CYBEROPTICS

Doc No: QM42_001
Rev H

CORPORATE QUALITY MANUAL

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Corporate Quality Manual

Preface

The following Corporate Quality Manual is written within the framework of the ISO 9001:2008 Quality System by the employees of CyberOptics. CyberOptics recognizes the importance of international standards, and designs and builds products in conformance with these standards.

CyberOptics continually works to improve the processes and procedures outlined in this manual.

We invite anyone to review this manual.

Subodh Kulkarni
President/CEO
CyberOptics Corporation

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Revision History and Approval

This Corporate Quality Manual has been reviewed and is approved for use. Approval signatures can be found in the ECO.

Rev	Date	Description
A	11/02	Release
B	1/03	Added procedure references in several sections
C	7/04	A paragraph was added to section 5.1 explaining how the integrity of the quality management system is to be maintained with respect to cyclical business conditions.
D	6/05	Added another statement to Quality Policy under section 5.3 and re-arrange the order.
E	7/05	Added sections for Corrective and Preventive Actions under section 8.5. Added reference documents QP85_003 and QP85_004. Changed the block of 'Product Realization' to 'Production' and added 'Product Realization' with product development. Corrected typo under section 4.2.3. Omit reference of QP83_00X and QW71_001 from section 8.3.1 and 8.3.2 respectively. Revised section 8.5.1 to reflect the ISO QMS section for continual improvement.
F	7/07	Updated section 5.6 to match the practice
G	11/09	Updated All to make it corporate level document and compliant to ISO 9001:2008.
H	09/15	Change President from Kitty Iverson to Subodh Kulkarni. Change Quality Policy in this manual to match that on the intranet. Add "Customer Requirements Document" to section 7.3.6. Changed "Director of Quality" to "Head of Quality". General update.

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1.0   Introduction

The objective of the quality management system is to provide CyberOptics with methods to effectively determine customer requirements, create solutions to meet those requirements, and manufacture goods conforming to those requirements.

The following sections (1-8) of this Corporate Quality Manual describe our organization's conformance to the requirements of the ISO 9001:2008 standard. Each element reflects our organization's vision of quality as seen through the requirements of the standard, the needs of our customers, and our internally-defined quality goals and objectives.

This Quality Manual is a controlled document, and is intended to be part of the total quality system documentation. It has been prepared, and is maintained by, corporate Quality Assurance personnel. All suggestions for revisions to this document should be forwarded to the Head of Quality. In addition to any revision requests, this manual is reviewed yearly by the Head of Quality. Changes in requirements or context must be agreed to and approved by Senior Management.

2.0   Purpose

The purpose of this manual is to describe CyberOptics' Quality System. This Corporate Quality Manual is applicable to all CyberOptics personnel.

3.0   Related Documents

This Corporate Quality Manual is supported by the procedures and other process control documents that define the Quality System in detail.

Specific documents related to each section can be found on-line in the CyberOptics Internal Web using the on-line index.

This document refers to terms and concepts found in ISO 9001:2008, Quality Management Systems—Requirements

4.0   Quality Management System

4.1   General

CyberOptics has established and maintains a Quality System to ensure consistent delivery of products that conform to specifications, and to encourage continual improvement of CyberOptics processes. The system conforms to the requirements of ISO 9001:2008.

This framework, while imposing a significant level of standardization, also allows for division and manufacturing site differences in addressing and complying with the requirements of this manual

Document Requirement: To provide a complete description of the system, each CyberOptics Division, and each manufacturing site, will develop and maintain documents detailing that site's specific deployment of the Management System. These shall include those Level 2 documents specifically required herein, and any and all
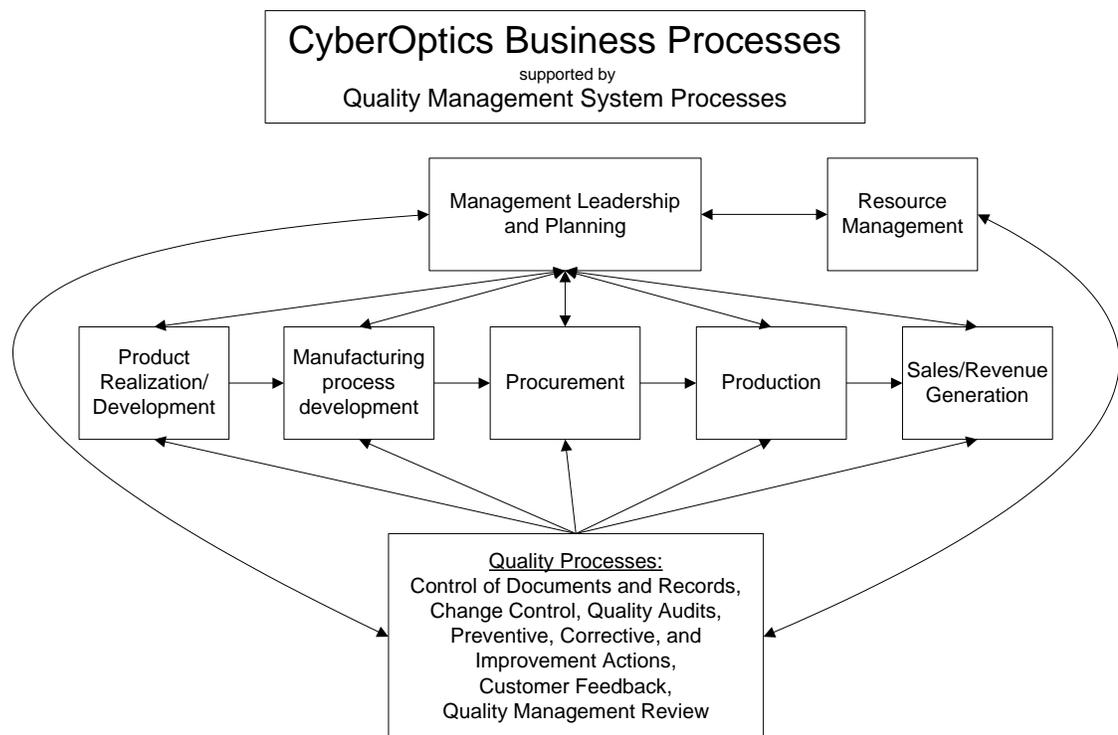
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documents that Division or site management determine are needed to provide additional direction and to clearly describe the system.

