# CBM-00-01

# BUSINESS QUALITY MANUAL

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| | APPROVALS | DATE | REVISIONS (SEE SHEET 2) |
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| WRITER | JCAR | 4/23/18 | |
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# Revision history

| REVISION | ECN | DESCRIPTION | DATE | APPROVAL |
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| **A** | 21917 | Formatted to reflect the new ISO standard format and define the Curtis business quality management system. Replaces QOP-00-02. | 4/23/2018 | JCAR |
| **B** | 31123 | Revised Organizational roles, responsibilities and authorities section on page 10 to reflect current practices. | 8/4/2021 | GT |
| **C** | 31708 | Revised document to be formatted as a traditional Quality Manual, to fully describe the ISO 9001:2015 based Quality Management System, and to reference applicable management system documents. | 5/3/2022 | GT |
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# 1 SCOPE

## 1.1 General

This manual describes the Curtis Instruments, Inc. Quality Management System. All Curtis Instruments businesses and facilities share ownership and use of the Quality Management System. This drives consistency into the management system, enabling increased use of common processes where practical, improved sharing of best practices, and pooling of resources to better serve the organization.

This manual is used to convey information about the Quality Management System (QMS) to employees and customers. The manual and associated procedures, along with site procedures, is intended to aid employees in understanding and implementing the quality assurance activities associated with their functions.

## 1.2 Application

This document applies to the entire Curtis Instruments organization; it specifies minimum quality system requirements governing these sites to the extent that requirements are applicable with site operations.

# 2 REFERENCE DOCUMENTS

| | |
|---|---|
| ISO 9001:2015 | Quality Management Systems, Requirements |
| CBM-00-01-01 | Addendum to CBM-00-01 – Quality Management System Application of IATF 16949 Requirements |
| Curtis CSR | Curtis Corporate Social Responsibility Report |
| COP-01-05 | Corporate Operating Procedure, Part Realization Process |
| COP-01-06 | Corporate Operating Procedure, Inspection, Measuring, and Test Equipment |
| COP-01-07 | Corporate Operating Procedure, Corrective Action |
| COP-01-12 | Corporate Operating Procedure, Supplier Audit and Qualification Process |
| COP-01-18 | Corporate Operating Procedure, Procurement of Fabricated Parts |
| COP-01-24 | Corporate Operating Procedure, Quality and Environmental Record Control |
| COP-02-02 | Corporate Operating Procedure, Packaging |
| COP-03-03 | Corporate Operating Procedure, Engineering Change Management |
| COP-09-06 | Corporate Operating Procedure, Data Backup and Retention |
| EOP-04-01 | Engineering Operating Procedure, Design Control, Product Development System |

| | |
|---|---|
| EOP-04-02: | Engineering Operating Procedure, Product Change Validation Process |
| EOP-05-01 | Engineering Operating Procedure, Document and Data Control |
| HOP-18-01 | Human Resources Operating Procedure, Competence, Training and Awareness |
| MOP-15-01 | Manufacturing Operating Procedure, Handling, Storage, Packaging, and Delivery |
| POP-06-01 | Purchasing Operating Procedure, Supplier Assessment and Control |
| QOP-01-01 | Quality Operating Procedure, Management Review |
| QOP-05-02 | Quality Operating Procedure, Documentation Control |
| QOP-07-01 | Quality Operating Procedure, Control of Customer Furnished Property |
| QOP-17-01 | Quality Operating Procedure, Internal Audit |
| QOP-82-01 | Quality Operating Procedure, Customer Satisfaction |
| SOP-03-01 | Sales Operating Procedure, Contract Review for Standard Curtis Products |
| SOP-03-02 | Sales Operating Procedure, Contract Review for Custom Curtis Products |

## 3 TERMS AND DEFINITIONS

Quality: Fulfilling the needs and expectations of customers and other relevant interested parties. The quality of an organization's products and services is determined by the ability to satisfy customers, and the intended and unintended impact on relevant interested parties. The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customer.

Quality Management System (QMS): A QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results. It manages the interacting processes and resources required to provide value and realize results for relevant interested parties. The QMS enables top management to optimize the use of resources considering the long and short term consequences of their decision. It provides the means to identify actions to address intended and unintended consequences in providing products and services.

Audit: Systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Awareness: Understand responsibilities and how actions contribute to the achievement of the organization's objectives.

Competence: Understanding and applying the skills, training, education and experience needed to perform roles and responsibilities. It is the responsibility of top management to provide opportunities for people to develop these necessary competencies.

Configuration: interrelated functional and physical characteristics of a product or service defined in product configuration information.

Context of the Organization: The factors which influence the organization's purpose, objectives and sustainability. It considers internal factors such as values, culture, knowledge and performance of the organization. It also considers external factors such as legal, technological, competitive, market, cultural, social and economic environments. An organization's purpose includes its vision, mission, policies and objectives.

Corrective Action: Action to eliminate the cause of a nonconformity and to prevent recurrence.

Customer Satisfaction: Customer's perception of the degree to which the customer's expectations have been fulfilled.

External Provider: An external supplier that is not part of the organization. A producer, distributor, retailer or vendor of a product or a service.

Feedback: Opinions, comments and expressions of interest in a product, a service, or a complaints-handling process.

Infrastructure: System of facilities, equipment and services needed for the operation of an organization.

