

<div style="border: 1px solid black; padding: 5px; text-align: center;"> GOWANDA <i>The Only Name in Magnetics</i> </div>	Document: QM – ISO13485 Quality Manual	
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	Issued by ISO Management Representative Signature/Date: <i>Ken Hicks 2/20/06</i>	Approved by Chief Operating Officer Signature/Date: <i>Don McElheny 2/20/06</i>



Electronics

Quality Policy

To supply superior quality products and services to our customers that will meet or exceed their requirements, both real and perceived. Every employee must share in the responsibility of a quality product.

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Introduction

This manual is published, distributed and maintained by the Quality Assurance department. It is the purpose of this manual to outline the procedures and practices required to establish an effective Quality Management System in accordance with the ISO9000:2000 standard element requirements. This manual is distributed on a “controlled” and “uncontrolled” basis and only holders of controlled copies will receive newly revised copies. All controlled copies are assigned to senior management and supporting staff level personnel as required. The Quality Assurance Manager maintains a master list of all controlled and distributed copies.

Mission Statement

To provide our customers with market-leading product solutions to their specific design and application needs; and in doing so, establish ourselves as the market-leader in Quality, Delivery and Customer-Focused Service.

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Gowanda Electronics Environmental Policy

We take our responsibility as a company towards protecting, nurturing, and improving our natural environment very seriously. To this end, we shall:

- ❖ Work aggressively to reduce our waste stream by all means possible including finding recycling methods for all unused materials possible,
- ❖ Work aggressively to replace ozone depleting chemicals, other environmentally-harmful products, and potentially human-harmful chemicals from our processes and operations,
- ❖ Diligently monitor our processes and operations to verify that we are in full compliance with the spirit, intent, and letter of all laws dealing with the protection of the environment.

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Company History

Gowanda Electronics was incorporated in 1963 by four local businessmen who purchased an “Economy Coil” product line from another Western New York manufacturer. In 1965, an additional product line, the tunable coil form line, was purchased. These two lines were the foundation upon which the company was built.

The first RF Molded Chokes were produced in 1967 and were qualified for listing on the MIL-C-15305 QPL in 1968. Gowanda Electronics continues to be one of the country’s leading manufacturers of board-level passive magnetic components. Over the years, we have earned a reputation for being a customer-driven supplier of high-quality electronic components. This proven ability to serve our customers is the key reason that Gowanda Electronics today enjoys “Preferred Vendor and Partnership” status with so many of the world’s leading OEM companies.

Gowanda Electronics participates in ship-to-stock programs with many of our customers in order to support JIT manufacturing. In addition, Gowanda Electronics has EDI, bar code, and CAD/CAM capabilities. Our worldwide on-time delivery performance record, with a minus 3 days - plus zero day’s window, has been in the high ninety percentile for many years. Gowanda Electronics is committed to maintaining “World Class” status.

Gowanda Electronics has two facilities located in Gowanda, New York and one facility located in Tijuana Mexico.

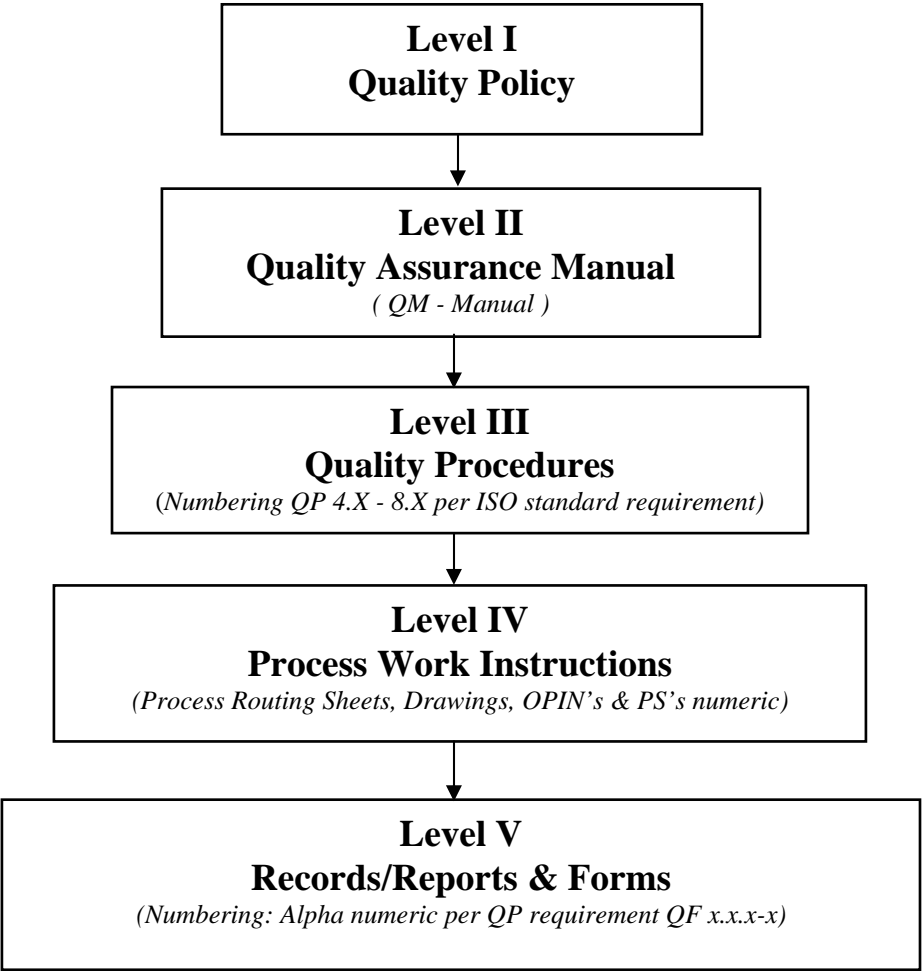
In August of 2001 the company moved its headquarters and manufacturing operations into a new 40,000 sq. foot state of the art facility located in Gowanda NY. This facility is highly automated and manufactures a wide variety of surface mount, through hole and toroidal inductors servicing both RF & Power markets, with the capacity of producing between 40 to 50 million units per year. In addition also located in Gowanda NY is our Advanced Manufacturing Technology Center. Built in 1989 and approximately 5,000 square feet in size the Technology Center is dedicated to the development and implementation of advanced manufacturing technologies in both equipment and processes.