Furthermore, each Division and each manufacturing site will establish and maintain a Level 2 document that specifically lists all the Level 2 documents that are currently in use by that Division or at that site.

a. **Required processes:** The Quality system must add value to the organization. Suppliers to the system include all CyberOptics employees. System inputs include this manual, procedures, work instructions, and forms. The quality system processes include auditing; control of documents and records; data collection and analysis on customer feedback, product and process performance, and status of preventive and corrective actions; management review of the Quality System, and continual improvement of the quality system.   System outputs include essential record maintenance, resolution of audit non-conformances, improvement, corrective, and preventive action documentation, and completion of action items determined through management reviews. These outputs apply throughout the organization by maintaining customer and supplier records, and by creating and coordinating paths for all process improvements (see graphic below).

CyberOptics Business Processes
supported by
Quality Management System Processes

Management Leadership and Planning

Resource Management

Product Realization/ Development

Manufacturing process development

Procurement

Production

Sales/Revenue Generation

Quality Processes:
Control of Documents and Records,
Change Control, Quality Audits,
Preventive, Corrective, and
Improvement Actions,
Customer Feedback,
Quality Management Review

b. **Process Sequence and interaction:** Audit schedules are published at the beginning of each calendar year. Control of documents and records occurs continuously through the document control area. Data collection and analysis on customer feedback occurs

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through the CyberOptics Service organization, product and process performance is monitored through the Customer Service and Manufacturing Engineering functions, and status of preventive and corrective actions is monitored by the manager of the Quality system.   The Management Representative is responsible for semi-annual management review of the Quality System, and continual improvement of the quality system is the responsibility of CyberOptics Senior Management.

c. **Effective Operation and Control:** The management representative is responsible for determining the criteria and methods needed to ensure the effective operation and monitoring of Quality processes.

d. **Resources, monitoring, and implementation:** The Management Representative is responsible for assuring that adequate resources and information are available to support the operation and monitoring of the quality system. The Management Representative is also responsible for assuring that the monitoring, measurement, and analysis of the process occurs, and for implementing actions necessary to achieve planned results and continual improvement of quality system processes.

## 4.2   Documentation Requirements

4.2.1   General

The quality system is documented at multiple levels to ensure the planning and building of quality into CyberOptics' products, services and processes.   Inputs to the documentation system include not only Customer Requirements, but also statutory and regulatory requirements and the CyberOptics Quality Policy.

The hierarchy of documents that govern and implement the quality system is shown below in figure 4.2.1.

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CyberOptics Quality System Documentation
Figure 4.2.1
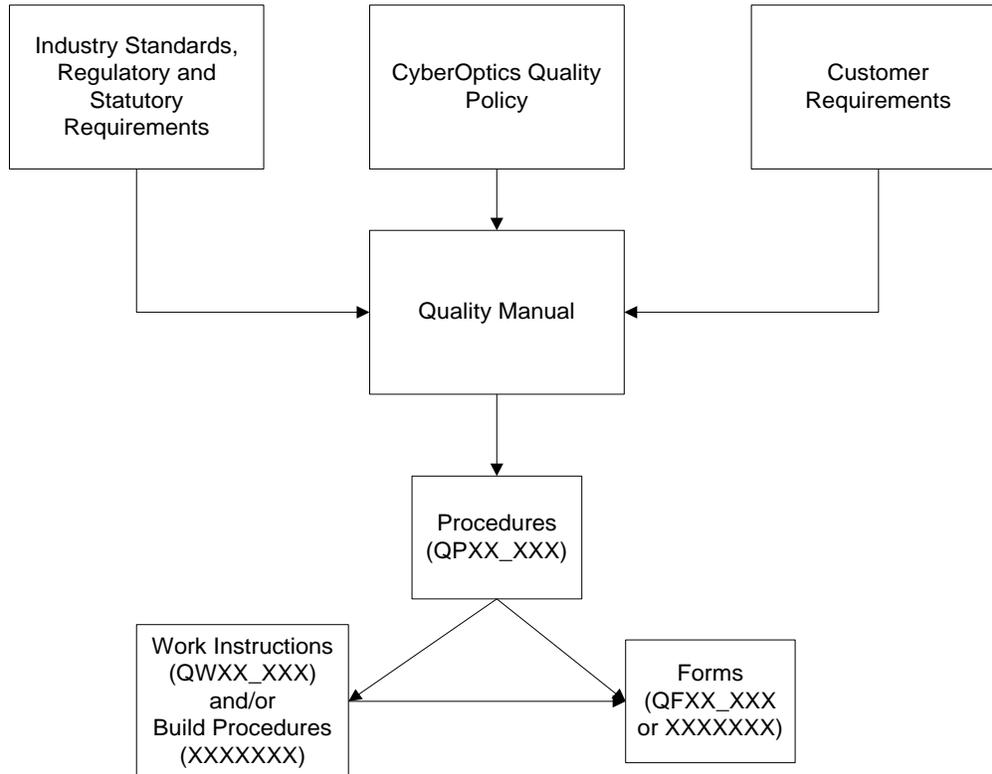
The **Corporate Quality Manual**, which is the top level document, describes the quality system.