Interested Parties: A stakeholder, person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity. Interested parties extend beyond the customer. Relevant interested parties are those that provide significant risk to organizational sustainability if needs and expectations are not met.

Organization: person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.

Preventive Action: Action to eliminate the cause of a potential nonconformity or other potential undesirable situation.

Quality Planning: quality management focused on setting quality objectives and specifying necessary operational processes, and related resources to achieve the quality objectives.

Risk: The possibility of events or activities impeding the achievement of an organization's strategic and operational objectives. Risk is often characterized by reference to potential events and consequences. Risk can be positive or negative.

Site: One geographic location of Curtis Instruments, including Headquarters, Design Centers, Manufacturing Facilities, and Sales & Service centers.

Top Management: Person or group of people who directs and controls an organization at the highest level. Top management has the power to delegate authority and provide resources within the organization.

Traceability: Ability to trace the history, application or location of an object. When considering a product or a service, traceability can relate to the origin of materials and parts; the processing history; and the distribution and location of the product or service after delivery.

Validation: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

Verification: Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

## 4 CONTEXT OF THE ORGANIZATION

### 4.1 Understanding the Organization and its Context

4.1.1 Each Curtis Instruments business, facility, and organization determines the external and internal issues that are relevant to its purpose and its strategic direction, and that affect its ability to achieve the intended results of the QMS.

4.1.2 Curtis monitors and reviews these external and internal issues, understanding that they may be positive and negative factors or conditions.

- External context could be issues related to legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.
- Internal context could be issues related to values, culture, knowledge and performance of the organization.

4.1.3 Context describes who Curtis is, and the issues it faces at the global, national, company, organizational, and department level. Examples are listed in the table below:

| **Internal/External Issues (Context)** | |
|---|---|
| **Internal Issues** | **External Issues** |
| Core competencies limiting ability to provide technology breakthroughs | Regional economic status not conducive to grow business |
| Product and service capability and performance | Highly fluctuating exchange rates |
| Top management changes | Availability of skilled employees |

| | |
|---|---|
| Cultural challenges in sharing the same vision | Political instability, peace and security of business regions |
| Delays in product and service validation, not economically scalable within scheduled timeframe | Uncertain continuity of trade agreements and tariffs |
| Employee performance issues, safety, culture | Stringent regulatory requirements |

4.1.4 Curtis Instruments, Inc. is a subsidiary of Kohler Co., and is headquartered in Mount Kisco, New York, USA. Curtis has multiple design centers and manufacturing facilities, strategically located in the United States, Europe and Asia. The company also has a global network of sales and service offices, serving Curtis customers worldwide.

4.1.5 Curtis' primary focus is providing integrated systems consisting of controllers, instrumentation and power conversion products for the global electric vehicle (EV) industry. Curtis designs, manufactures, and markets instrumentation, controls and integrated systems for electric and hybrid vehicles including:

- Medical Mobility
- Material Handling
- Golf and Recreational
- Light On-Road
- Aerial Work Platforms
- Floor Care and Ground Support
- Industrial Vehicles
- Turf and Agricultural

4.1.6 Vehicle designers at major OEMs depend on Curtis' technology to develop and enhance their vehicles. Curtis provides cutting-edge integrated system solutions for electric and hybrid-powered vehicles, equipment, and machinery, including:

- Traction, Steering and Pump Motor Speed Controllers
- Systems Control, I/O, and Diagnostic Modules
- Powered Wheelchair Mobility Control Systems
- Programmable CAN & Serial Instrumentation and Hour Meters.
- Battery-State-of-Charge Instruments and Battery Monitoring Systems
- DC/DC Converters and Battery Chargers.
- CAN I/O Modules including I/O expansion and hydraulic control

- Programmers and Programming Software
- Input Devices - Switches, Throttles, Foot Pedals, Tiller Heads, Senders and Potentiometers, Warning Devices, Code Switches
- Contactors and Disconnect Switches

4.1.7 The Curtis 10-Points are formally documented corporate guidelines which apply to all employees and operations worldwide.

**The CURTIS 10-POINTS**

1. Our people are our most important resource.
2. Our customers are the source of our well-being: every person in the company is responsible for exceeding customer expectations.
3. Our products must embody the best technology that is available, while meeting the needs of our markets.
4. We strive to design and manufacture only one level of quality—the highest.
5. Each person in the company is responsible for its progress, and each person must share in its success.
6. As a global company, we recognize that strength comes from the diversity of our culture.
7. We believe in a work environment that encourages and permits each person a sense of his/her own worth.
8. Relations with colleagues, with customers and with vendors must be conducted with integrity and fairness.
9. Creativity in our engineering and in all aspects of our activities is the most essential ingredient of our progress.
10. Curtis companies are citizens of the larger community and we have a responsibility to contribute to the well-being and progress of that community.

The 10 Points must be supported as an inherent, integrated, and routine element of our corporate culture. Every Curtis employee is expected to understand and put them into practice.

4.1.8 Curtis sites participate in the high-level operating system shown in Figure 1. Each determines the external and internal issues that are relevant to their purpose and strategic direction. This includes issues determined and identified by Curtis, as well as those that affect the ability to achieve the intended results of the Quality Management System (QMS).

