



# QUALITY MANUAL

353 James Record Rd  
Huntsville, AL 35824

QM001 Revision: K  
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## Preface:

This Quality Manual is written to incorporate the practices, requirements, and recommendations of the following International Organization of Standards documents:

ISO 9001:2015 Quality Management Systems – Requirements

This Quality Manual is supported and adhered to by:

The CDI Electronics Senior Management Team listed below:

President/CEO:

Controller:

Eng/Quality/Tech Service Mgr:

Manufacturing Manager:

Sales/Marketing Manager:

Tim Bock

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Reviewed by ISO Management Representative

**Gary DeBoer**

Signature: *Gary L. DeBoer*

Date: 01-07-2020

Approved by President/CEO

**Tim Bock**

Signature: *Tim Bock*

Date: 01-07-2020

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## 1. Scope

### 1.1 General

Our QMS utilizes the process approach and quality management principles contained in the international standards (ISO 9000) to enhance our ability to continually improve.

CDI Electronics, Inc. has based the Quality Management System (QMS) described in this manual so that we can demonstrate our capability to consistently provide products/services that meet customer and applicable regulatory requirements, and to operate with increased effectiveness and efficiency with the overall aim of enhancing customer satisfaction.

Our QMS supports, emphasize, and promote our Vision Statement listed below:

CDI Vision Statement: “CDI/Balmar strives to be a Leading Producer of Electronic Engine and DC Charging Components for Marine and Industrial Applications; providing Value to our Customers through Design, Quality, Reliability and Service.”

### 1.2 Application and Exclusions

Our QMS complies with all applicable requirements contained in ISO 9001:2015 except section 8.5.1 - Validation of processes for production and service provision. CDI Electronics does not have any processes where deficiencies become apparent only after the product is in use. The QMS covers the design and provision of all company products, and encompasses all operations at our facility located at 353 James Record Road, Huntsville, AL 35824.

## 2. Reference Documents.

The following external documents contain provisions which, through reference in this manual, constitute provisions of our QMS:

QF-119	ISO Terms and Definitions
<u>ISO 9001:2015</u> ,	Quality management systems – Requirements

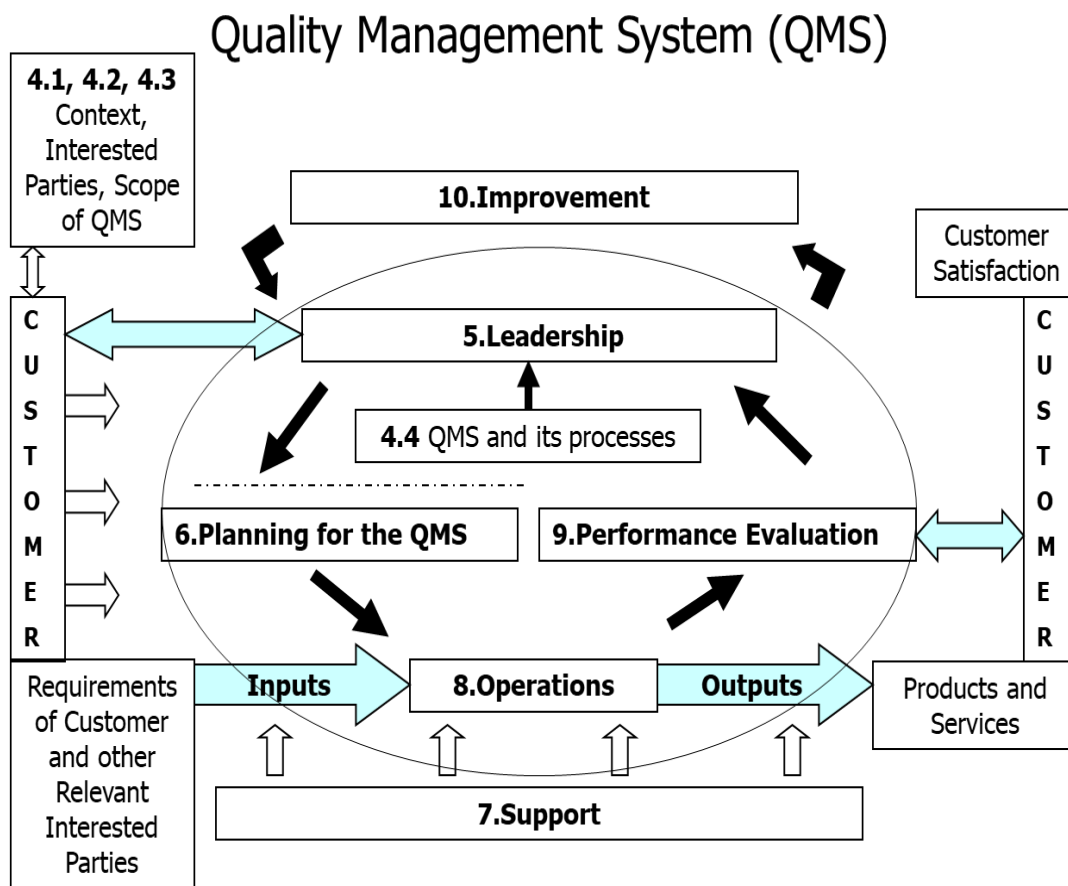
[Appendix A](#) contains a List of Key QMS documents referenced in this manual and defines the key senior level processes for implementing our quality policy. Note: documents are referenced throughout this manual only by document number; see [Appendix A](#) for complete titles.

## 3. Terms and Definitions.

Our QMS uses the same internationally recognized terms, vocabulary and definitions listed in QF-119. Throughout this Quality Manual, the term “organization” refers to CDI Electronics.

Quality Management System (QMS) refers to a system that considers the three main components: quality control, quality assurance and quality improvement. Quality management is focused not only on product or service quality, but also the means to achieve it. A QMS, therefore, uses quality assurance and control of processes, as well as products/services to achieve more consistent quality.

### ISO 9001:2015 Quality Management System Model



## 4. Quality Management System

### 4.1 General requirements

Our QMS is that part of our overall management system which establishes documents and implements our quality policy, and related processes for providing products and

services which meet or exceed customer requirements. We continually improve its effectiveness in accordance with the requirements of ISO 9001:2015.

The organization:

- has determined 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 needed to ensure that both the operation and control of these processes are effective,
- ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
- monitors, measures where applicable, and analyzes these processes, and
- implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by the organization in accordance with the requirements of ISO 9001:2015.

