain information clearly describing the product or service ordered, including where appropriate:

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

The Practice is to review and approve purchasing documents for adequacy of the specified requirements prior to release.

## **7.4.3 VERIFICATION OF PURCHASED PRODUCT**

The activities necessary for verification of purchased product are identified and implemented by the use of procedures, drawings, and work instructions. Where the organization or its customer proposes to perform verification activities at the supplier's premises, the intended verification arrangements are specified and the method of product release in the purchasing documentation.

Verification by the customer neither absolves the organization of responsibility to provide product, which are acceptable to the customer, nor does it preclude subsequent rejection by the customer.

## **7.5 PRODUCTION PROVISION**

### **7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION**

Operations are controlled through:

- The availability of information that specifies the characteristics of the product or service
  - The provision of suitable working environment
  - The availability of work instructions, as necessary
  - The use of suitable equipment
  - The availability and use of suitable monitoring and measuring devices
-



**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 35 OF 40

DATE 2/4/10

REVISION M

- The implementation of monitoring and measuring activities
- Suitable methods for release, collection, delivery and applicable post-delivery or on-site activities.

## **7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION**

Any production processes where the resulting output cannot be verified by subsequent measuring or monitoring, including those where deficiencies may become apparent only after the service is in use or has been delivered is validated. Validation demonstrates the ability of the processes to achieve planned results and include the following arrangements:

- Defined criteria for review and approval of processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation.

## **7.5.3 IDENTIFICATION AND TRACEABILITY**

Where appropriate the organization identifies the product by suitable means throughout product realization, identifying the product status with respect to monitoring and measurement requirements,

Where traceability is a requirement, the organization controls and records the unique identification of the product or service.

## **7.5.4 CUSTOMER PROPERTY**

The organization exercises care with customer property while it is under our control or being used by us. We identify, verify and protect and safeguard customer property provided for use or incorporation into the product. The customer is notified and records are maintained of any lost damaged or unsuitable customer property.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 36 OF 40

DATE 2/4/10

REVISION M

## **7.5.5 PRESERVATION OF PRODUCT AND SERVICE**

Conformity of product and service with customer requirements is preserved during collection, during internal processing and while in transit to the intended destination is preserved. This includes identification, handling, packaging, storage and protection.

## **7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT**

Monitoring and measurements to be made are identified and the monitoring and measuring equipment required to ensure conformity of product and service to specified requirements.

Measuring and monitoring equipment are used and controlled to ensure that measurement capability is consistent with the monitoring and measurement requirements.

Where applicable, measuring equipment is:

- Calibrated and adjusted periodically or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration shall be recorded
- Adjusted or re-adjusted as necessary
- Be identified to enable the calibration status to be determined
- Be safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage
- Recorded with the results of their calibration
- Required to have the validity of previous results re-assessed if they are subsequently found to be out of calibration.

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

## **8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 MEASUREMENT, ANALYSIS AND IMPROVEMENT GENERAL**

The organization plans and implements the monitoring, measurement, analysis and improvement processes needed to:

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 37 OF 40

DATE 2/4/10

REVISION M

- Demonstrate conformity of the product or service
- Ensure conformity of the quality management system
- Continually improve the effectiveness of the quality management system.

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

## **8.2 MONITORING AND MEASUREMENT**

### **8.2.1 MONITORING AND MEASUREMENT OF CUSTOMER SATISFACTION**

As one of the measurements of the performance of the quality management system, information relating to customer perception as to whether the organization has met customer requirements is monitored. The method's for obtaining and using this information is determined.

### **8.2.2 INTERNAL AUDIT**

An internal audit system is established for performing periodic internal audits of the quality management system and related processes. The purpose of the internal audit is to determine whether:-

- The quality management system conforms to the requirements of this International Standard
- The quality management system has been effectively implemented and maintained.

A planned audit program has been put in place taking into consideration the status and importance of the activities and areas to be audited as well as the results from previous audits. The audit scope, frequency and methodologies are defined. Personnel other than those who perform the activity being audited conduct audits.

The documented procedure includes the responsibilities and requirements for conducting audits, ensuring their independence, recording results and reporting to management.

Management ensure that timely corrective action is taken on deficiencies found during the audit. Follow up action includes the verification of the implementation of corrective action, and the reporting of verification results.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 38 OF 40

DATE 2/4/10

REVISION M

## **8.2.3 MONITORING AND MEASUREMENT OF PROCESSES**

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

## **8.2.4 MONITORING AND MEASUREMENT OF PRODUCT**

Documented procedures have been established and maintained to monitor and measure the characteristics of the product to verify that requirements for the product are met. This is carried out at appropriate stages of the service realization process in accordance with the planned arrangements.

Evidence of conformity with the accepted criteria is maintained and records indicate the person(s) authorizing release of the product. Release and product delivery does not proceed until 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**

A documented procedure is in place to ensure that products, which do not conform to requirements, is identified and controlled to prevent its unintended use or delivery.

Non-conforming product and service is dealt with in one of the following ways:

- By taking action to eliminate the detected nonconformity
- By authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- By taking action to preclude its original use or application.

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

When non-conforming product or service is corrected it is subject to re-verification to demonstrate conformity to the requirements.

When non-conforming product or service detected after collection, delivery, or use has started, the organization takes action appropriate to the effects, or potential affects, of the nonconformity.

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**CURTIS INSTRUMENTS INC.**  
200 KISCO AVE  
MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 39 OF 40

DATE 2/4/10

REVISION M

## **8.4 ANALYSIS OF DATA**

Data is effectively collected and analyzed to determine 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 includes data generated as a result of monitoring and measurement and from other relevant sources.

Data is analyzed to provide information on customer satisfaction, conformance to customer, product or service requirements, characteristics and trends of processes, products and services including opportunities for preventive action, and suppliers.

## **8.5 IMPROVEMENT**

### **8.5.1 CONTINUAL IMPROVEMENT**

The process necessary for the continual improvement of the quality management system is planned and organized.

Continual improvement of the quality management system is facilitated 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**

A corrective action program is established and maintained to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action appropriate to the impact of the problems encountered is appropriately carried out.

The documented procedure for corrective action defines requirements for:-

- Identifying and reviewing nonconformities including customer complaints
  - Determining the causes for nonconformities
  - Evaluating the need for actions to ensure that nonconformities do not recur
  - Determining and implementing the corrective action needed
  - Recording results of action taken
  - Reviewing of corrective action taken.
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**CURTIS INSTRUMENTS INC.**  
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MOUNT KISCO, NY 10549 USA

**OPERATING PROCEDURE**

NO. QOP-00-02

PAGE 40 OF 40

DATE 2/4/10

REVISION M

## **8.5.3 PREVENTIVE ACTION**

Documented procedures have been established and are maintained for implementing preventive action to eliminate the causes of potential nonconformities in order to prevent occurrence. Preventive actions are appropriate to the effects of potential problems.

The documented procedure for preventive action defines requirements for:

- Identifying potential non-conformities and their causes
- Evaluating the need for action to prevent occurrence of non-conformities
- Determining and ensuring the implementation of action needed
- Recording results of action taken
- Reviewing preventive action taken.