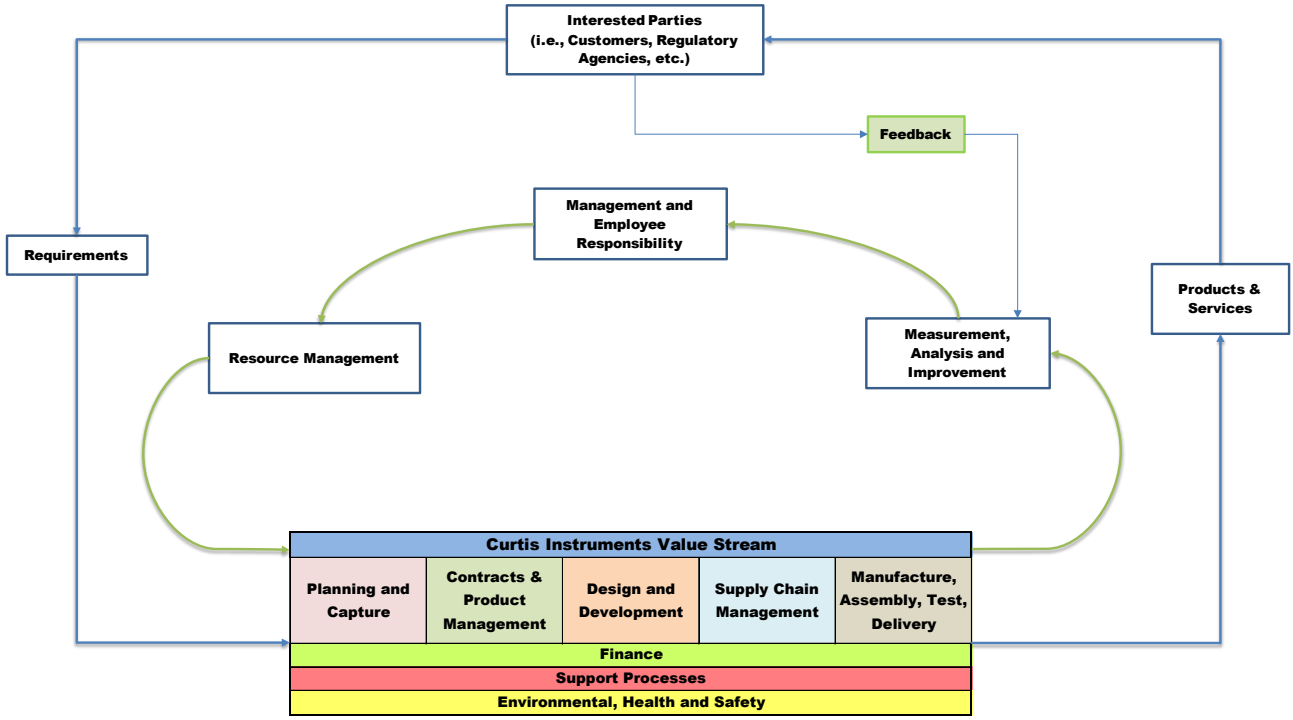


**Figure 1**

Business performance involves receiving inputs and providing outputs, or both. Output of a process or procedure is often directed to the input of another process or procedure. In this manner, Curtis and its customers are internally and externally linked through written policies and procedures intended to detail the obligations required, and the conduct of our business. This manual plus any relevant site policies collectively define the Curtis QMS, in accordance with ISO 9001.

## 4.2 Needs and Expectations of Interested Parties

4.2.1 Interested parties are those that can effect or potentially effect the organization's ability to consistently provide products and services that meet the customer requirements. Interested parties can be internal or external in origin, and have both a negative and positive impact on the organization. Curtis determines and monitors the requirements of those interested parties relevant to the QMS.

4.2.2 Examples of interested parties and their needs and expectations are listed in the table below, and shown in Figure 2. Each site maintains documented evidence of monitoring and reviewing information about interested parties, and their relevant requirements in accordance with section 7.5 of this document.

| **Requirements of Interested Parties** | |
|---|---|
| **Interested Party** | **Requirements** |
| Customers | Quality, price and delivery of products and services |
| Owners | Sustained profitability, transparency |
| Bankers, Investors | Contracts, bankability of projects |
| External Providers (material and service) | Material service agreements, NDA, service-level agreements, vendor-managed inventory agreements |
| Third Party Auditors | Regulation, contract and project requirements, risk assessment, management system standards, finance and project contracts, corporate social responsibility |
| Industry groups, associations and action committees | R&D, standards development, publications, best practices, early warning, participation |
| Employees | Improved standard of living, benefits, and compensation, safe workplace, geographical employment regulations, social accountability, job satisfaction, work-life balance, career progression, recognition |
| Society/Community | Bylaws, sustainability, local business and economy, local labor, corporate citizenship, education and charitable foundations |
| Competition | Market intelligence, customer perception, competitive benchmarking |