The facility located in Tijuana Mexico is approximately 10,000 square feet in size and provides us with extended manufacturing capabilities specializing in custom specific designs.

All facilities are equipped with the latest in both manufacturing and test equipment with a strong emphasis on computer integration in all phases of the business.

Web site- www.gowanda.com

Quality Management System Documentation Structure



1. Scope

1.1 General

Gowanda Electronics is a *World Class Manufacturer of Magnetic Components* and has developed and implemented the Quality Management System (QMS) described in this manual to help our organization operate with increased effectiveness, consistency and customer satisfaction. Our QMS utilizes the process approach and quality management principles contained in the international standards ISO13485:2003, ISO 9000:2000, ISO 9001:2000 and ISO 9004:2000 to enhance our ability to continually improve as an organization.

1.2 Application

Our QMS complies with all applicable requirements contained in ISO13485:2003, covers the design and provisions of all company products, and encompasses all operations at our facility located at One Magnetics Parkway, Gowanda NY, USA 14070. The following table identifies ISO13485:2003 requirements not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our QMS:

ISO13485 Requirements EXCLUSION TABLE

Clause or Sub-clause	Exclusion	Justification
7.4.3	Verification of Purchased Product (at source)	Gowanda Electronics does not verify purchased product at source.
7.5.2	Validation of (special) Processes for Product and Service Provision.	Gowanda Electronics does not perform or outsource any process where the resulting output cannot be verified by subsequent monitoring or measurement.
7.5.1.2	Control of production and service provision – Specific Requirements – All section requirements	Gowanda Electronics products do not require sterilization, installation or servicing activities.
7.5.2.2	Particular requirements for sterile medical devices	Gowanda Electronics products do not require sterilization, installation or servicing activities.

2. Reference Documents

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

- ISO13485:2003 Quality management systems – Medical devices
- ISO 9000:2000, Quality management systems – Fundamentals and vocabulary
- ISO 9001:2000, Quality management systems – Requirements
- ISO 9004:2000, Quality management systems – Guidelines for performance improvements

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CFR21 Part 820

Appendix A, contains a master list of key QMS Documents, including the Quality Procedures (QP's) other internal documents referenced in this manual which define the key top level processes for implementing our quality policy.

The latest edition of each referenced document applies. [QP 4.2.3](#) contains procedures governing the control of these and other QMS documents. 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 given in ISO13485: 2003.

Acronyms, terms, vocabulary and definitions unique to our organization, customers, industry and region and referenced throughout our QMS are contained in Appendix B, Terms and Definitions.