Quality Procedures are level 2 documents that directly support the Quality Manual, providing expanded, site-specific detail relative to the requirements stated in the Manual.

Work Instructions and **Manufacturing Build Procedures** are level 3 documents. These are department- or product-specific, and provide the detail required for individuals to perform their work.

Quality documents can be found on-line on the CyberOptics Internal Web using the online index. **Manufacturing Build Procedures** can be found in the Matrix document control system.

Records are level 4 documents, and can be in the form of hard copy media, electronic media or other forms. Storage and maintenance of Quality Records are specified in documented procedures.

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4.2.2 Corporate Quality Manual

The Corporate Quality Manual describes the scope of the management system, describes where to find the documented procedures established for the quality management system, and describes the interaction between processes in the quality management system (see section 4.1).

4.2.3 Control of Documents

The Corporate Quality Manual is controlled and maintained at corporate headquarters; copies of the manual will be available at each site.   All site documents are controlled and maintained at each location.

The Management Representative is responsible for ensuring that the documentation system is properly maintained and revised according to the appropriate procedures.

All documents changes/ revisions follow the change control process administered by the documentation personnel.

Personnel who obtain documents from outside CyberOptics are responsible for identifying these documents and controlling their distribution.

A revision or change will be considered complete when obsolete material is properly eliminated, marked as obsolete, or moved to Inactive, Superseded, or Obsolete status in Matrix (Electronic Documentation Database System)

Each department is responsible for removing copies of obsolete documentation from their areas, or for applying suitable identification to obsolete documents if retained for any purpose.

Documents must be approved via the designated approval process prior to being authorized for use.

Documents of external origin are identified and their distribution controlled.

Document Requirement: Each manufacturing site will develop and maintain one or more Level 2 procedures that detail the system for ensuring control of all documents and data needed to fulfill the requirements of the Quality Management System.   In addition to internal documents, the procedures should address the control of documents of external origin such as customer drawings, industry standards, etc.

In addition, each Division and each manufacturing site will maintain a master list of controlled documents showing the current revision status, the document owner and the next scheduled document review date. This list may be electronic or paper-based.

4.2.4 Control of Records

The maintenance of quality records is addressed within individual procedures. Quality records are indexed by their identification numbers or titles unless stated in the procedure.

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Quality records are accessible to all CyberOptics employees unless marked as confidential. Confidential records are only accessible to authorized personnel.

Upon notification that a controlled document has been revised, it is the responsibility of any CyberOptics employee to remove outdated or obsolete documentation. When obsolete records are destroyed, those considered to be company confidential are shredded. Non-confidential records may be disposed of normally.

Quality records are maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.

All quality records are maintained in legible condition, and are stored and retained in such a way that they are readily retrievable, using facilities that provide a suitable environment to prevent damage, deterioration, or loss.

5.0   Management Responsibility

It is senior management's responsibility to provide a consistent and effective Quality policy to the organization, allowing and encouraging individual commitment to quality. Senior management is responsible for ensuring that this Quality policy is understood, implemented and maintained at all levels of the organization.

5.1   Management commitment

CyberOptics management is committed to the development and implementation of the Quality management system, as well as to continually improving its effectiveness. All managers are responsible for communicating the importance of meeting customer, statutory, and regulatory requirements on products and services offered. Further, management demonstrates its commitment through the establishment of the CyberOptics Quality Policy (section 5.3), by establishing and monitoring quality objectives through the management review process, and by ensuring the availability of resources, consistent with corporate viability, to the quality system.
Senior management is responsible for assuring the continued integrity of the Quality Management System in response to significant personnel changes that may occur due to cyclical business conditions. All managers are responsible for maintaining a list of projects on hold or terminated for review during corporate planning sessions.

Document Requirement: Corporate Quality Goals and Objectives for the organization as a whole will be documented in a record maintained by Corporate Quality personnel.