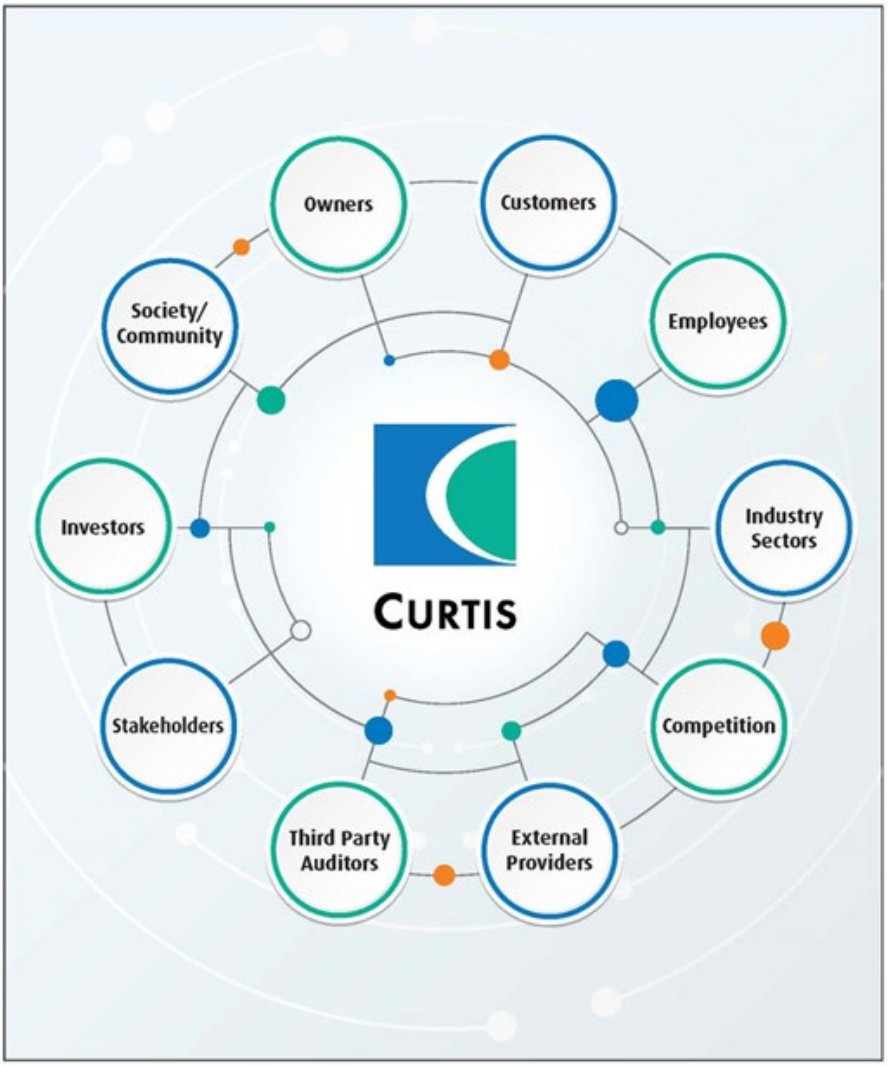


**Figure 2**

## 4.3 Scope of the Quality Management System (QMS)

4.3.1 All Curtis Instruments facilities and businesses are involved to varying degrees in offering products, services, and solutions to customers and their applications. These include design, development, manufacturing, integration, testing, service, and support.

4.3.2 Curtis determines the boundaries and applicability of the QMS to establish its scope, and applies requirements as applicable within the scope of the QMS. Curtis applies the requirements of ISO 9001, the International Standard for

Quality Management System Requirements, when they are within the determined scope of its quality management system. Curtis considers:

a) the external and internal elements from 4.1;
b) the requirements of relevant interested parties from 4.2;
c) the products and services of the site.

**Note**: The requirements of IATF 16949, the Automotive Quality Management System Standard, may apply to select sites. Compliance to the requirements of IATF 16949 is covered in the addendum of this document, CBM-00-01-01: Quality Management System Application of IATF 16949 Requirements.

## 4.4 Quality Management System and Processes

4.4.1 This Quality Manual, Curtis Instruments business and site policies, and the associated procedures collectively define the Curtis QMS. The QMS also addresses customer and applicable statutory and regulatory requirements. The Quality Manual is applicable to all functions within Curtis, and all sites are required to operate with and to a variety of written policies and procedures. The collection of policy and procedure documents specify the obligations of employees in the conduct of company business.

4.4.2 The objective of the management system is to:

a) provide products and services that consistently meet customer, and applicable statutory and regulatory requirements;
b) enhance customer satisfaction through effective application of the system;
c) facilitate improvement of the system and associated processes.

4.4.3 The QMS, including its processes and interactions, has been established, implemented, and is maintained and continually improved through the use of corrective action, internal auditing and the Management Review process. Curtis:

a) determines the inputs required and the outputs expected from these processes;
b) determines the sequence and interaction of these processes;
c) determines criteria and methods needed to ensure that both the operation and control of these processes are effective;
d) determines the resources needed for these processes and ensure their availability;
e) assigns the responsibilities and authorities for these processes;
f) addresses the determined risks and opportunities;
g) evaluates the processes and implements any changes needed to ensure the processes achieve their intended results;
h) improves the processes and the QMS.

4.4.4 To the extent necessary, Curtis maintains documented information to support the operation of its processes, and retains documented information/records to show that the processes are being carried out as planned.

4.4.5 Curtis has adopted a process-oriented method of management. For each process in use, the sequence and interaction of processes has been determined. Assignment of responsibilities and authorities for processes are identified. Processes are controlled, monitored, and measured; data is gathered and analyzed to ensure effectiveness.