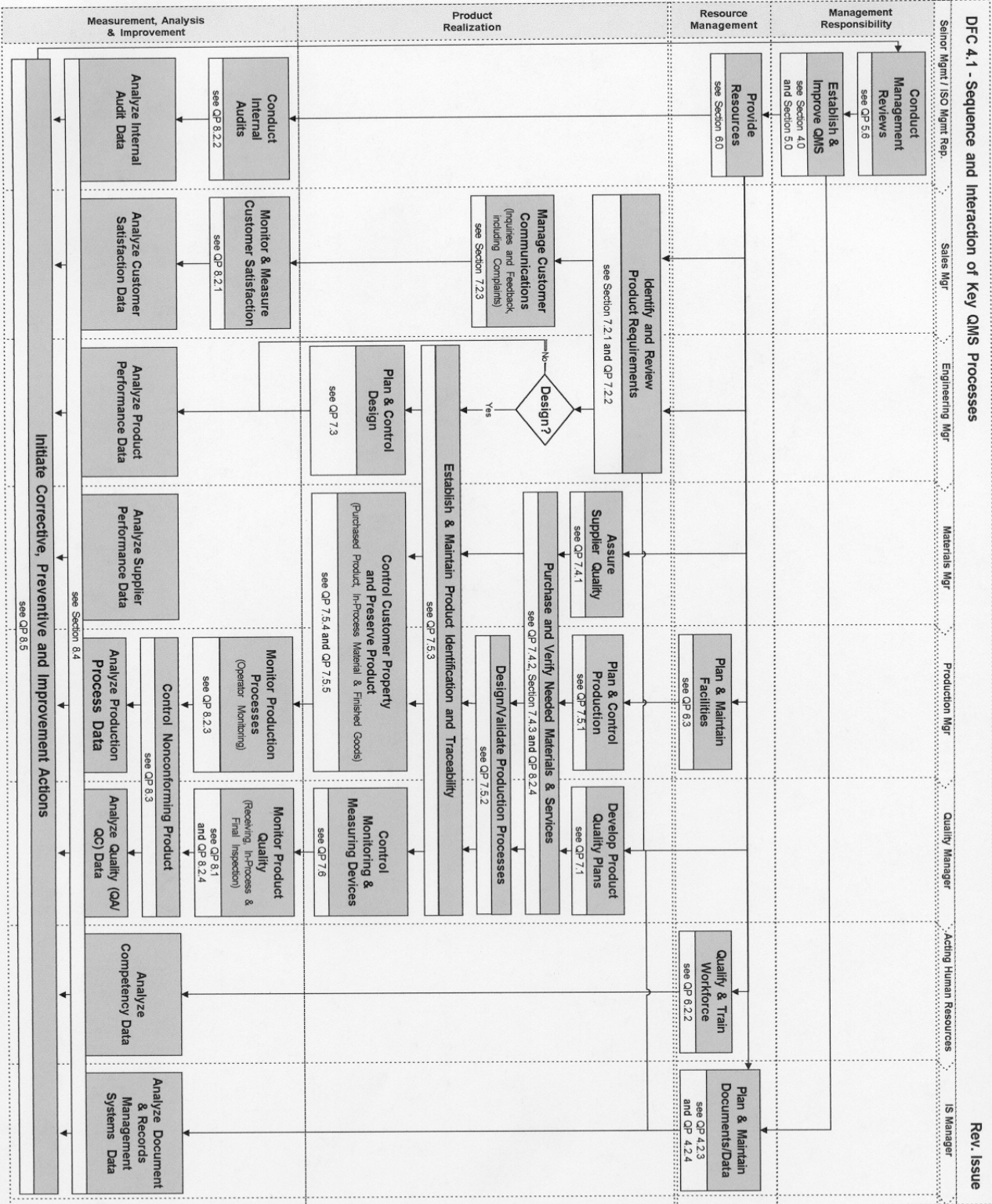
4. Quality Management System

4.1 General requirements

Our QMS is that part of our overall management system which implements our quality policy, establishes processes for providing products and services which meet or exceed customer requirements, and satisfies the ISO13484:2003 quality system requirements while maintaining the system effectiveness as defined in this standard.

The processes needed for our QMS include those required by ISO13485:2003 as well those required by our customers, and a number of product/service realization processes unique to our business and operations. Responsibilities for and the sequence and interaction of all of our QMS processes are detailed in our Quality Procedures (QP's) and associated documentation as referenced on page 4 of this document.

Responsibilities for and the overall sequence and interaction of the QMS processes described in this manual are depicted in [DFC \(Deployment Flow Chart\) 4](#), on the following page.



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4.2 Documentation requirements

4.2.1 General

Our QMS includes documented statements of our quality policy and objectives, documented procedures required by ISO13485:2003 and other documentation needed to ensure effective operation and process control.

The QMS documentation developed is appropriate to the size and type of our organization, the complexity and interaction of our processes, and the competence of our personnel. System documents and data may be in hard copy or electronic media. Documentation includes this quality manual, QPs, QFs, and other internal and external documents and data needed to manage, perform or verify work affecting process or product quality.

We use QPs to implement and manage many of our key system processes; we also may use flow charts if and where a visual depiction of the process flow best communicates the sequence of the interaction and responsibilities of all involved. We also develop and control Work Instructions, Process Routing Sheets, Job Descriptions, and other documents and data as appropriately needed to effectively manage our QMS. (See appendix A for a complete listing of key documents)

In addition we have established individual Device History Record files that contain product specifications, product routing flows, materials and any regulatory information that may be required for particular product builds.

4.2.2 Quality manual

This manual is that part of our QMS that defines the scope of our overall system interaction within the organization and documents the policies, procedures and processes that will be needed to implement our quality policy and achieve our quality objective goals.

4.2.3 Control of documents

The Quality Technician has the overall responsibility for ensuring that all QMS documents, those referenced in Appendix A are controlled. This includes the base *Quality Procedure (QP)* documents and any associated forms required to document quality. [QP 4.2.3](#) provides procedures necessary to:

- 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 are identified and their distribution controlled.

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- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Gowanda Electronics retains all Device History Records for a period of time equal to the life of the product, this includes all obsolete documents that have become inactive throughout the product's life history.