In accord with QMS ISO 9001:2008 Site Quality Management Review Team, each manufacturing site will establish and maintain one or more Level 2 procedures outlining the workings, membership and responsibilities of the Quality Management Review Team which include, but are not limited to;

a)   determining how best to deploy the CyberOptics Quality Management System at that site,

b)   establishing the site's annual Quality Goals and Objectives,

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c) communicating the Quality Policy and the importance of meeting customer, statutory and regulatory requirements to all site employees,

d) periodically reviewing the effectiveness of the site's deployment of and improvements to the QMS (the Level 2 document will detail what inputs need to be considered during this review),

e) determining and implementing any changes necessary to improve the effectiveness of quality system deployment,

f) reviewing, evaluating and ensuring the adequacy and availability of the resources necessary to 1) verify work affecting quality, and 2) conduct on-going audits of the quality system, and

g) maintaining a record of committee initiatives and decisions (meeting minutes).

5.2   Customer Focus

CyberOptics management is committed to ensuring customer requirements are determined and met, with the aim of enhancing customer satisfaction. See sections 7.2.1 and 8.2.1.

5.3   Quality Policy

CyberOptics strives to exceed our customer's expectations by:

- Understanding the environment of the customer.

- Early identification of defects and reduction of variation.

- Designing and delivering high quality products and services.

- Relentless pursuit of design for quality and control process improvement.

- Regular assessment of customer satisfaction.

5.4.   Quality Planning

Quality planning for new products and projects is defined and documented as part of the product development process.   During the product development process documents are generated in which the quality requirements are specified. The documents generated for each project are listed in the project folder directory.

Quality planning for existing products and projects is accomplished through continuous improvement efforts and documented in current manufacturing procedures. The change control process is integral to recording results of corrective, preventive, and improvement efforts.

During quality planning, consideration is given to the following activities in meeting the specified quality requirements:

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Identification of the manufacturing controls, processes, equipment, and fixtures are addressed during the product development process and documented in the project folder directory. The required resources are listed in the project plan and are updated during each development phase.

The compatibility of the design, the manufacturing process, installation, servicing and inspection and test procedures are also addressed and identified during the product development process and documented in the project folder directory.

Change control is maintained over all documentation pertaining to quality control, inspection and testing techniques.

The identification of Customer Requirements is addressed during the feasibility and planning phase of the product development process. This phase addresses any high-risk areas and develops a conceptual design and a specification for the project.

Verification requirements and standards of acceptability at appropriate stages are addressed during the product development process and documented in the project folder.

Document Requirement: Quality improvement plans, detailing targeted product and process quality improvements, will be documented and maintained by the Quality Management Review Team at each manufacturing site. Plans will comply with the requirements stated in QMS ISO 9001:2008

5.5 Responsibility, Authority, and Communication

5.5.1. Responsibility and Authority

The site management will ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2. Management Representative

The President and CEO delegates to the Head of Quality the corporate quality responsibility,

- to ensure and verify that the Quality Management System, as described herein, is established, implemented, maintained and improved;

- to periodically report to top management on the performance and effectiveness of the quality system, including an assessment of the need for improvement,

- to ensure the promotion of awareness of customer requirements throughout the organization, and

- Has the responsibility and authority to provide interpretation of the CyberOptics Corporate Quality Manual.

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- The Head of Quality, in turn, delegates to either a Quality Engineer or a Management Representative at each location, corresponding site responsibilities. The site-based quality representative is supported by the site management group for addressing and implementing quality improvements

5.5.3 Internal Communication

The Manager of each functional area has the authority and responsibility to:

- Initiate action to prevent the occurrence of any non-conformities relating to product, process, and quality system;

- Identify and record any problems relating to the product, process, and quality system;

- Initiate, recommend, or provide solutions through designated channels;

- Verify the implementation of solutions;

- Control further processing, delivery, or installation of non-conforming product until the deficient product or process condition has been corrected.

Key responsibilities of CyberOptics personnel are defined by their position profiles, which are found in the CyberOptics Internal Web. Individuals review their position profiles and performance with their supervisors at least annually. Managers are accountable for the performance of their direct reports. Senior management's accountability includes measures of customer satisfaction, growth, and profitability.

5.6. Management Review

On a regular basis, senior management evaluates the Quality System's suitability and effectiveness in satisfying the ISO 9001 standard and the CyberOptics Quality Policy and objectives contained in this manual.

Document Requirement: The output from each manufacturing site and Senior Management reviews of the Quality Management System will be documented in records maintained by the appropriate Management Representative.

6.0 Resources Management

6.1 Provision of Resources

Resources are allocated according to the priorities established in the annual strategic planning process. The adequacy of resources is reviewed and modified during department budget reviews and through the Quarterly Quality Management review.

6.2 Human Resources

6.2.1 General

CyberOptics Human Resource policies are designed to assure that all personnel performing work affecting product quality will have the appropriate education, training, skills, and experience.