The Key Business Processes of the organization are:

- Quality Management
- Customer Service
- Purchasing and Receiving
- Order Fulfillment
- Product Design and Development

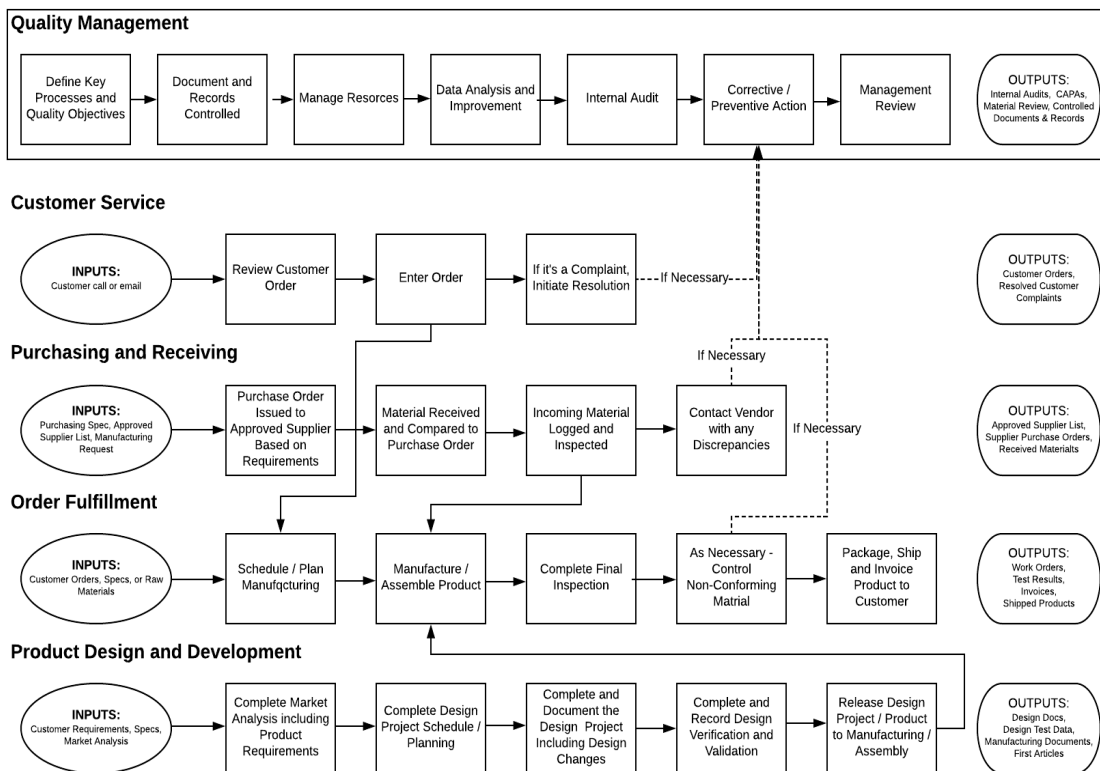
Our 'SOP' Standard Operation Procedures, have been put in place to assist CDI in the most effective and efficient manner possible in meeting specific needs of our external customers, to help meet the specific needs of management and our share holders, and/or to meet management requirements which directly relate to requirements of ISO 9001:2015 and other external standards and regulatory requirements.

Techniques and tools for process management are discussed in [Section 8](#).

Specific responsibilities for and the sequence and interaction of our key QMS processes are detailed in Standard Operating Procedures (SOPs), many of which contain or reference deployment flow charts depicting the process or procedure described in the narrative SOP; [Appendix A](#) contains a List of Key QMS Documents, including all SOPs and other key Senior level QMS documents.

We also recognize the significant role that subcontractors play in achieving desired results and recognize that we must ensure proper control over outsourced QMS processes ([Section 7.4.1](#)). Outsourced processes are also depicted in our procedures governing their management and are described in documents referenced in applicable SOPs.

The Process Map below shows the sequence and interactions of these processes.



Process Effectiveness Matrix		Quality Objectives			
		On Time Delivery	Efficiency	Customer Phone Response Time	FPY and Quality Rejects
Key Processes	Quality Management	X	X	X	X
	Customer Service	X		X	X
	Purchasing and Receiving	X	X		X
	Order Fulfillment	X	X		X



	Product Design and Development	X	X		X
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## 4.2 Documentation requirements

### 4.2.1 General

The QMS includes this quality manual with documented statements of our quality policy and quality objectives. It references documented procedures and records required by ISO 9001:2015 including Document Control, Record Control, Internal Audit, Control of Nonconforming Product, Corrective and Preventive Action. Also included are other documents needed to ensure effective planning, operation and control of our key QMS processes.

QMS documents and data may be in hard copy or electronic media. SOPs, work instructions, job descriptions, other internal and external documents are used as needed to effectively manage our QMS ([Section 4.2.3](#)).

### 4.2.2 Quality manual

The organization has established and currently maintains a quality manual that includes:

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

The Engineering/Quality Manager is responsible for maintaining the quality manual.

### 4.2.3 Control of documents

The Engineering/Quality Manager has overall responsibility for ensuring that all QMS documents, including forms used to create quality records are controlled per procedures detailed in [SOP 4.2.3](#) and summarized below:

- a) Approve documents for adequacy prior to issue.
- b) Review, update as necessary and re-approve documents.
- c) Identify the current revision status of documents.
- d) Ensure that relevant versions of applicable documents are available at points of use.
- e) Ensure that documents remain legible, readily identifiable and retrievable.
- f) Ensure that documents of external origin (including customer engineering standards/specifications) are identified and their distribution controlled.
- g) Prevent the unintended use of obsolete documents, and to apply suitable

identification to them if they are retained for any purpose.

The Engineering/Quality Manager oversees our process for assuring the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule; CDI Electronics, Inc. uses a MRP data management system and SharePoint to electronically manage and control engineering records and data as well as maintaining some hard copy data files (see [SOP 4.2.3](#)).

Requirements for the establishment and maintenance of Master Lists of internal and external QMS documents are defined in [SOP 4.2.3](#).

#### 4.2.4 Control of records

The Engineering/Quality Manager has overall responsibility for ensuring that all records required for the QMS (including customer-specified records) are controlled and maintained to provide evidence of conformance to requirements and effective operation of the QMS. Records may be in the form of hard copy or electronic media.

A documented procedure ([SOP 4.2.4](#)) has been established to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records shall remain legible, readily identifiable and retrievable.