4.2.4 Control of records

The Quality Manager has overall responsibility for ensuring that all records required for the QMS are controlled and maintained to provide evidence of conformance to requirements. Records may be in the form of hard copy or electronic media. [OP 4.2.4](#) provides procedures necessary to control all records, including documentation that describes:

- a) results of processes performed, including identification of the individual performing the activity.
- b) product/process evaluation for acceptance criteria.
- c) procedures, drawings or instructions used to perform an activity, including revision or date of document.
- d) identification of material, parts, or equipment used in the making of the product.
- e) personnel, material or equipment qualifications.
- f) pertinent technical records from sub-contractors.

Gowanda Electronics retains all Device History Records for a period of time equal to the life of the product but not less than 2 years from the date of product release unless specified by the customer or applicable regulatory requirement.

5. Management Responsibility

5.1 Management commitment

Gowanda's senior management provides evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness through the following management responsibilities.

- a.) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.
- b.) establishing the Quality Policy ([section 5.3](#))
- c.) ensuring the quality objectives are established ([section 5.4](#))
- d.) conducting management reviews and ([section 5.6](#))
- e.) ensuring the availability of resources ([section 6.1](#))

5.2 Customer focus

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Gowanda Electronics senior management ensures that all customer requirements are determined and met as defined in sections 7.2 and 8.2 of this quality manual in addition to any statutory and regulatory requirements defined by the customer.

5.3 Quality policy

To supply superior quality products and services to our customers that will meet or exceed their requirements, both real and perceived. Every employee must share in the responsibility of a quality product.

Our quality policy statement indicates our commitment and focuses on what is important to us as an organization: *achieving customer satisfaction by consistently meeting or exceeding their requirements* and maintaining the effectiveness of the quality management system. Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing key corporate level performance measures and related improvement objectives (see [section 5.4.1](#)).

In order to meet this objective GEC will allocate resources to: Educate and train our work force to fully participate in the creation of quality products and services; Automate where practical, to support the goals of product consistency and reduced material handling; Address the full range of quality expectations and implications into the product design phase; Implement a broad range of techniques and tools to monitor and measure operational performance, along with product and process design.

Our quality policy statement is controlled by inclusion in this manual, and is reviewed annually during management review meetings (see [OP 5.6](#)) for continuing suitability.

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5.4 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 that satisfies international requirements for ISO registration. At the corporate level, responsible managers will monitor and measure performance in the areas outlined below and, where needed, establish measurable improvement objectives annually.

- Customer Satisfaction: The Sales Manager; see [QP 8.2.1](#).
- Supplier Performance: The Materials Manager; see [QP 7.4](#).
- Overall QMS Effectiveness: Quality Manager; see [QP 8.5](#).
- Overall Operational Efficiency: The Chief Financial Officer (CFO).
- Competency and Training Effectiveness: Quality Manager and the Production Manager; see [QP 6.2.2](#).
- Overall Product Performance : The Quality Manager with input from Engineering Manager; see [QP 7.3](#).
- Overall Effectiveness of GEC Production Operations: The Production Manager; see [QP 7.5.1](#), [QP 7.5.5](#), and [QP 6.3](#).
- Overall Product Quality: The Quality Manager; see [QP 8.2.4](#).

Annual corporate level improvement objectives will be documented, deployed and reviewed for achievement and continuing suitability during management reviews conducted by senior management; see [QP 5.6](#).

At the operational level, all officers, managers and supervisors will monitor and measure performance of processes within their area(s)of responsibility and, where appropriate, establish measurable improvement objectives annually. Annual improvement objectives will be documented and reviewed as necessary; see [QP 6.2.2](#).

5.4.2 Quality management system planning

The QMS planning process involves the establishment and communication of our quality policy and objectives through issuance of this manual and its associated procedures and the provision of resources needed for implementation; see [section 5.3](#), [section 5.4.1](#), and [section 6](#). Our management review process (see [QP 5.6](#)) and internal audit process (see [QP 8.2.2](#)) ensure the integrity of our quality system is maintained when significant changes are made.

As required the Quality Manager develops quality plans for specific products, projects or contracts whenever customer requirements exceed the capability or intent of the product/service; see [QP 7.1](#).