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6.2.2   Competence, Awareness, and Training

Training is directed towards the development and improvement of work-related skills. The term "training" includes technical and academic education, skills, and experience required or recommended for performance of work to ensure that personnel are qualified to perform tasks. Managers are responsible for setting requirements and recommendations for training, education and experience for their employees as documented in their position profiles. The Human Resources Manager is responsible for identifying and documenting general training requirements relating to products, quality, confidentiality, benefits and employment law and to provide for this training. Individuals are responsible for obtaining the required training for their jobs.

Records of education, training, and experience for individual employees are maintained by the Human Resources Department.

> **Document Requirement:** Each manufacturing site will establish and maintain one or more Level 2 procedures that describe how the requirements of Section 6.2.2 are met within that organization. The procedures will comply with the requirements stated in QMS ISO 9001:2008.

6.3   Infrastructure

CyberOptics is committed to assuring that the buildings, work spaces, process equipment, and supporting services are adequate to achieve conformity to product requirements. Individual plant operations managers are responsible for maintaining local plant infrastructure.

6.4   Work Environment

Individual plant operations managers are responsible for maintaining a work environment needed to achieve conformity to product requirements.

> **Document Requirement:** Each manufacturing site will document and maintain the rating of any and all cleanroom-like enclosures. Particle count measurements will be made on a periodic basis, and the measurement data will be maintained as a quality record.

7.0   Product Realization

7.1   Planning of Product Realization

Product realization planning is detailed in the Product Development plan for each product manufactured at CyberOptics (see section 7.3). These plans: set up product requirements and quality objectives for each product; establish processes, documents, and resource requirements specific to the product; delineate verification, validation, monitoring, inspection, and test activities, and; specify records needed as evidence to assure conformance to customer requirements.

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Document Requirement: Each manufacturing site will maintain product drawings and Workmanship Standards (as defined in build procedure) to communicate acceptance criteria.

7.2   Customer-related processes

7.2.1   Determination of Requirements Related to the Product

In preparation for introducing a new product, each Division and manufacturing site will follow the procedures detailed in QMS ISO 9001:2008 New Product Introduction to determine;

- The requirements specified by the customer, including the requirements for delivery and post-delivery activities

- Requirements not stated by the customer, but necessary for specified or intended use, where known

- Statutory and regulatory requirements related to the product, and

- Any additional requirements determined by CyberOptics Corporation.

7.2.2   Review of Requirements Related to the Product

CyberOptics Corporation shall review product requirements. The reviews will be proportionate to the product or service provided.

Reviews shall be conducted prior to CyberOptics Corporation's commitment to supply a product or service to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders).

The review shall ensure that:

- Product requirements are defined

- Contract or order requirements differing from those previously expressed are resolved

- CyberOptics Corporation has the ability to meet the defined requirements

- Records of the results of reviews and actions arising from reviews shall be maintained.

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

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

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7.2.3   Customer Communication:

CyberOptics has established, documented procedures for reviewing and communicating product information, order handling, and customer feedback, including complaints, contracts, quotes and orders, and for the coordination of these activities. These contract review procedures apply to standard products, non-standard products, and service contracts.

7.3.   Design and Development

7.3.1   Design and Development Planning

Product design is planned, controlled, documented and updated per the product development process. Senior management identifies and selects product development projects. Resources are assigned to development projects by functional managers through negotiation with the Project Manager, under the direction of senior management.

7.3.2   Design and Development Input

Product functional and performance requirements including applicable statutory and regulatory requirements are identified, documented, and reviewed for adequacy by the Project Manager, Product Manager, and senior management. The design inputs are captured for the development team in the System Specification.

The Project Manager identifies and resolves incomplete, ambiguous, or conflicting requirements.

7.3.3   Design Output

Design output is documented and expressed in data that can be verified against design input requirements. Design output documents are reviewed before release.

Design output:

- Meets the design input requirements.

- Contains or references acceptance criteria.

- Provides appropriate information for purchasing, production, and service provisions,

- Identifies those characteristics of the design that are crucial to the safe and proper functioning of the product.

- Follows the ECO Release Procedure when the product is ready for release.

7.3.4   Project Review

Two types of review must occur in each project.

- Phase Reviews are held at the end of each phase to assure that the objectives of the phase are complete and planning is completed for the next phase.

- Technical Reviews are held as called out in the Project Plan.

Both types of review follow the Design Review Procedure.

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Customer Reviews may also be held as necessary as part of the project. These reviews also follow the Design Review Procedure.

7.3.5 Design Verification

At appropriate stages, the design is verified to ensure design output matches design input per product specification. Verification measures are recorded. Thoroughness of verification is reviewed in each phase review.

7.3.6 Design Validation

Designs are validated to the established criteria to ensure that product conforms to defined customer needs/requirements as defined in the Market Requirements Document, Customer Requirements Document, Product specification, or supporting project documentation. Completeness of validation is assessed during each phase review.

Document Requirement: Each CyberOptics manufacturing site will be responsible for its product design, maintain records of the results of the validation and any necessary actions.

7.3.7 Design Change

Changes, modifications, and revisions are controlled through the Engineering Change Order (ECO) system. This system identifies, documents, and establishes the appropriate review and approvals for the changes.

Document Control is responsible for administering the ECR/ECO process, including review, approval, implementation, distribution of ECOs, and maintaining the Matrix files.