## 5. Management Responsibility

### 5.1 Management commitment

The Senior Management Team provides evidence of its commitment to the development, implementation, accountability, and improvement of our QMS and its effectiveness by:

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

### 5.2 Customer focus

Senior management ensures a proper customer focus is established and maintained through the following activities:

New product requests from customers are processed per [SOP 7.2](#) and SOP 7.3 to assure customer requirements are identified and met with the aim of satisfying the customer. Customer complaints and other customer input/feedback are continually monitored and measured to identify opportunities for improvement per [SOP 8.2.1](#) ([Section 8.2.1](#)).

We continually look for other ways to interact directly with individual customers to ensure a proper focus to their unique needs/expectations is established and maintained: e.g. customer audits, customer visits, trade shows, joint planning sessions, etc.

In addition, we have established an interactive web site: <http://www.cdielelectronics.com/> to provide customers with quick access to information and points of contact within our organization ([Section 7.2.3](#)).

These customer focused communications and interactions ultimately yield clear, explicit customer requirements and expectations in the form of a contractual agreement or customer order ([Section 7.2](#)).

### 5.3 Quality policy

*CDI is dedicated to continuous improvement and providing quality products and services which meet or exceed customer requirements*

Our quality policy statement indicates our commitment and focuses on what is important to us as an organization is achieving customer satisfaction. CDI Electronics will accomplish this by continually improving processes, products, and services to ensure they consistently meet or exceed requirements.

Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing and reviewing quality objectives.

We ensure that our quality policy is communicated and understood at all levels of the organization through documented training, regular communication, and reinforcement during annual employee performance reviews.

Our quality policy statement is controlled by inclusion in this manual, and along with all policies contained in this manual, is reviewed for continuing suitability during management review meetings ([Section 5.6.2](#)).

### 5.4 Quality Management System Planning

#### 5.4.1 Quality objectives

Our overall quality goal is to achieve our quality policy, and maintain the integrity of and continually improve a QMS compliant with ISO 9001:2015.

The Senior Management Team ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization.

The quality objectives are measurable and consistent with the quality policy.

The President/CEO is responsible for establishing and maintaining the following quality objectives:

Measure/Quality Objective	Owner	Reporting Frequency	Target
On Time Delivery	Customer Service Manager	Daily – Core Team Monthly – Management	98% on Time
Efficiency	Manufacturing Manager	Daily – Core Team Monthly – Management	90% Efficiency
Customer Service Efficiency	Engineering/Quality Manager	Daily – Core Team Monthly – Management	Average <2 Minute Wait Time
FPY/Quality Rejects	Manufacturing Manager	Daily – Core Team Monthly – Management	98% Yield & < 1% Defects

#### 5.4.2 Quality management system planning

The QMS planning process involves the establishment and communication of our quality policy ([Section 5.3](#)) and objectives ([Section 5.4.1](#)) through issuance of this manual and its associated procedures, and through the provision of resources needed for its effective implementation ([Section 6.1](#)).

Accordingly, this manual constitutes our overall plan for establishing, maintaining and improving an effective QMS. Our management review process ([Section 5.6](#)) and internal audit process ([Section 8.2.2](#)). The Senior Management Team will ensure the integrity of our QMS is maintained when significant changes are planned and implemented that affect our key QMS processes.

### 5.5 Responsibility, authority and communication

#### 5.5.1 Responsibility and authority

The President/CEO sets direction and ensures the success of our business through the clear definition and communication of QMS responsibilities and authorities. Other members of Senior Management include: the Controller, the Manufacturing Manager, Engineering/Quality/Tech Service Manager, Marketing/Sales Manager, and Customer Service Manager. The interrelationship of Senior Management and other key personnel is depicted our Organization Chart, CDI Electronics Form [QF-401](#).

Responsibility and Interaction for QMS processes.

- Senior Management – Members of Senior Management are ultimately

responsible for the quality of CDI Electronics' products and services since they control the systems and processes by which work is accomplished. Senior Management is responsible for QMS Planning, development and communication of our quality policy ([Section 5.3](#)), QMS Planning ([Section 5.4.2](#)) including the establishment and deployment of objectives ([Section 5.4.1](#)), the provision of resources needed to implement and improve the QMS ([Section 6.1](#)) and management reviews ([Section 5.6](#)).

- Management – All managers are responsible for execution of the QMS and implementation of the policy, procedures (SOPs), processes and systems, and reviews described in this manual
- Employees - All employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform ([Section 8.2.3](#)). Personnel responsible for product quality have the authority to stop production to correct quality problems ([Section 8.3](#)). Employees are motivated and empowered to identify and report any known or potential problems and recommend related solutions through internal audits ([Section 8.2.2](#)) and/or the continual improvement and corrective/preventive action processes ([Section 8.5](#)).

Other areas of responsibilities and authorities for QMS implementation and improvement are contained in other QMS documents including procedures, flow charts, job descriptions, work instructions, etc.

#### 5.5.2 Management representative

The President/CEO has appointed the Engineering/Quality Manager as CDI Electronics' ISO Management Representative, with delegated responsibilities for ensuring that:

- An *ISO 9001:2015* compliant QMS is established, implemented, and maintained,
- It promotes awareness of customer requirements throughout the organization ([Section 5.5.3](#));
- The performance of the QMS is reviewed by Senior Management for effectiveness, continuing suitability and the need for improvement ([Section 5.6](#)).
- Quality system issues are communicated to external parties as required.

#### 5.5.3 Internal communication

The Senior Management Team communicates information regarding QMS processes and their effectiveness through documented training ([Section 6.2.2](#)), the internal audit process ([Section 8.2.2](#)), continual improvement and corrective/preventive action processes ([Section 8.5](#)), and regular formal and informal communications as follows:

- Quality objectives and other information on KPI boards throughout the facility to convey information regarding customer requirements, and the status and importance of quality activities.
- Internal audits ([Section 8.2.2](#)) are also used to reinforce or communicate

- appropriate information to employees.
- The HR Manager posts information on employee bulletin boards throughout the facility to convey information regarding employee benefits, programs, involvement opportunities, and applicable statutory/regulatory requirements. The HR Manager is also responsible for publication of CDI Electronics, Inc.'s newsletter, *ISO-ONLINE*.
- The Sales/Marketing department ensures that consistent and effective formal communication is facilitated through our Intranet system and interactive web site: <http://www.cdielelectronics.com/>.

All officers, managers and supervisors, are responsible for establishing internal communications as needed to convey to their employees the relevance and importance of their activities; typically, this information is conveyed through production team meetings and cross-functional improvement projects. Communications regarding how employees contribute to the achievement of objectives is also conveyed and reinforced during employee performance reviews.