## 5 LEADERSHIP

### 5.1 Leadership and Commitment

5.1.1 Top management for Curtis Instruments sites have executive responsibility or delegated authority to manage the site. Management provides evidence of its leadership and commitment to the development and implementation of the QMS, and all sites continually improve its effectiveness by:

a) taking responsibility for the effectiveness of the QMS;
b) establishing the quality policy and quality objectives, and ensuring that they are compatible with the context and strategic direction of the organization;
c) ensuring the QMS requirements are integrated into the Curtis business processes;
d) promoting the use of the process approach and risk-based thinking.
e) ensuring the availability of resources;
f) communicating to the organization the importance of an effective QMS and conformance to the requirements;
g) ensuring the QMS achieves its intended results;
h) engaging, directing, and encouraging employees to contribute to the effectiveness of the QMS;
i) promoting improvement;
j) supporting other relevant management roles to demonstrate leadership as it applies to areas of responsibility.

5.1.2 Top Management demonstrates its leadership and commitment to customer focus by ensuring:

a) customer requirements, and applicable statutory and regulatory requirements are determined, understood, and met;
b) risks and opportunities are determined and addressed;
c) the focus on enhancing customer satisfaction is maintained.

## 5.2 Policy

5.2.1 Establishing the Quality Policy

Curtis Instruments has established, implemented, and maintains a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;
b) provides a framework for setting quality objectives;
c) includes a commitment to satisfy applicable requirements;
d) includes a commitment to continual improvement of the QMS.

**Quality Policy**

Curtis endeavors to meet or exceed expectations from our customers for Curtis products and support and to comply with all customer statutory and regulatory requirements.

Curtis strongly supports ISO 9001 Quality Management Standard requirements and is committed to continually improve its products, support and its Business Quality Management System.

5.2.2 Communicating the Quality Policy

The quality policy is:

a) available and maintained as documented information;
b) communicated, understood, and applied within the organization;
c) available to relevant interested parties as appropriate; including customers, Curtis management, employees and other relevant interested parties.

## 5.3 Organizational Roles, Responsibilities, and Authorities

5.3.1 Curtis ensues experienced, competent staff manages its entire business. Organizational charts are maintained to present the structure of a company, to show how departments are organized, the reporting relationships across the organization, and roles and responsibilities.

5.3.2 Employees who manage, perform, and verify work affecting quality have the organizational freedom, responsibility, and authority to:

a) initiate action to prevent the occurrence of any nonconformity relating to the product, process, and QMS;
b) identify and record any problem relating to the product, process and management system;

c) initiate, recommend, or provide solutions through designated channels;
d) verify the implementation of solutions;
e) control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

**Note**: Any employee managing, performing or verifying work affecting quality has the authority to initiate action to prevent the occurrence of any non-conformity related to product, process, service or the QMS, until the nonconforming condition has been corrected.

5.3.3. Management assigns the responsibility and authority to the site Quality Leader for:

a) ensuring that the QMS conforms to requirements of applicable standards and customer quality requirements;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the QMS and on opportunities for improvement, in particular to top management;
d) ensuring the promotion of customer focus throughout the organization;
e) ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

## 6 PLANNING

### 6.1 Actions to Address Risks and Opportunities

6.1.1 Curtis Instruments sites regularly review the risks and opportunities that affect general business operations, and specific projects or programs at the site. These reviews may be conducted by individuals within the site, those participating in the project or program affected, and/or corporately with other sites and the Curtis leadership. Actions are identified to mitigate the risks and to capitalize on the opportunities.

6.1.2 The planning of the QMS is carried out in order to meet requirements, and determine the risk and opportunities to be addressed to:

a) ensure that the QMS can achieve its intended results;
b) enhance desirable effects;
c) prevent, or reduce undesired effects;
d) achieve improvement.

6.1.3 Curtis plans actions to address risks and opportunities, implements the actions, and evaluates the effectiveness of these actions. Actions taken shall be proportionate to the potential impact on the conformity of products and services.

### 6.2 Quality Objectives and Planning

6.2.1 During strategic and business planning, management identifies quality objectives and develops plans to achieve them. These include objectives that are specific to a given function, objectives at various levels of the organization, and objectives specific to certain processes. The quality objectives:

- are consistent with the quality policy;
- are communicated, monitored, measureable, updated, and documented;
- take into account applicable requirements;
- are relevant to conformity of products and service, and to the enhancement of customer satisfaction.

6.2.2 When planning for the quality objectives, management determines:

a) what shall be done;
b) required resources;
c) who is responsible;
d) when activities will be completed;
e) evaluation of the results.

### 6.3 Planning of Changes

Curtis identifies and implements changes to the QMS when required. When planning and/or making such changes, the following is considered:

a) the purpose of the change and potential consequences;
b) the integrity of the QMS;
c) available resources;
d) allocation of responsibilities and authorities.

## 7 SUPPORT

### 7.1 Resources

7.1.1 General

Curtis Instruments defines and provides the resources needed to implement, maintain, and continually improve the QMS. Consideration is given to the capabilities of, and constraints on internal resources, and what needs to be obtained from external providers.

7.1.2 People

Curtis determines and provides the personnel necessary for the effective implementation of the QMS, and for the operation and control of processes.

7.1.3 Infrastructure

Curtis sites determine, provide, and maintain the infrastructure needed for the operation of its processes and to achieve conformity to product requirements. Infrastructure includes, as applicable:

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

7.1.4 Environment for the Operation of Processes

Curtis sites determine and manage the work environment needed to achieve conformity to product and service requirements, and to furnish employees a place of employment that is free from recognized environmental, health, and safety hazards.