Document Control is responsible for administration of the Deviation Authorization (DA) process, including review, approval, and distribution.

Document Requirement: Each manufacturing site will document one or more Level 2 procedures describing the process for making and controlling product design changes at that site. Furthermore, each manufacturing site will maintain records of all design changes to products manufactured at that site. These records will provide objective evidence that the design changes were reviewed and verified, as appropriate, and approved before being implemented.

7.4 Purchasing

7.4.1 Purchasing Process

Each site shall develop and maintain processes to ensure that purchased materials conform to specified requirements. The type and extent of the control applied shall depend upon the effect of the purchased product on subsequent product realization.

Purchasing is responsible for maintaining records of potential and currently-approved suppliers. In selecting and approving suppliers, consideration is taken into the type of product and the impact that the supplier will have on the quality of the final product.

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Document Requirement: Each location will develop and maintain one or more Level 2 procedures that detail;

a) the processes and criteria used to evaluate and select suppliers,

b) the processes and methods used to communicate requirements to suppliers,

c) the processes for verifying that supplied materials meet requirements,

d) the need for, and the level to which, supplier performance records are maintained and how these records are used in on-going evaluation of supplier performance

e) the systems for identifying, communicating and resolving problems, and

f) the conditions under which materials may be purchased from other than approved suppliers.

In addition, each manufacturing site will maintain a list of approved suppliers as a quality record.

7.4.2 Purchasing Data

Purchasing documents clearly describe the product, material, part, or service ordered and the terms and conditions between CyberOptics and their suppliers.

Purchasing data is reviewed for adequacy of the specified requirements prior to release of the purchase order.

7.4.3 Verification of Purchased Product

Incoming material/parts are verified according to the appropriate procedure. Verification of incoming material takes into consideration controls exercised by the subcontractor.

When specified by contract/written agreement, CyberOptics has the right to perform product verification at the source's facility.

When specified by contract/written agreement, our customer or their representative has the right to perform subcontracted product verification at the subcontractor's or our facility. If verification by the customer is performed, CyberOptics is still responsible for providing acceptable product and the customer is still afforded the right to subsequent rejection.

Document Requirement: Document Requirement: Each Division and each manufacturing site will develop and maintain one or more Level 2 procedures describing the specification for purchased product, sampling plan, and criteria for acceptance.   These will be developed in accord with QMS ISO 9001:2008 Customer Feedback and Complaints.

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7.5 Production and service provision

7.5.1 Control of Production and Service provision

Manufacturing Engineering is responsible for manufacturing process control and documentation. This documentation includes information that describes the characteristics of the product, and product-specific build procedures, operating procedures, and work instructions. Manufacturing Engineering is also responsible for:

- development and management of appropriate manufacturing and assembly processes

- maintenance and implementation of suitable equipment for manufacturing, monitoring, and measuring the product

- process control guidelines.

For software distribution, provisions are made in the duplication and distribution process to verify that the software being produced meets specifications.

Where the results of processes cannot be fully verified by subsequent inspection and testing, these processes are carried out by qualified operators and/or undergo continuous monitoring and control to ensure that specified requirements are met.

Identification of any qualification of manufacturing processes, equipment and personnel is addressed and identified during the product development process and is documented in the project folder directory.

Customer Service is responsible for providing warranty and post warranty service and support for CyberOptics products. Customer Service employs technicians who are trained as appropriate, to install, service and support its products. Product Support Plans and procedures are developed as appropriate to install, service and support CyberOptics products.

Document Requirement: In compliance with QMS ISO 9001:2008 Process Control, each value-adding manufacturing process (including, as appropriate, packaging) shall be documented with, and operate under the requirements and guidance of;

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

In addition, each manufacturing site shall develop and maintain one or more Level 2 documents to detail the system for identifying the inspection and test status of each and every material lot on the production floor.

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7.5.2   Validation of Production and Service provision.

Validation of new production processes and re-validation of significantly modified production processes will comply with the requirements detailed in QMS ISO9001:2008. Manufacturing Engineering is responsible for validating manufacturing processes, i.e. to demonstrate that processes have the ability to achieve planned results. Validation may include defining criteria for review and approval of processes, approval of equipment and qualification of personnel, use of specific methods and procedures, record requirements, and re-validation after process changes.

7.5.3   Product Identification and Traceability

Document Requirement: Each site will retain traveler documents and/or work orders as quality records.

Components, parts, and/or assemblies requiring identification and/or traceability are defined in manufacturing procedures and/or work instructions. The assembly procedures and test procedures include provisions to identify the inspection and test status. Work in process is identified, where appropriate, by product-specific build procedures.

7.5.4.   Control of Customer Supplied Product

Document Requirement: Each site will maintain, as quality records, any and all reports to customers that detail instances where customer property is lost, damaged or otherwise found to be unsuitable for use.

In general, customer-supplied product refers to products returned from customers for repairs or updates. Customer Service Administration is responsible for the disposition, routing, and return of customer-supplied product. The Customer Service Administration Supervisor establishes and maintains procedures related to the customer-supplied product system and its operation.