## 5.6 Management review

### 5.6.1 General

Senior Management Team (SMT) conducts a management review meeting at least once annually to ensure the continuing suitability, adequacy, and effectiveness of our QMS in accordance with procedures detailed in [SOP 5.6](#).

The primary inputs reviewed include data that measures the conformance and performance of our QMS and recommendations based on analysis of such data.

The SMT may meet weekly, monthly or as needed to review specific areas of the QMS. Record of the management Review will be maintained by the Engineering/Quality Manager.

### 5.6.2 Review input

The management review meeting will be scheduled by the Engineering/Quality Manager and prepare and agenda which will include all the inputs defined in [SOP 5.6](#). It also will include a review of our quality policy ([Section 5.3](#)).

### 5.6.3 Review output

At a minimum, outputs from management review meetings include new/revised corporate level improvement objectives and any related actions required for improvement of the QMS and its processes, improvement of product related to customer requirements, and provision of resource needs. Results of management review meetings are recorded and maintained by the ISO Management Representative per [SOP 5.6](#).

## 6. Resource Management

### 6.1 Provision of resources

The President/CEO, with input from the Senior Management Team and all responsible managers, ensures, appropriate resources, including trained employees and appropriate equipment, facilities, support services and work environment needed to implement, manage and improve an effective/efficient QMS as well as enhance customer satisfaction.

### 6.2 Human resources

#### 6.2.1 General

We believe that our employees are our most valuable resource and we do our best to help them achieve their full potential through continual education and training.

#### 6.2.2 Competence, training, and awareness

Personnel performing work affecting conformity to product requirements are deemed competent on the basis of appropriate education, training, skills and experience. Human Resources and /or the employee supervisor are responsible for assessing competence. All current employees are considered to be competent. Competency requirements and training and awareness needs are determined through the following actions:

Senior Management identifies competency/needs during management reviews ([Section 5.6](#)). Competency, current needs and additional knowledge necessary to meet changing needs and trends are considered and modified into job descriptions for the type and number of positions that need to be filled through external recruitment, internal reassignment/promotion, and/or outsourcing actions.

The HR Manager, with input from responsible managers, evaluates and qualifies applicants for specific job openings based on documented or demonstrated competencies. Where possible, we help existing employees qualify for new/changed jobs through the provision of appropriate education and training, including on-the-job-training (OJT), and training from external providers, as applicable.

The HR Manager, with input from responsible managers, establishes and maintains job descriptions for each position held at CDI Electronics to document the specific competencies needed to ensure the quality of CDI Electronics' products and services.

Training needs identified based on the activities discussed above are passed on to the HR Manager for appropriate planning and timely provision.



The effectiveness of all actions taken to meet competency and training needs is evaluated through immediate feedback from the employee and the manager, officer, or supervisor who identified the training requirement. Training effectiveness is collected and documented by the responsible manager for each training event. The HR Manager, with input from other responsible managers, monitors and measures the overall effectiveness of training and other actions taken to meet competency needs and provides related recommendations to Senior Management for review and action ([Section 5.6](#)).

Employees are made aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives and meeting customer. This is accomplished through awareness training, employee performance reviews, and employee participation in our internal audit ([Section 8.2.2](#)) and improvement ([Section 8.5](#)) processes.

Records of appropriate education, training, skills and experience will be maintained in accordance with provision of [Section 4.2.4](#). Training records, qualification/competency review records and annual performance review results are maintained by the HR Manager.

### 6.3 Infrastructure

The President/CEO has overall responsibility for planning, providing and maintaining the resources needed to achieve product conformance, including buildings, workspace and associated utilities; process equipment (hardware and software); and supporting services (such as internal transportation and material handling systems and communications systems).

The Manufacturing Manager has overall responsibility for managing our Facilities and Equipment Maintenance programs in accordance with [SOP 6.3](#); these programs include:

- facilities management, maintenance and repair
- housekeeping/custodial services management
- process equipment management, maintenance and repair
- production tooling management, and
- transportation and material handling equipment management, maintenance and repair

### 6.4 Work environment

The Senior Management Team provides a work environment that will meet or exceed the requirements for producing product which satisfies the customer. The work environment is evaluated regularly with input from employees during team meetings for continual improvement.



## 7. Product Realization

### 7.1 Planning of product realization

Our QMS identifies plans and documents our product and service realization. The planning of product realization is consistent with other CDI processes and meets all applicable customer requirements in the QMS.

[SOP 7.1](#) defines:

- Quality objectives and requirements for specific products/services.
- The needs, to establish processes, resources, and documents for specific products/services.
- Required verification, validation, monitoring, measurement, inspection and test activities, specific to products/services including acceptance criteria.
- Records needed to provide evidence the product requirements are met.

The outputs of quality planning (i.e. work order packets, quality control plans, etc.) are carried out in accordance with planned monitoring and measurement activities ([Section 8.2](#)), which may also include the use of appropriate statistical techniques ([Section 8.1](#)).

### 7.2 Customer-related processes

Achieving our quality policy “to meet or exceed customer requirements” requires that we determine, understand, and consistently meet or exceed our customers’ requirements and expectations, and that we establish effective communication systems with our customers with regards to product information, inquiries, contract or order handling and related changes, and customer feedback, including complaints. These efforts are described below. The Sales/Marketing Manager has overall responsibility for developing and implementing effective customer-related processes in accordance with the policies in this section and [Section 8.2.1](#).

#### 7.2.1 Determination of requirements related to the product

Sales personnel generate quotes/bids and negotiate final contracts/orders; Customer Service personnel receive customer orders for standard (catalog) items or for items included previously bid or negotiated.

Requirements for most major customers are identified in documented contracts. In other cases, a customer order constitutes a contract, and we ensure that the customer’s requirements are clearly identified and confirmed prior to acceptance. [SOP 7.2](#) defines our process for determining product related requirements, including:

Product requirements not specified by the customer but necessary for intended or specified use and obligations related to product, including regulatory and legal requirements; this may include recycling, environmental impact, and characteristics identified as a result of CDI Electronics' knowledge of the product and related production processes.

All applicable government, safety, and environmental regulations applied to the acquisition, storage, handling, recycling, elimination or disposal of materials.