NOTE: The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors. A suitable environment can be a combination of human and physical factors, such as:

a) Social (e.g., non-discriminatory, calm, non-confrontational);
b) Psychological (e.g., stress-reducing, burnout prevention, emotionally protective);
c) Physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

Curtis sites determine and provide the resources needed to ensure valid and reliable results when monitoring or measurment is used to verify the conformity of products and services to requirements. Curtis ensures that:

a) resources are suitable for the specific type of monitoring and measurement activities being undertaken;
b) resources are maintained to ensure continued fitness of purpose;
c) documented information/records are retained as evidence of fitness for purpose of monitoring and measurement resources.

7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is considered to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

a) calibrated and/or verified at specified intervals or prior to use, against measurement standards traceable to international or national

measurement standards; when no such standards exist, the basis used for calibration or verification is retained;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

When measuring equipment is found to be unfit for its intended purpose, Curtis investigates to determine if the validity of previous measurement results have been adversely affected, and takes appropriate action as necessary.

**Reference** COP-01-06: Corporate Operating Procedure, Inspection, Measuring, and Test Equipment

7.1.6 Organizational Knowledge

7.1.6.1 Curtis Instruments sites determine the knowledge necessary for the operation of its processes, and to achieve conformity of products and services. This knowledge is maintained and made available to the extent necessary.

7.1.6.2 When addressing changing needs and trends, Curtis sites consider current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

7.1.6.3 Organizational knowledge is knowledge specific to Curtis, and is generally gained by experience. It is information that is used and shared to achieve the organization's objectives. Organizational knowledge is typically based on:

a) internal sources (e.g., intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g., standards, academia, conferences, customers, or external providers).

## 7.2 Competence

Curtis Instruments ensures the competence of employees doing work that affects the performance and effectiveness of the QMS. Curtis also ensures:

a) employees are competent, with the appropriate education, training, and/or experience;

b) actions are taken to acquire the necessary competence, and to evaluate the effectiveness of the actions taken;

c) retention of appropriate documented information/records as evidence of competence.

Applicable actions may include training, mentoring, the re-assignment of current employees, or the hiring or contracting of competent persons.

### 7.3 Awareness

Curtis Instruments ensures that employees are aware of the relevance and importance of their activities, and how they contribute to the achievement of the quality objectives. Employees are made aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the QMS, including the benefits of improved performance;
d) the implications of not conforming with QMS requirements.

**Reference** HOP-18-01: Human Resources Operating Procedure, Competence, Training and Awareness

### 7.4 Communication

Curtis Instruments determines the internal and external communications relevant to the QMS, including:

a) what is communicated, when and to whom;
b) how it is communicated;
c) who conducts the communication.

### 7.5 Documented Information

7.5.1 General

The QMS includes documented information required by ISO 9001 and determined to be necessary for the effectiveness of the QMS.

7.5.2 Creating and Updating

When creating and updating documented information, Curtis ensures appropriate

a) identification and description (e.g., a title, date, author, or reference number);
b) format (e.g., language, software version, graphics) and media (e.g., paper, electronic),
c) review and approval for suitability and adequacy.

7.5.3 Control of Documented Information

7.5.3.1 Documented information required by the QMS is controlled to ensure:

a) it is available where and when it is needed;
b) it is suitable for use;
c) it is adequately protected from loss of confidentiality, improper use, or loss of integrity.

7.5.3.2 For the control of documented information, Curtis sites ensure the following is addressed as applicable:

a) distribution, access, retrieval and use;
b) storage and preservation, including preservation of legibility;
c) control of changes (e.g., revision/version control);
d) retention and disposition.

- Documented information of external origin necessary for the planning and operation of the QMS is identified and controlled.
- Documented information/records retained as evidence of conformity are protected from unintended alterations.

**Reference:** COP-01-24: Corporate Operating Procedure, Quality and Environmental Record Control

COP-05-02: Corporate Operating Procedure, Engineering Change Management

COP-09-06: Corporate Operating Procedure, Data Backup and Retention

EOP-05-01: Engineering Operating Procedure, Document and Data Control

QOP-05-02: Quality Operating Procedure, Documentation Control

# 8 OPERATION

## 8.1 Operational Planning and Control

Curtis Instruments plans, implements and controls the processes necessary to meet the requirements for products and services, and to implement the actions determined in section 6 of this document (Planning) by:

a) determining the requirements for the products and services;
b) establishing criteria for processes, and the acceptance of products and services;
c) determining the resources needed to achieve conformity to the product and service requirements;
d) implementing control of the processes in accordance with the criteria;
e) determining, maintaining and retaining documented information/records as required:
   1) to have confidence that the processes have been carried out as planned;
   2) to demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the organization’s operations.

Curtis controls planned changes, reviews the consequences of unintended changes, and acts to mitigate any adverse effects, as necessary. Curtis also ensures that any outsourced processes are controlled.

## 8.2 Requirements for Products and Services

8.2.1 Customer Communication

Curtis determines and implements effective arrangements for communicating with customers that include:

a) providing information relating to products and services;
b) handling inquiries, contracts, orders, and associated changes;
c) obtaining customer feedback relating to products and services, including customer complaints;
d) handling or controlling customer property;
e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining Requirements for Products and Service

When determining the requirements for the products and services offered to customers, Curtis ensures that:

a) requirements for the products and services are defined, including applicable statutory and regulatory requirements, and requirements considered necessary by Curtis;
b) claims for the products and services offered can be met.