Customer-supplied product is identified by contract, lot number, order number, or other customer-provided product documentation, and is tracked internally by a return material authorization (RMA) number. Customer-supplied product is appropriately verified as to correctness, quantity, and suitability.

7.5.5   Preservation of product

To ensure and maintain process and product conformance, CyberOptics has established procedures that control product handling, storage, packaging, preservation and delivery. The Customer Service organization establishes, documents, and is responsible for the general requirements and procedures necessary for handling, storage, packaging, preservation, and delivery.

Preservation is in accordance to contractually agreed or specified company procedures, which consider the characteristics of the prevailing environment, transportation, and destination.

Preparation for delivery is in accordance with contract requirements, using materials and markings specified. Marking and labeling must be legible and remain intact until delivery.

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7.6   Control of Inspection, Measuring and Test Equipment

Document Requirement: In accord with QMS ISO 9001:2008 Control of Monitoring and Measuring Devices, each manufacturing site will establish and maintain one or more Level 2 documents that describe the processes for conducting, reporting and recording measurement system capability.

In addition, each manufacturing site will establish one or more Level 2 documents that describe how measurement and monitoring devices;

a) are calibrated and adjusted periodically (or prior to use), against measurement standards traceable to national or international standards (note: where no such standards exist, say for example, at Electrical Test, the basis used for calibration is recorded),

b) are identified to enable the calibration status to be determined,

c) are safeguarded from adjustment that would invalidate the calibration, and

d) are protected from damage and deterioration during handling, maintenance and storage.

Records of monitoring and measurement device calibration are maintained as quality records.

Each manufacturing site will establish and maintain one or more Level 2 documents that describe the processes to assess and address the validity of previous measurement results when the measurement equipment is subsequently found not to conform to requirements. These procedures will also detail how the responsible site personnel determine what action to take regarding the equipment and any product affected. Records of the instances and determinations will be maintained as quality records.

Inspection, measuring and test equipment that is necessary to ensure the performance, quality, and safety of our products is:

- Identified,
- Controlled,
- Maintained, and
- Calibrated as required on a periodic basis.

Manufacturing Engineering is responsible for establishing and maintaining procedures related to product-specific equipment that provides validation

Equipment requiring calibration is marked, tagged or labeled in a manner to indicate the equipment identification, current status and next certification or calibration date.

Equipment not requiring calibration is plainly marked or labeled to indicate calibration is not required.

Test software is checked at prescribed intervals to prove that it is capable of verifying the acceptability of product.

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Where appropriate, calibration of instrumentation is performed by a certified external test laboratory, which is accredited and traceable to the National Institute of Standards and Technology (NIST) or equivalent. Where not practicable, the means of calibration will be specified.

Equipment that has accuracy or functional problems is immediately removed from use. When equipment is found to be out of calibration, the manufacturing engineer is responsible to develop recovery plans proportionate to the situation.

8.0   Measurement, Analysis, and Improvement

8.1   General

Each CyberOptics manufacturing site shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- To demonstrate conformity of the product

- To ensure conformity of the quality management system

- To continually improve the effectiveness of the quality management system

This shall include determination of applicable methods, including statistical techniques, and the extent of their use. Engineering and Manufacturing Engineering are jointly responsible for development and implementation of inspection and test procedures

8.2   Monitoring and Measurement

8.2.1   Customer Satisfaction

Each manufacturing site will establish and report on a supporting metric that is based on their specific customer base

As one of the measurements of the performance of the quality management system, each site shall monitor information relating to customer satisfaction. Customer satisfaction can be obtained from sources such as customer report cards, customer incoming quality data, or data from returned material authorization (RMA).

8.2.2   Internal Quality Audits

Internal quality audits verify that the Quality System conforms to the ISO 9001 standard and to the CyberOptics Quality Management System, and identify improvement opportunities.

The Quality Department Supervisor structures and establishes the CyberOptics audit program.

The managers for the area under audit are responsible for timely corrective action for any deficiencies found. Follow-up audit activities verify and record the effectiveness of the corrective action taken.

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The Management Representative is responsible for reviewing the internal Quality audit program operation and effectiveness and making recommendations for improvement. Audit records are maintained.

8.2.3   Monitoring and Measurement Processes

Document Requirement: Each CyberOptics Division and/or each manufacturing site will monitor and measure the characteristics of products in accord with the documented traveler or checklist, or product control plan. Product release from that site will not proceed until all the listed requirements of the documents have been satisfactorily met, unless otherwise approved by a relevant authority, (for example, the Quality Manager at the site) and, where applicable, by the Customer.
Evidence of conformity with the acceptance criteria will be maintained. These quality records will indicate the authority authorizing the release of the products.

CyberOptics Corporation shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

These methods shall demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4   In-process and Final Inspection and Testing

In-process inspection and testing is conducted in accordance with the product-specific build procedure.

Final inspection and test is performed per the build procedure. No product is shipped until all the activities specified in the quality plan and/or documented procedures have been completed and the associated data and documentation is available and approved. Final inspection is performed by authorized personnel.