#### 7.2.2 Review of requirements related to the product

Sales or Customer Service personnel review customer requirements identified during the determination process ([Section 7.2.1](#)) to ensure that they are clearly stated, understood, and recorded. Our process for reviewing all applicable requirements is defined in [SOP 7.2](#) to ensure:

- all applicable product requirements are defined, understood and confirmed with the customer prior to acceptance
- manufacturing feasibility of proposed (new or changed) products is investigated, confirmed and documented prior to making a commitment to supply
- contract or order requirements differing from those previously expressed are resolved
- records of the review and actions resulting from the review are maintained ([Section 4.2.4](#))

The Sales Manager obtains necessary customer authorizations to waive formal reviews where it is deemed impractical for each order.

Where product requirements are changed, we ensure relevant documents are amended and relevant personnel are made aware of the changed requirements; see [SOP 7.2](#).

#### 7.2.3 Customer communication

Customers are provided information for the following 'key' customer contact personnel: Buyer, Engineering/Quality Manager, and Design Team Leader.

Customers will also be provided points of contact the following key functions: Manufacturing / Production, Materials Management / Logistics, and Purchasing when requested.

*Customer communications* are established through a variety of channels:

- Sales and Customer Service personnel provide *product information* directly to

customers including verbal and printed information on our standard product offerings as well as customized information for unique customer applications.

- *Inquiries* are handled by our Sales or Customer Service personnel depending on the nature of the inquiry or who made initial contact; [Section 7.2.1](#). Engineering personnel provide *technical assistance* and related information as needed.
- Through a wide sales network, customer feedback is encouraged, including customer satisfaction, suggestions regarding products and/or services and customer complaints. A toll-free number is available (1-800-467-3371).
- Customer satisfaction is evaluated on an on-going basis per [SOP 8.2.1](#).
- Our Information Systems Manager maintains a user/customer friendly web site, <http://www.cdielelectronics.com/> which contains extensive product information, a list of contacts of use to both customers and suppliers, and an electronic customer feedback form.
- Our Information Systems Manager establishes/maintains an ability to communicate necessary information, including data, in a customer specified language and format, including but not limited to computer-aided design data and electronic data interchange (EDI).

### 7.3 Design and development.

Design and development processes transform customer requirements into specifications, products, processes or systems. This includes testing, verification and validation of the design.

The Engineering/Quality Manager maintains a list of products/services for which CDI Electronics, Inc. has design responsibility, i.e. the authority to establish a new, or change an existing, product specification.

The Engineering/Quality Manager has overall responsibility for managing product design and development activities in accordance with [SOP 7.3](#) and summarized in the following sections.

7.3.1 Design planning. The Engineering/Quality Manager assigns a qualified Design Engineer to serve as Design Team Leader for design projects for new/changed products or services. The Design Team Leader utilizes project management planning tools (available software etc.) to establish a Design Plan that, at a minimum, identifies design stages, predetermined design reviews, scheduled verification and validation activities. The Design Team Leader forms a Design Team composed of design, manufacturing, engineering, quality, production and other appropriate qualified personnel to prepare for product realization.

7.3.2 Design inputs. The Design Team Leader identifies, documents ([Section 4.2.4](#)) and reviews design inputs; and, before finalizing documentation of required inputs, resolves any incomplete, ambiguous or conflicting requirements ([Section 7.2.2](#)):

- the functional and performance requirements as derived from customer input, legal and regulatory requirements which apply
- useful information or experience from previous similar design efforts
- targets for product quality, life, reliability, risks, durability, maintainability, timing and cost

7.3.3 Design outputs. The Design Team Leader ensures that design outputs comply with the design input requirements; include information needed for production and service provision; include or reference acceptance criteria; indicate design characteristics critical to the safe and proper operation of the product; and are approved before issuance.

#### 7.3.4 Design review

During the evolution of each design project, the Design Team Leader conducts design reviews as planned and records results and any necessary actions. All functions concerned with the stage being reviewed are represented at the planned review(s). Design reviews are intended to assure that requirements are being fulfilled; when they are not, the Design Team Leader utilizes input from those involved in the review to propose a remedy for each identified problem.

#### 7.3.5 Design verification

The Design Team Leader ensures design verification activities are carried out as planned (per the Design Plan) and records results and any necessary actions. Design verification activities are intended to determine if design output meets design input requirements; design reviews can be a form of design verification.

#### 7.3.6 Design validation

The Design Team Leader ensures design validation is carried out as planned (per the Design Plan) and records results and any necessary actions. Design validation is performed to ensure the product or service resulting from design efforts performs as intended for all specified or known uses/applications. As applicable, the Design Team Leader plans and carries out or oversees:

#### 7.3.7 Control of design changes

The Design Team Leader ensures all design changes are identified, documented, reviewed, approved, communicated to all affected organizations and functions, and results and any necessary actions are recorded throughout the product program. Design change control includes an assessment of the impact of changes upon component parts and completed products, including those that may have already been delivered. Control

also includes the determination of treatment required for each change, which may include verification or validation.

## 7.4 Purchasing

We work in partnership with our suppliers to ensure that purchased products and services meet all applicable requirements. The processes applicable to the planning, acquisition and verification of all products and services that affect customer requirements (such as subassembly, sequencing, sorting, rework and calibration services) are defined in [SOP 7.4.1](#), [SOP 7.4.2](#) and [SOP 8.2.4](#) in accordance with the policies outlined in this section.

### 7.4.1 Purchasing process

The type and extent of control applied to our suppliers and purchased product is dependent upon the effect on subsequent realization processes and their output, as well as consideration of other characteristics including: the type of product; the potential impact of the product on our processes, products, or services; the results of supplier evaluations; and past performance.

Purchased products are verified ([Section 7.4.3](#) and [SOP 7.4.2](#)) to ensure conformity to specified purchase requirements ([Section 7.4.2](#)).

The Logistics Manager defines and documents the supplier approval process, including criteria for selection, the extent of control to be exercised and periodic evaluation; [SOP 7.4.1](#). Suppliers are evaluated and selected based on their ability to supply products or services in accordance with our requirements.

Where specified (by contract, customer engineering drawing, or specification) we purchase products, materials or services from customer-approved sources.

A master list of approved suppliers is maintained in the ERP system to ensure we only purchase product from CDI Electronics qualified sources or customer-approved sources. The results of evaluations and follow/up actions are recorded.

Supplier performance is monitored by the Controller/Logistics Manager per [SOP 7.4.1](#) through one or more of the following indicators: delivered product quality; customer disruptions including field returns; delivery schedule performance (including incidents of premium freight); and special status customer notifications related to quality or delivery issues.