8.2.3 Review of the Requirements for Products and Services

8.2.3.1 Curtis ensures that it has the ability to meet the requirements for products and services offered to customers. Reviews are conducted before committing to supply products and services, including:

a) customer specified requirements, including those for delivery and post-delivery activities;
b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
c) Curtis specified requirements;
d) statutory and regulatory requirements applicable to the products and services;
e) contract or order requirements differing from those described above.

8.2.3.2 Curtis retains documented information/records on the results of the review, and on any new requirements for the products and services.

**Reference**: SOP-03-01: Sales Operating Procedure, Contract Review, Standard Curtis Products

SOP-03-02: Sales Operating Procedure, Contract Review, Custom Curtis Products

8.2.4 Changes to Requirements

Curtis ensures that relevant documented information is amended, and that relevant personnel are notified when changes to requirements are made for products and services.

## 8.3 Design and Development of Products and Services

8.3.1 General

Curtis Instruments has established, implemented and maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and Development Planning

Curtis plans and controls the design and development of products. During the design and development planning, Curtis considers:

a) the nature, duration and complexity of the design and development activities;
b) the required process stages, including applicable design and development reviews;
c) the required design and development verification and validation activities;
d) the responsibilities and authorities involved in the design and development process;
e) the internal and external resource needs for the design and development of products and services;
f) the need to control interfaces between persons involved in the design and development process;
g) the need for involvement of customers and users in the design and development process;
h) the requirements for subsequent provision of products and services;
i) the level of control expected for the design and development process by customers and other relevant interested parties;
j) the documented information/records needed to demonstrate that design and development requirements have been met.

8.3.3 Design and Development Inputs

Curtis determines the requirements essential for the specific types of products and services to be designed and developed. Curtis considers:

a) functional and performance requirements;

b) information derived from previous similar design and development activities;
c) statutory and regulatory requirements;
d) standards or codes of practice that Curtis has committed to implement;
e) potential consequences of failure due to the nature of the products and services.

Curtis also:

- reviews inputs to ensure that they are adequate for design and development purposes, complete, and unambiguous;
- resolves conflicting design and development inputs;
- retains documented information/records on design and development inputs.

8.3.4 Design and Development Controls

Curtis applies controls to the design and development process to ensure that:

a) the results to be achieved are defined;
b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
f) documented information/records of these activities are retained.

Design and development reviews, verification and validation can be conducted separately or in any combination, as is suitable for the products and services of Curtis Instruments.

8.3.5 Design and Development Outputs

Curtis ensures that design and development outputs:

a) meet the input requirements;
b) are adequate for the subsequent processes for the provision of products and services;
c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

Documented information/records on design and development outputs are retained.

**Reference**: EOP-04-01: Engineering Operating Procedure, Design Control, Product Development System

8.3.6 Design and Development Changes

Curtis identifies, reviews, and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

Curtis retains documented information/records on:

a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

**Reference**: EOP-04-02: Engineering Operating Procedure, Product Change Validation Process

COP-03-03: Corporate Operating Procedure, Engineering Change Management

## 8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 General

Curtis Instruments ensures that externally provided processes, products, and services conform to requirements. Curtis determines the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the Curtis' own products and services;
b) products and services are provided directly to the customer(s) by external providers on behalf of Curtis;
c) a process, or part of a process, is provided by an external provider as a result of a decision by Curtis.

Curtis determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Curtis retains documented information/records of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and Extent of Control

Curtis ensures that externally provided processes, products, and services do not adversely affect Curtis' ability to consistently deliver conforming products and services to its customers. Curtis:

a) ensures externally provided processes stay within the control of the QMS;
b) defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) takes into consideration:
    1) the potential impact of the externally provided processes, products and services on Curtis' ability to consistently meet customer and applicable statutory and regulatory requirements;
    2) the effectiveness of the controls applied by the external provider;
d) determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for External Providers

Curtis ensures the adequacy of requirements prior to its communication to the external provider. Curtis communicates requirements for:

a) the processes, products and services to be provided;
b) the approval of:
    1) products and services;
    2) methods, processes and equipment;
    3) the release of products and services;
c) competence, including any required qualification of persons;
d) the external providers' interactions with Curtis;
e) control and monitoring of the external providers' performance to be applied;
f) verification or validation activities that Curtis or its customer intends to perform at the external providers' premises.

**Reference:** COP-01-12: Corporate Operating Procedure, Supplier Audit and Qualification Process

COP-01-05: Corporate Operating Procedure, Part Realization Process

COP-01-18: Corporate Operating Procedure, Procurement of Fabricated Parts

POP-06-01: Purchasing Operating Procedure, Supplier Assessment and Control

## 8.5 Production and Service Provision

8.5.1 Control of Production and Service Provision

Curtis Instruments implements production and service provisions under controlled conditions. Controlled conditions include, as applicable:

a) the availability of documented information that defines:
   1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
   2) the results to be achieved;
b) the availability and use of suitable monitoring and measuring resources;
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery and post-delivery activities.

8.5.2 Identification and Traceability

Curtis uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Curtis identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Curtis controls the unique identification of the outputs when traceability is a requirement, and retains the documented information/records necessary to enable traceability.

8.5.3 Property Belonging to Customers or External Providers

Curtis exercises care with property belonging to customers or external providers while it is under the control of, or being used by Curtis.