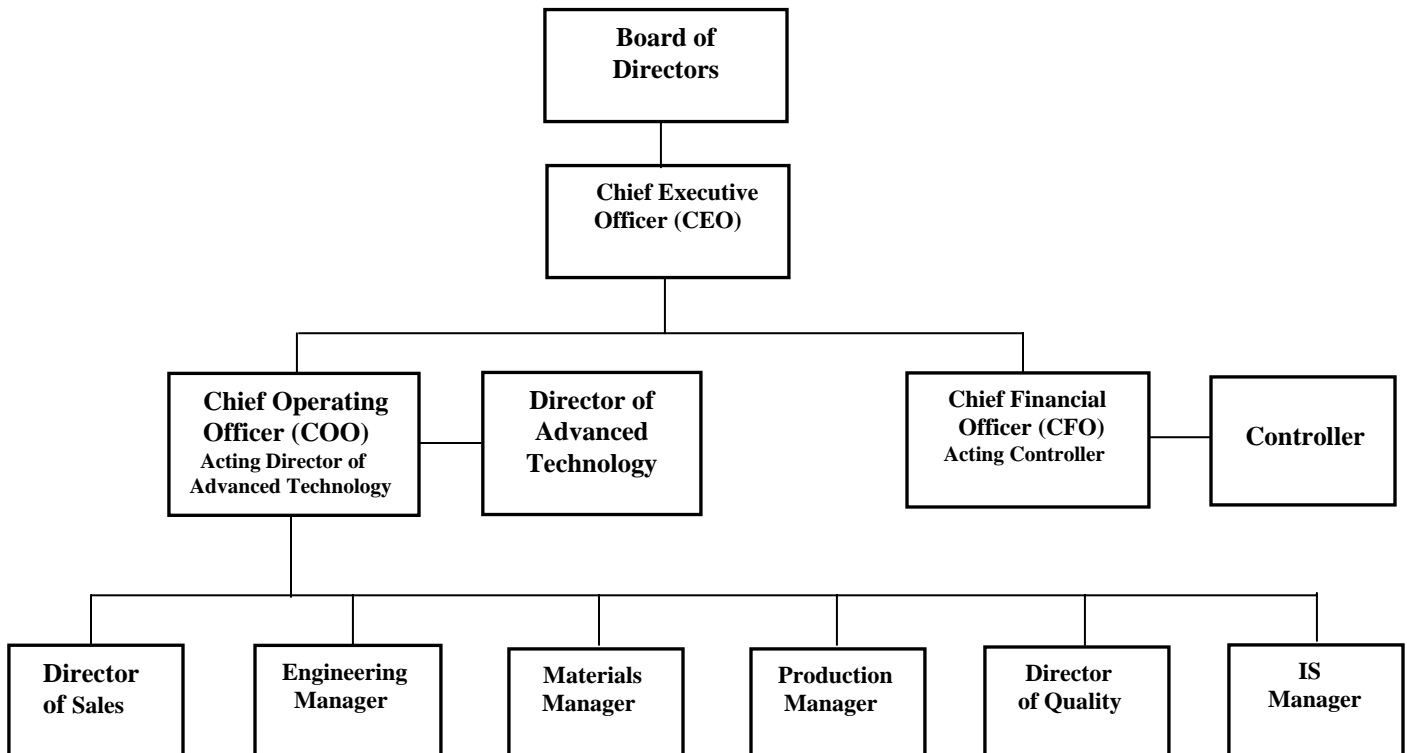
5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The Chief Executive Officer (CEO) sets direction and ensures the success of Gowanda Electronics. Other members of top management include: the Chief Operations Officer (COO), the Chief Financial Officer (CFO). The interrelationship of top management and other key personnel are depicted in our organization chart; see *Exhibit 5.5.1* following:

Gowanda Electronics Organizational Chart

Exhibit 5.5. 1
as of April 2003



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Overall QMS responsibility and authority is as follows:

Senior Management – Members of senior management are ultimately responsible for the quality of GEC products and services since they control the systems and processes by which work is accomplished. Senior Management is responsible for strategic planning, development and communication of our quality policy, QMS Planning, including the establishment and deployment of corporate level objectives, and the provision of resources needed to implement and improve the quality system.

Management – All officers, managers and floor supervisors are responsible for execution of the strategic plan and implementation of the policy, processes and systems described in this manual. All managers are responsible for planning and controlling quality system processes within their area(s) of responsibility, including the establishment and deployment of operational level objectives, and the provision of resources needed to implement and improve these processes. Managers also conduct employee performance reviews as needed.

Employees - All employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform. Employees also identify and report any known or potential problems and recommend related solutions through the internal audit and/or corrective/preventive action processes.

5.5.2 Management representative

The Quality Manager has been appointed as the ISO Management Representative for Gowanda Electronics with delegated responsibilities for ensuring that a quality system is established, implemented, and maintained in accordance with ISO 9001:2000 requirements. Additional responsibilities include reporting to Senior Management on performance of system activities, for promoting awareness of customer requirements throughout the organization, and for ensuring that the performance of the quality system is reviewed for effectiveness.

5.5.3 Internal communication

We communicate information regarding quality system processes and their effectiveness through documented training, the internal audit and corrective/preventive action processes, and regular formal and informal communications as follows:

- The Quality Manager may post information on bulletin boards throughout the facility to convey information regarding customer requirements, and the status and importance of quality activities. Note: internal audits (see [QP 8.2.2](#)) are also used to communicate this information to employees.
- The Materials Manager may post information on safety bulletin boards throughout the facility to convey information regarding the status of the Safety and Environmental Management Program, and related statutory/regulatory requirements. Note: safety inspections are also used to communicate this information to employees.

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- The Production Manager posts information on employee bulletin boards throughout the facility to convey information regarding employee benefits, programs, involvement opportunities, and applicable statutory/regulatory requirements.
- Senior Management personnel meet on a weekly basis to review current business activities and solutions as needed.

Note: Any postings may be performed by delegated employees as Senior Management desires.