### 7.4.2 Purchasing information

The Controller/Logistics Manager ensures the adequacy of specified purchase requirements prior to communication to the supplier per procedures defined in [SOP 7.4.2](#) and the following policies:

Purchasing information communicated to our suppliers contains the appropriate data needed to clearly and fully describe requirements for purchased materials and services; including, where appropriate, requirements for approval/qualification of product, procedures, processes/systems, equipment; qualification of personnel; and quality management system requirements.

#### 7.4.3 Verification of purchased product

The Engineering/Quality Manager has overall responsibility for ensuring the quality of purchased products using one or more of the following methods:

Receiving is performed per [SOP 7.4.2](#).

1. Receipt directly to stock based upon:
  - Previous quality history.
  - Certification of product by the supplier or third party inspection/audits
2. Receiving inspection and/or testing (such as sampling based on performance)

All products produced for the first time requires the supplier to submit samples for approval as a first article. The Engineering/Quality Manager or designee will verify the products meet the requirements before approving the parts. Upon approval the product will be released for stock/production.

As applicable, the Engineering/Quality Manager documents and communicates the intended verification arrangements and method of product release related to verification activities performed internally and at our suppliers' premises.

### 7.5 Production and Service Provision

#### 7.5.1 Control of production and service provision

The organization plans and carries out production and service provision under controlled conditions. Quality plans will be used to help define controlled conditions. They shall include, as applicable:

- the availability of information that describes the characteristics of the product
- the availability of work instructions, as necessary
- the use of suitable equipment and environment
- the availability and use of monitoring and measuring equipment
- the implementation of monitoring and measurement

- the implementation of product release, delivery and post-delivery activities

The Manufacturing Manager ensures that production/service jobs are planned, scheduled, and carried out in accordance with procedures detailed in [SOP 7.5.1](#) as summarized below:

#### Information

The Manufacturing Manager, through Product Line Team Leaders, Production Shift Supervisors and Production Control Supervisors, ensures that all appropriate information including final product/service specifications, raw material characteristics and the required product parameters, is provided to production personnel throughout the product/service provision process. Such information is provided through job schedules/plans, production team meetings, work instructions posted in areas where they are needed, and/or through job specific information included in individual job packs (including control plans, where applicable).

#### Work Instructions

The necessity for and required detail of work instructions is dependent upon the knowledge, skills, and abilities of our employees and the complexity of the work process they are assigned to perform. Product Line Team Leaders, with input from Engineering, Quality and other technical personnel identify critical production/service work steps in process sheets included in the job pack or other information included in work instructions posted in areas where they are needed.

#### Equipment

The Maintenance Manager ensures the suitability and availability of all equipment, facilities and tooling used for production and service operations; [Section 6.3](#).

#### Monitoring and Measurement Devices.

The Engineering/Quality Manager ensures that monitoring and measurement equipment capable of meeting our measurement requirements are available for use during production and service provision; [Section 7.6](#).

#### Monitoring Activities

The Manufacturing Manager, through Production Shift Supervisors, ensures that production personnel monitor the quality of their own work and understand the procedures for reporting related problems and/or suspected nonconforming conditions; [SOP 7.5.1](#) and [Section 8.2.3.1](#). The Engineering/Quality Manager is responsible for planning and implementing in-process test/inspections needed to ensure process control and product quality; [Section 8.2.4](#).

#### Release, Delivery, and Post-Delivery Processes.

Release of product is dependent on its compliance with statutory, regulatory, and all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order.



The Controller/Logistics Manager, the Manufacturing Manager, and the Engineering/Quality Manager, ensures that records of product approval are maintained and clearly indicate the authorizing employee.

The Controller/Logistics Manager periodically reviews operational data as well as progress towards achievement of corporate level product/service performance objectives ([Section 5.4.1](#)) and provides related recommendations for review by Senior Management; [Section 5.6.1](#).

#### 7.5.2. Validation of processes for production and service provision

This section is excluded from CDI QMS because does not have any processes in which results cannot be verified by subsequent monitoring or measurement as “Special Processes”; this includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered. Should a process meeting these requirements be incorporated as an additional process, this section will be revised.

#### 7.5.3 Identification and traceability

The Engineering/Quality Manager has overall responsibility for establishing and maintaining product identification throughout all stages of design, production, installation and delivery in accordance with procedures defined in [SOP 7.5.3](#). Where product traceability is a customer-specified requirement, appropriate controls and records are established and maintained.

Product is identified either:

- Directly on the part

- With, tags/labels,

- In a group/batch; such as bags, boxes, containers, etc.

- Designated area – such as marked off section on floor, work table, shelf, etc.

The Controller/Logistics Manager, the Production Manager, the Customer Service Manager, and the Engineering/Quality Manager, ensures that all incoming, in-process, and final product is suitably identified and the current status is appropriately tracked and displayed in accordance with procedures detailed in [SOP 7.5.3](#).

Where contractually required, the Engineering/Quality Manager plans for, establishes and maintains appropriate traceability records in accordance with customer requirements; [Section 7.1](#). Some products may be identified with a lots or batches number which relates to the work order.

#### 7.5.4 Customer property

Customer property includes customer-owned material, tools (including returnable packaging), tooling (including test/inspection tooling and equipment), and intellectual property. We identify, verify, protect and maintain customer property provided for use or



incorporation into the product, by applying the same process controls as we do to purchased product ([Section 7.4](#)).

Whenever customer-specified requirements for property management are beyond the control or capability of our established QMS, the Engineering/Quality Manager has overall responsibility for planning, documenting and communicating such requirements to all appropriate personnel as a part of product quality planning; [Section 7.1](#). Additional special requirements applicable to customer supplied product are detailed in [SOP 7.5.4](#).

The Engineering/Quality Manager ensures that lost, damaged or unsuitable customer property is recorded and reported to the customer; [Section 8.3](#).

#### 7.5.5 Preservation of product

The Controller/Logistics Manager, Manufacturing Manager, Engineering/Quality Manager, and Maintenance Manager, has overall responsibility for establishing and implementing a material management system to ensure product conformity is preserved during internal processing and through delivery to the intended destination. This system, defined in [SOP 7.5.5](#), includes the handling, storage, packaging, delivery, and protection of final product as well as raw materials and in-process constituents of the final product, to ensure:

- Components and products are handled and stored in a manner that prevents damage or deterioration pending use or delivery.
- Each department ensures controls are implemented to prevent mixing conforming and non-conforming materials.
- Packing ensures specified or original manufacturing packaging is utilized.
- All components and products are suitably packed to prevent deterioration or damage during storage and delivery.