Curtis identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, Curtis reports this to the customer or external provider and retains documented information on what has occurred.

A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

**Reference** QOP-07-01: Quality Operating Procedure, Control of Customer Furnished Property

8.5.4 Preservation

Curtis preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. Preservation includes identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

**Reference** COP-02-02: Corporate Operating Procedure, Packaging

MOP-15-01: Manufacturing Operating Procedure, Handling, Storage, Packaging, and Delivery

8.5.5 Post-Delivery Activities

Curtis meets requirements for post-delivery activities associated with products and services. In determining the extent of post-delivery activities that are required, Curtis considers:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of Changes

Curtis reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Curtis retains documented information/records describing the results of the review of changes, the personnel authorizing the change, and any necessary actions arising from the review.

**Reference**: COP-03-03: Corporate Operating Procedure, Engineering Change Management

## 8.6 Release of Products and Services

8.6.1 Curtis Instruments implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

8.6.2 Curtis retains documented information/records on the release of products and services. The documented information includes:

a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.

## 8.7 Control of Nonconforming Outputs

8.7.1 Curtis Instruments ensures that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery.

8.7.1.1 Curtis takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This also applies to nonconforming products and services detected after delivery of products, and during or after the provision of services.

8.7.1.2 Curtis handles nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return, or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession.

Conformity to the requirements are verified when nonconforming outputs are corrected.

8.7.2 Curtis retains documented information/records that:

a) describe the nonconformity;
b) describe the actions taken;
c) describe any concessions obtained;
d) identify the authority deciding the action in respect of the nonconformity.

# 9 PERFORMANCE EVALUATION

## 9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 General

Curtis Instruments determines:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analyzed and evaluated.

Curtis evaluate the performance and the effectiveness of the QMS, and retains appropriate documented information/records as evidence of the results.

9.1.2 Customer Satisfaction

Curtis monitors customer's perception of the degree to which their needs and expectations have been fulfilled. Curtis determines the methods for obtaining, monitoring and reviewing this information.

Monitoring of customer perception may include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

**Reference**: QOP-82-01: Quality Operating Procedure, Customer Satisfaction

9.1.3 Analysis and Evaluation

Curtis analyzes and evaluates appropriate data and information arising from monitoring and measurement. The results of analysis is used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the QMS;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the QMS.

NOTE: Methods to analyze data may include statistical techniques.

## 9.2 Internal Audit

9.2.1 Curtis Instruments conducts internal audits at planned intervals to provide information on whether the QMS:

a) conforms to Curtis' QMS requirements, and the requirements of applicable International management system standards;.

b) is effectively implemented and maintained.

9.2.2 Curtis plans, establishes, implements and maintains audit programs that:

a) includes the frequency, methods, responsibilities, planning requirements and reporting;

b) takes into consideration the importance of the processes concerned, changes affecting Curtis, and the results of previous audits;

c) defines the audit criteria and scope for each audit;

d) utilizes auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

e) ensures that the results of the audits are reported to relevant management;

f) take appropriate correction and corrective actions without undue delay;

Curtis retains documented information/records as evidence of the implementation of the audit program and the audit results.

**Reference**: QOP-17-01: Quality Operating Procedure, Internal Audit

## 9.3 Management Review

9.3.1 General

Curtis Instruments management reviews the organization's QMS at planned intervals to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

9.3.2 Management Review Inputs

The management review is planned and conducted, taking into consideration:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the QMS;

c) information on the performance and effectiveness of the QMS, including trends in:

1) customer satisfaction and feedback from relevant interested parties;

2) the extent to which quality objectives have been met;

3) process performance and conformity of products and services;

4) nonconformities and corrective actions;

5) monitoring and measurement results;
6) audit results;
7) the performance of external providers;

d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities;
f) opportunities for improvement.

9.3.3 Management Review Outputs

The outputs of the management review include decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the QMS;
c) resource needs.

Curtis retains documented information/records as evidence of the results of management reviews.

**Reference**: QOP-01-01: Quality Operating Procedure, Management Review

## 10 IMPROVEMENT

### 10.1 General

Curtis Instruments determines and selects opportunities for improvement, and implements the necessary actions to meet customer requirements and enhance customer satisfaction. These include

a) improving products and services to meet requirements as well as to address future needs and expectations;
b) correcting, preventing or reducing undesired effects;
c) improving the performance and effectiveness of the QMS.

Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

### 10.2 Nonconformity and Corrective Action

10.2.1 When a nonconformity occurs, including any arising from complaints, Curtis Instruments:

a) reacts to the nonconformity and, as applicable:
1) takes action to control and correct it;
2) deals with the consequences;
b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
1) reviewing and analyzing the nonconformity;

2) determining the causes of the nonconformity;
3) determining if similar nonconformities exist, or could potentially occur;

c) implements any action needed;
d) reviews the effectiveness of any corrective action taken;
e) updates risks and opportunities determined during planning, if necessary;
f) makes changes to the QMS, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered.

10.2.2 Curtis retains documented information/records as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

**Reference**: COP-01-07: Corporate Operating Procedure, Corrective Action

### 10.3 Continual Improvement

Curtis Instruments continually improves the suitability, adequacy and effectiveness of the QMS through the use of corrective action, internal auditing and the management review process.

Curtis considers the results of analysis and evaluation, and the outputs from management reviews, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.