All officers, managers and supervisors, are responsible for establishing internal communications as needed to convey to their staff and employee personnel the relevance and importance of their activities; typically this information is conveyed through interoffice memos, production team meetings, and or cross-functional improvement projects as required. (see [QP 6.2.2.](#))

5.6 Management review

5.6.1 General

Senior Management conducts management review meetings annually to ensure the continuing compliance, adequacy, and effectiveness of the QMS in accordance with provisions contained in [QP 5.6](#). The primary inputs reviewed include data that measures the conformance and performance of our QMS. Performance is primarily assured through the deployment of corporate/operational level objectives and demonstrated through a review of our demonstrated ability to achieve desired results. The primary output of management review meetings are actions taken to make necessary changes to our quality management system, including our quality policy (see [section 5.3](#)) and corporate level improvement objectives (see [section 5.4.1](#)), along with the provision of resources needed to implement these actions.

5.6.2 Review input

The management review meeting includes a review of current performance measures including the following, see [QP 5.6](#), and [section 5.4.1](#) of this quality manual

- a.) results of audits,
- b.) customer feedback,
- c.) process performance and product conformity,
- d.) status of preventive and corrective actions,
- e.) follow-up actions from previous management reviews,
- f.) changes that could affect the quality management system
- g.) recommendations for improvements,
- h.) new or revised regulatory requirements.

5.6.3 Review output

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At a minimum, the outputs from management review meetings shall include any decisions and actions related to, see [QP 5.6](#) and [section 5.4.1](#) of this quality manual

- a) improvements needed to maintain the effectiveness of the quality management system and its processes,
- b.) improvement of product related to customer requirements and,
- c.) resource needs.

6. Resource Management

6.1 Provision of resources

Appropriate resources, including trained employees, are identified and provided throughout the documented quality system. These include the resources needed to ensure implementation and improvement of the overall QMS and to maintain its overall effectiveness to meet customer and regulatory requirements as needed.

6.2 Human resources

6.2.1 General

We believe that our employees are our most valuable asset and we do our best to help them achieve their full potential through *continuos* education and training; see [QP 6.2.2](#).

6.2.2 *Competence, awareness and training.* The competency of people assigned responsibilities defined in the QMS is determined on the basis of education, training, skills, and experience. The Quality Manager and Production Manager have the overall responsibility for implementation of this requirement; see [QP 6.2.2](#).

6.2.2. a *Need Determination.* We determine competency needs, including employee training and awareness needs, through various methods. Senior management identifies emerging competency needs during weekly review and or annual planning meetings in accordance with [QP 6.2.2](#) as required.

6.2.2. b *Provision.* Training needs identified as a result of the need determination activities discussed above are passed on to the applicable departmental manager to determine further training needs. In addition any training required due to process changes would take place prior to the release of the new or changed *QP*'s and or other quality system documents. Training records are kept on both hard copy and electronic file by the document control authority.

6.2.2. c *Effectiveness.* We evaluate the effectiveness of all actions taken to meet competency needs. Training provided 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; see [QP 6.2.2](#).

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Actions taken to meet competency needs are reviewed during management review meetings per [QP 5.6](#).

6.2.2. d *Employee Contributions*. We ensure that our employees are aware of the relevance and importance of their activities and how they contribute to the achievement of our quality objectives. This is accomplished through team meetings, quality system training, and participation in the internal audit and continual improvement processes as required.

6.3 Infrastructure

The COO has overall responsibility for identifying, providing and maintaining the resources needed to achieve product conformance, including workspace and associated facilities, equipment, hardware and software, and supporting services. see [section 7.1](#), [section 7.5.1](#) and [QP 6.3](#). The Information Systems Manager has overall responsibility for establishing and maintaining our information management systems.

The equipment maintenance supervisor has the overall responsibility of maintaining the preventative maintenance activities as defined in [QP 6.3](#).

6.4 Work environment

We provide employee benefits, job and schedule flexibility, interesting work, and involvement of our employees in an empowered environment of *continual* improvement. We encourage total participation by involving employees in internal audit and *continual* improvement activities.

We monitor and improve workplace safety, health, and ergonomics including adherence to good manufacturing practices, safety team meetings, and training as required. A suitable working environment is maintained to ensure product quality. The Materials Manager has the overall responsibility for identifying, implementing and maintaining both safety and environmental management systems, to ensure statutory and regulatory requirements are achieved.

7. Product Realization

7.1 Planning of product realization

Our QMS identifies, plans for and documents our product and service realization processes to ensure consistency with all applicable requirements, including customer requirements, statutory/legal requirements, as well as GECs product/service performance objectives (see [section 5.4.1](#)). The outputs of product/service realization planning include the specific methods, facilities, equipment, people and materials/support services needed to achieve all desired results for a particular product, service, or contract. Product/service planning also includes the identification of verification and validation activities, the criteria for acceptability; and the records necessary to provide confidence of product conformance.

Gowanda Electronics has established a risk management system to be used on products that are identified as special products as determined applicable by the Sales and or Engineering

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departments. Products that require the need for the risk management process will be identified with an “SP” (Special Product) prefix in front of the part number.

Risk assessment is performed primarily by using a FMEA approach during the development of a product or process as defined in Gowanda *Quality Procedure* [QP 7.1](#)

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. These efforts are described below. The Sales Manager has overall responsibility for developing and implementing effective customer-related processes; also see [QP 7.2](#) and [QP 8.2.1](#).