In order to detect deterioration, the condition of stock is periodically assessed. Further, obsolete product (including expired age dated material, e.g.), and unidentified or suspect stock is controlled as nonconforming product; [Section 8.3](#).

#### 7.6 Control of monitoring and measuring equipment

The Engineering/Quality Manager is responsible for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measuring equipment used to provide evidence of product conformance to established requirements. These controls, defined in [SOP 7.6](#), apply to CDI Electronics owned, customer-owned and employee-owned equipment.

The calibration program is kept electronically. It keeps track of all the equipment and gauges requiring calibration which includes the gauge ID, calibration intervals, and identification of standards of traceability. Where no such standards exist, the basis used for calibration is documented.

Where necessary to ensure valid results, measuring-equipment and gauges is:

- calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded
- adjusted or re-adjusted as necessary
- identified in order to determine its calibration status
- safeguarded from adjustments that would invalidate the measurement result
- protected from damage and deterioration during handling, maintenance and storage

Product which has been approved by a gauge which is out of tolerance will be evaluated and processed through the Nonconforming Material procedure if necessary SOP-8.3.

## **8. Measurement, Analysis and Improvement**

### **8.1 General**

This section describes how we define, plan, and implement the monitoring, measurement, analysis and improvement activities needed to assure product and QMS conformity, and continual improve the effectiveness of the QMS.

These activities include assessment the quality objectives, customer satisfaction, conduct of internal audits, process monitoring and measurement, and product monitoring and measurement to meet customer requirements. [SOP 8.1](#) details procedures governing the selection and use of appropriate statistical techniques used in monitoring, measurement, and analysis and improvement activities.

### **8.2 Monitoring and measurement**

#### **8.2.1 Customer Satisfaction**

The Sales/Marketing Manager has overall responsibility for obtaining, monitoring and measuring customer satisfaction per [SOP 8.2.1](#), summarized as follows:

- On Time Delivery
- Customer Returns
- Customer feed back from trade shows, training seminar, and customer visits
- Corrective actions

- Customer survey

The Sales Manager periodically reviews customer satisfaction survey data and other customer feedback (including complaints), as well as progress towards achievement of corporate level customer satisfaction improvement objectives ([Section 5.4.1](#)) and provides related recommendations for review by Senior Management; [Section 5.6](#).

#### 8.2.2 Internal audit

Internal audit results are critical inputs to aid in assessing the effectiveness of our QMS, in identifying opportunities for improvement, and in promoting awareness of customer requirements and effectiveness of the QMS to our workforce.

QMS audits will be conducted to determine conformity to *ISO 9001:2015* and any additional QMS requirements that may apply. The overall measure of QMS effectiveness is the absence of repeat problems/findings, as an indicator that our QMS was effective in eliminating the cause of such problems.

Internal audits are conducted in accordance with a published schedule that identifies the audit scope and frequency. Each of our key QMS processes is reviewed to determine effectiveness. The schedule is updated yearly or sooner based on the status and importance of the activity to be audited and previous audit results.

The QMS process, function or quality system element under review is effective if it is achieving the desired results or established objectives; [Section 5.4.1](#). In addition, employee involvement in identifying process effectiveness or efficiency improvements is actively sought during internal audits. Internal audit results are used to determine the scope, nature and frequency of future internal audits of processes, products, functions or quality system elements where ineffectiveness or inefficiency is most likely to be found.

The ISO Management Representative has overall responsibility for managing the internal audit process in accordance with [SOP 8.2.2](#) as summarized below:

Audits are carried out by qualified personnel ([Section 6.2.2](#)) who do not have direct responsibility for the activity being audited. Auditors record audit results and submit findings to management personnel with responsibility for the process, function or quality system element audited.

Management responsible for the area audited implement timely corrective action to eliminate detected non-conformances and their causes, and initiate other appropriate action in response to opportunities for improvement identified by process participants or managers. Follow-ups are conducted to verify timely and effective implementation of the proposed action.

The ISO Management Representative maintains all internal audit records, including internal auditor training records, results of internal audits and related follow-ups;

periodically reviews internal audit results as well as progress towards achievement of corporate level objectives aimed at improving overall QMS effectiveness ([Section 5.4.1](#)); and provides related recommendations for review by the Senior Management Team; [Section 5.6](#).

### 8.2.3 Monitoring and measurement of processes

Senior Management will apply suitable methods for monitoring and measuring all QMS processes. These methods will demonstrate the ability of the processes to achieve planned results. Processes are documented measured, controlled and evaluated to ensure they are effective (i.e. achieve desired results) and to identify opportunities for improvement. The Managers analyze process performance opportunities ([Section 8.4](#)) and takes appropriate improvement, corrective or preventive action ([Section 8.5](#)).

### 8.2.4 Monitoring and measurement of product

The Engineering/Quality Manager has overall responsibility for planning ([Section 7.1](#)) and implementing inspection and test activities needed to verify product requirements are met at appropriate stages of the product realization process in accordance with the applicable control plan. When selecting product parameters to monitor compliance to internal and external requirements, product characteristics are determined leading to the types of measurement, suitable measurement means, and the required capability and inspection/test skills needed.

The scope of our product monitoring and measurement system is defined in the quality plan and will include the verification process and method to assure compliance to the customer requirements.

Products are not released for further processing or delivery until we have objective evidence that all requirements have been met ([SOP-8.2.4](#)).

*Evidence of Conformity.* Test and inspection records are maintained. These records include inspection authority, identify and confirm that established requirements and specifications were met and the release of product for delivery to the customer.

*Product Release and Delivery.* Product is not normally released or delivered until all planned inspections and tests have been completed, and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person(s) authorizing release.

In rare cases (due to customer demands and/or production emergencies) prototype samples may be released or delivered under controlled conditions and authorized by the Engineering/Quality Manager and, where applicable, approved by the customer. Nonconforming (or suspect) product is identified and controlled to prevent its inadvertent use; [Section 8.3](#).

### 8.3 Control of nonconforming product

The Engineering/Quality Manager has overall responsibility for implementing an effective process for identifying, documenting, segregating, evaluating, and disposing of nonconforming product. Personnel responsible for product quality have the authority to stop production to correct quality problems in accordance with [SOP 8.3](#).

Material will be segregated for disposition. Disposition will be either:

- Scrap – Product/Material will be disposed of.
- Returned to supplier – Product/Material sent back to the supplier to be replaced
- Repaired – Product/Material can be repaired by approved methods defined by engineering. Then all repaired product/material must be verified that it meets the requirements before it can be returned to stock or to the production process.
- Deviate – accept as is when approved by engineering and if necessary by the customer. procedures are summarized

The Sales/Marketing Manager or designee will contact the Customer when there has been nonconforming product shipped and provide the action they need to take regarding the product in question.