8.3.   Control of Nonconforming Product

Document Requirement: As detailed in QMS ISO 9001:2008 Identification and Control of Non-conforming Material, each manufacturing site will establish and maintain one or more Level 2 documents describing the systems in place to ensure that product that does not conform to stated requirements is identified and controlled to prevent its unintended use and delivery. The controls and related responsibilities and authorities for dealing with the non-conforming product will be defined in the Level 2 documents.
Non-conforming product is any material/part/assembly/unit which does not conform to specification
Non-conforming product is promptly identified, documented, and, if appropriate, segregated. Manufacturing Engineering and or Quality Engineering has the responsibility to review Material Action Records (MAR's), and disposition the referenced non-conforming parts

Manufacturing Engineering reviews suspected or identified non-conforming product in accordance with approved and documented procedures. Product identified as non-conforming may be:

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(a) Reworked to meet the specified requirement
(b) Accepted with or without repair, by concession
(c) Re-graded for alternative applications
(d) Rejected or scrapped

8.4   Analysis of Data

Document Requirement: Each manufacturing site will determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where improvement of the system can be made. This data analysis process is intended to provide data on, and, as such, should be focused on

a) customer satisfaction
b) conformance to product requirements
c) rankings of and trends in process and product characteristics, including opportunities for preventive action, and
d) suppliers

Engineering, Manufacturing Engineering and Software share the responsibility for identifying the need for the application of Statistical Techniques required for establishing, controlling and verifying process capability and product characteristics.

Where appropriate, documented procedures to implement and control the application of statistical techniques are established and maintained.

8.5   Improvement

8.5.1   Continual Improvement

Each site shall establish and implement the systems and processes necessary to ensure the continual improvement of the quality management system. At least in part, facilitation of continual improvement shall be accomplished through the use of the quality policy, quality objectives, audit results, analysis of quality data, corrective and preventive action, and management review.

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Document Requirement: As detailed in QMS ISO 9001:2008 Corrective and Preventative Action, each manufacturing site will establish and maintain one or more Level 2 documents describing the systems and procedures used to take corrective action and preventive action.

8.5.2 Corrective Action

Corrective action is directed towards eliminating the causes of actual non-conformities and preventing recurrence.

The procedure(s) for Corrective Action will define:

a) the methods used to collect and review complaints and reports of product non-conformity,

b) the requirements for, and methods used to determine the cause(s) of non-conformities (root cause analysis).

c) the requirements and responsibilities for evaluating when, and what, action is needed to ensure that the non-conformities do not recur,

d) the requirements for and methods used to assign responsibility for implementing the actions,

e) the requirements and responsibilities for verifying the implementation and the effectiveness of the corrective action, and

f)   the requirements and methods for recording the Corrective Action taken and the results of the verification.

8.5.3 Preventive Action

Preventive action is directed towards eliminating the causes of potential non-conformities. Preventive action involves using the appropriate information to detect, analyze, and eliminate potential causes of non-conformities and application of controls to ensure that the preventive action is effective.

The Preventive Action will define;

a)   the methods used for identifying potential Preventive Actions,

b)   the requirements and responsibilities for evaluating when, and what action should be taken,

c)   the requirements and responsibilities for verifying the implementation and the effectiveness of the Preventive Action, and

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     d)   the requirements and methods for recording the Preventive Action taken and the results of the verification.

9.0   Appendix A

TERMS AND DEFINITIONS

Level 2 Document	A level 2 document is a document that describes a major facet of the quality management system. In the documentation structure, level 2 documents are those that directly support the Quality Manual, providing expanded, site-specific detail relative to the requirements stated in the Manual. At CyberOptics they are listed as Quality Procedure (QPXX_XXX)
Quality	The total of the features and characteristics of a product or service that directly influences its ability to satisfy the customer's stated or implied requirements, needs and expectations.
Quality Assurance	The systematic, planned and disciplined actions necessary to ensure that the quality of a product or service will meet stated requirements (the systems and tools for defect prevention).
Quality Control	The operational techniques and activities used to measure and assess the quality or a product or service against stated requirements (the system and tools for defect detection).
Quality Management System	The organization structure, procedures, processes, responsibilities and resources for achieving quality.
Quality Plan	Documentation that describes how the processes of the quality management system are applied for a specific product, project or contract.
Quality Policy	The overall quality intentions and directions of a company as expressed by senior management.
Site Management	The personnel who direct and control CyberOptics at the site level.
Senior Management	The group of people who direct and control CyberOptics at the corporate level.

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<u>Continual Improvement</u>	A method and/or a system approach that improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analyses of data, and preventive actions and management review.
<u>Finished Good</u>	Manufactured and/or assembled product per customer requirements that is ready to be delivered to internal and/or external customers.
<u>Verification</u>	Confirmation and provision of objective evidence that specified requirements have been fulfilled. This may include alternate calculations, comparisons with similar proven designs, undertaking tests and demonstrations, reviewing design stage documents before release.
<u>Validation</u>	Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.
<u>Traveler/Work Order Document</u>	A document that contains the process steps, product recipes, and material used for each process step.
<u>Internal Audit</u>	Internal audit is the quality systems audit which is performed to strengthen the set quality systems.