7.2.1 Determination of requirements related to the product

Sales personnel generate quotes/bids and negotiate the 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 contracts documented and reviewed as required. Where no annual contract exists, an order constitutes a contract, and we ensure that the customer’s requirements are clearly identified.

Applicable customer requirements include product requirements specified by the customer, including the requirements for availability, delivery and support; product requirements not specified by the customer but necessary for intended or specified use; and obligations related to product, including regulatory and legal requirements; see [QP 7.2](#).

7.2.2 Review of requirements related to the product

Sales or Customer Service personnel review customer requirements identified during the determination process to ensure that they are clearly stated, understood, and recorded. This includes ensuring that product requirements are defined; that where the customer provides no documented statement of requirement the customer requirements are confirmed before acceptance; that contract or order requirements differing from those previously expressed are resolved; and that we have the ability to meet defined requirements; see [QP 7.2](#).

We ensure that these criteria are met prior to making a delivery commitment. Where product requirements are changed, we ensure relevant documents are amended and relevant personnel are made aware of the changed requirements; see [QP 7.2](#).

7.2.3 Customer communication

Product information is available through a number of different channels. First, Sales and Customer Service personnel provide product information directly to customers including verbal

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and printed information on our standard product offerings as well as customized information for unique customer applications. Secondly, Engineering personnel provide technical assistance and related information as needed. Thirdly, our Information Systems Manager along with the Sales Manager maintains a user friendly web site, www.gowanda.com which contains extensive product information, including specifications and technical information, product catalogs, new product information as well as an electronic customer feedback form.

Inquiries are handled by our Sales or Customer Service personnel depending on the nature of the inquiry or who made initial contact; see [QP 7.2](#).

We pay particular attention to customer feedback, including *customer complaints* and customer satisfaction. *Customer satisfaction* is evaluated on an on-going basis by customer contact personnel, i.e. Sales and Customer Service personnel; also see [QP 8.2.1](#).

Advisory notices will be issued as required in accordance with Gowanda Quality Procedure [QP 8.5.1](#).

7.3 Design and development.

Design and development processes are employed at GEC to transform customer requirements into specifications, products and processes. At GEC, the term's design and development are used synonymously and are referred to hereafter only as "design". Processes related to the provision of all products/services are discussed in [section 7.5.1](#); the process for designing products/services for which GEC has design responsibility is discussed in this section. All design activities are maintained in accordance with [QP 7.3](#) and [QP 4.2.4](#). The Engineering Manager has overall responsibility for managing the design engineering, technical and administrative support processes defined in [QP 7.3](#).

Design transfer activities will be performed as required in accordance with Gowanda Quality Procedure [QP 7.3](#)

7.3.1 Design planning

The Engineering Manager assigns a qualified Engineer to serve as the design project leader for each new design project. The design project leader establishes a design plan that at a minimum, identifies design stages, predetermines design reviews, and schedules verification & validation activities. Design plans are retained in a Design Folder established and maintained for each design project by the Design Project Leader in the Engineering department.

7.3.2 Design inputs

The Design Project Leader defines design input requirements including, the functional and performance requirements as derived from customer input, legal and regulatory requirements which

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apply, useful information or experience from previous similar design efforts, and other necessary requirements. Before finalizing documentation of required inputs, the Design Project Leader resolves any incomplete, ambiguous, or conflicting requirements and reviews any outputs generated by the risk management process; see [QP 7.2](#) and [QP 7.3](#).

7.3.3 Design outputs

The Design Project Leader ensures that the design output will comply with the design input requirements and reviews information needed for production and service provisions; (see [section 7.5](#)) ensures references for acceptance criteria are in place, indicates design characteristics that are critical to the safe and functional operation of the product, and approves before final product release; see [QP 7.3](#). Records for design and development inputs will be maintained in accordance with *Quality Procedure* [QP 4.2.4](#).

7.3.4 Design review

During the evolution of each product design or process development, the Design Project Leader conducts design reviews as planned; see [QP 7.3](#). All functions concerned with the stage being reviewed are represented at the review. Design reviews are intended to assure that all requirements are being fulfilled; the Design Project Leader utilizes input from those involved in the review to propose a remedy and action plan for each identified problem. Records for the results of reviews and any necessary actions will be maintained in accordance with [QP 4.2.4](#).

7.3.5 Design verification

The Design Project Leader ensures design verification activities are carried out as planned; see [QP 7.3](#). 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 project leader ensures design validation is carried out as planned; see [QP 7.3](#). Design validation is performed to ensure the product or service resulting from design efforts performs as intended for all specified or known applications. Note any clinical evaluations for a medical device will be performed by the customer and or end user. Gowanda does not supply medical devices in its product offerings.

7.3.7 Control of design changes

The design project leader ensures all design changes are identified, documented, reviewed, approved, and communicated to all affected organizations and functions; see [QP 7.3](#). Control includes the assessment of the impact of changes upon component parts and completed products

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including those that have already been delivered.

7.4 Purchasing

We work in partnership with our suppliers to ensure that purchased products and services meet all applicable requirements.