Where required, the Engineering/Quality Manager obtains a deviation permit prior to further processing whenever the product or product realization process is different from that which is currently approved.

### 8.4 Analysis of data

Senior Management and other officers, managers and supervisors identify processes and product to collect and analyze data using appropriate statistical techniques ([Section 8.1](#)) to determine the suitability and effectiveness of key QMS processes applicable to their area(s) of responsibility and to identify opportunities for improvement.

KPI's are used to manage our key QMS processes through the use/application of standard industrial quality/process tools, charts, programs, diagrams and statistical methods to define and analyze the selected process in terms of inputs, throughputs/activities, and outputs.

The Senior Management Team uses the management review inputs to measure continuous improvement and the effectiveness of the QMS.

### 8.5 Improvement

#### 8.5.1 Continual improvement

At CDI Electronics, the continual improvement process begins with the establishment of our quality policy ([Section 5.3](#)) and objectives for improvement ([Section 5.4.1](#)), based on objectives created by the Senior Management Team.

Customer satisfaction, internal audit, process and product performance data are then compared to progress against objectives to identify additional opportunities for improvement; [Section 8.4](#). Appropriate improvement initiatives are established, supported and monitored for achievement through our management review process ([Section 5.6](#)).

We also consider corrective and preventive actions a vital part of our continual improvement program. Corrective actions are initiated when desired results are not achieved and preventive actions are initiated to prevent the occurrence of problems or to implement other improvement actions. Procedures governing our continual improvement system are detailed in [SOP 8.5.1](#).

The overall effectiveness of continual improvement program (including corrective and preventive actions taken as well as the overall progress towards achieving corporate level improvement objectives) is assessed through our management review process ([Section 5.6](#)).

Essentially, such actions are effective if the problems corrected do not reoccur, potential problems identified do not occur, and other improvement actions accomplish the desired results or objectives. Inputs to the management review process are used to establish new/changed improvement objectives and to initiate/prioritize additional improvement actions; [Section 5.6](#).

#### 8.5.2 Corrective action

The Engineering/Quality Manager has overall responsibility for managing our corrective action process defined in [SOP 8.5.2](#) and summarized below:

Evidence of nonconforming product, customer dissatisfaction, or ineffective processes is used to drive our corrective action system. Investigating with consideration to the risks involved and eliminating the root cause of these failures is a critical part of our continual improvement process. Management with responsibility and authority for corrective action are notified promptly of product or process non-conformities for immediate action per [SOP 8.5.2](#).

Follow-ups are conducted (through the internal audit process; [Section 8.2.2](#)) to ensure that effective corrective action is taken appropriate to the impact of the problem encountered. The corrective action system is considered effective if specific problems are corrected and data indicates that the same or similar problems have not recurred. Results of this analysis and related recommendations are presented to Senior Management for review and action during management reviews; [Section 5.6](#).

### 8.5.3 Preventive action

The Engineering/Quality Manager has overall responsibility for managing the preventive action process defined in [SOP 8.5.2](#) and summarized below:

Data from internal audits, customer feedback, employee suggestions, and other appropriate data is collected and analyzed ([Section 8.4](#)) to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. Investigating and eliminating the root cause of potential failures is a critical part of our continual improvement process. We review and initiate preventive actions through our preventive action process defined in [SOP 8.5.2](#).

We apply controls and follow-up to ensure that effective preventive action is taken appropriate to the risk and impact of potential problems and losses. The preventive action system is considered effective if potential losses were avoided. Results of this analysis and related recommendations are presented to Senior Management for review and action during management reviews; [Section 5.6](#).

**Appendix A****List of Key Internal QMS Documents Referenced in this Manual**

(Master lists for these and other QMS Documents are defined in [SOP 4.2.3](#))

<b><u>Document No.</u></b>	<b><u>Title</u></b>
<a href="#">QM-001</a>	<i>Quality Manual</i>
<a href="#">SOP 4.2.3</a>	<i>Control of Documents</i>
<a href="#">SOP 4.2.4</a>	<i>Control of Records</i>
<a href="#">QF-401</a>	<i>CDI Electronics Organization Chart</i>
<a href="#">SOP 5.1</a>	<i>Management Requirements</i>
<a href="#">SOP 5.2</a>	<i>Customer Focus</i>
<a href="#">SOP 5.4</a>	<i>Quality Planning &amp; Implementation</i>
<a href="#">SOP 5.6</a>	<i>Management Review</i>
<a href="#">SOP 6.2.2</a>	<i>Competence, Training and Awareness</i>
<a href="#">SOP 6.3</a>	<i>Facilities and Equipment Maintenance</i>
<a href="#">SOP 7.1</a>	<i>Product Planning Realization</i>
<a href="#">SOP 7.2</a>	<i>Product Requirements Identification and Review</i>
<a href="#">SOP 7.3</a>	<i>Design and Development</i>
<a href="#">SOP 7.4.1</a>	<i>Supplier Evaluation</i>
<a href="#">SOP 7.4.2</a>	<i>Purchasing</i>
<a href="#">SOP 7.5.1</a>	<i>Job Planning and Control</i>
<a href="#">SOP 7.5.3</a>	<i>Production Identification and Traceability</i>
<a href="#">SOP 7.5.4</a>	<i>Control of Customer Supplied Property</i>
<a href="#">SOP 7.5.5</a>	<i>Preservation of Product</i>
<a href="#">SOP 7.6</a>	<i>Control of Monitoring and Measuring Equipment</i>
<a href="#">SOP 8.1</a>	<i>Statistical Techniques</i>
<a href="#">SOP 8.2.1</a>	<i>Customer Satisfaction</i>
<a href="#">SOP 8.2.2</a>	<i>Internal Audit</i>
<a href="#">SOP 8.2.3</a>	<i>Monitoring and Measurement of Processes</i>
<a href="#">SOP 8.2.4</a>	<i>Monitoring and Measurement of Product</i>
<a href="#">SOP 8.3</a>	<i>Control of Nonconforming Product</i>
<a href="#">SOP 8.3.1.1</a>	<i>Return Material Authorization (RMA)</i>
<a href="#">SOP 8.5.1</a>	<i>Continual Improvement</i>
<a href="#">SOP 8.5.2</a>	<i>Corrective / Preventive Action</i>