7.4.1 Purchasing process

The Materials Manager along with the Chief Engineer defines and documents the supplier approval process, including criteria for selection, the extent of control to be exercised and periodic evaluation; see [QP 7.4.1](#). Suppliers are evaluated and selected based on their ability to supply products or services in accordance with our requirements. The results of evaluations and follow/up actions are recorded; additionally, we electronically maintain a master list of approved suppliers via the system network.

7.4.2 Purchasing information

Purchasing documents contain the appropriate data to clearly and fully describe requirements for purchased materials and services; including, where appropriate, requirements for approval or qualification of product, procedures, processes, equipment, and personnel. The Materials Manager ensures that all purchasing documents are reviewed for completeness and adequacy prior to issuance or placement of an order; see [QP 7.4](#).

7.4.3 Verification of purchased product

The Quality Manager ensures that incoming product is approved prior to release; see [QP 8.2.4](#). In some cases, criteria for approval of incoming product will be specified in a product quality plan (see [QP 7.1](#)) and may include data submitted by the supplier, including statistical data, certificates of conformance, etc. The Quality Manager, plans and implements appropriate statistical techniques to verify purchased product; see [QP 8.1](#). All requirements for approval of purchased product and/or supplier procedures, processes, will be specified in applicable purchasing documents; see [QP 7.4](#).

Neither we nor our customers currently perform verification activities at our suppliers' premises. Should we or our customers choose to do so in the future, the Quality Manager along with Materials Manager will document the intended verification arrangements and method of product release.

7.5 Production and service provision

7.5.1 Control of production and service provision

We utilize a process-focused approach to control operations and support services related to the

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production and service provision. Our initial focus is to assure the quality of process inputs - that is, employees, material, facilities and equipment, and methods. Employees must be equipped to perform the process properly through appropriate education, training, and certification. Material must meet specified requirements and be properly identified, stored, and issued. Equipment and facilities must be adequate, accurate, available and properly utilized. Work instructions and other important data must be current and correct. Methods must be appropriate and capable of accomplishing the desired results.

The Production Manager has overall responsibility for managing our production processes. The COO periodically reviews operational data as well as progress towards achievement of corporate level performance objectives (see [section 5.4.1](#)) and provides related recommendations for review by senior management; see [QP 5.6](#).

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

a) *Information.* Information inputs to the process include both product characteristics and appropriate work instructions containing specific work methods and/or other pertinent information. The Production Manager, through *Production Control* and *Departmental Floor Supervisors* ensures that all appropriate information including final product 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, process routings and related cover sheets and/or through job specific information included in individual job packs.

b) *Work Instructions.* Work instructions are provided in various formats such as process routing and drawing cover sheets, operating instructions (OPIN's) and process specifications (PS's) which are all dependant on the product type and or process being used. Other technical information may be included in the form of work instructions posted in areas where they are needed.

c) *Equipment.* The COO ensures the suitability and availability of all equipment and facilities used for production and service operations; see [QP 6.3](#).

d) *Monitoring and Measurement Devices.* The Quality Manager ensures that monitoring and measurement devices capable of meeting our measurement requirements are available for use during production and service provision; see [QP 7.6](#).

e) *Monitoring Activities.* The Production 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; see [QP 7.5.1](#) and [section 8.2.3](#). The Quality Manager with input from the Engineering Manager, are responsible for planning and implementing in-process inspections needed to ensure process control and product quality; see [QP 8.2.4](#).

f) *Release, Delivery, and Post-Delivery Processes.* Release of product is dependent on its

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compliance with all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order. The Production Manager, Quality Manager and the Materials Manager share in the responsibility to ensure that records of product approval are maintained and clearly indicate the authorizing employee; see [QP 7.5.3](#). We do not currently perform post-delivery activities; see [section 7.5.5](#).

g) Packaging and labeling instructions are defined on the applicable product process routing flow.

7.5.1.2 through 7.5.1.3 are not applicable to Gowanda products, these activities will be completed by the customer or end user.

7.5.2. Validation of processes for production and service provision

We define processes in which the 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. GECs product / service provision processes and related support services do not currently include any special processes.

However, if/when applicable, requirements for special process validation, including qualification of the process, equipment and personnel the Quality Manager will develop the appropriate quality plan as required; see [QP 7.1](#).

Any software that is required for production activities will be validated and controlled by the IS department as defined in Quality Procedure [QP 6.3](#).

7.5.3 Identification and traceability

The identification and status of product is established and maintained throughout all product and service provision processes. Traceability records are established and maintained as required.

The Materials Manager has overall responsibility for establishing and maintaining product identification from raw material receipts through all stages of production and delivery of finished goods. The Engineering Manager has the responsibility for product identification through all stages of product design; see [QP 7.5.3](#).

We establish and maintain product monitoring and measurement status through the use of both physical identification tags/labels and electronic records via the system network. Additionally, physical location in designated hold or production areas is an indicator of product status. The Materials Manager along with the 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 [QP 7.5.3](#), [QP 8.2.4](#), and [QP 8.3](#).

Where contractually required, the Quality Manager establishes and maintains appropriate traceability records in accordance with customer requirements; see [QP 7.1](#). Where products are

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made in lots or batches we identify and record a unique lot or batch number and related information on the process sheet; see [QP 7.5.1](#) and [QP 7.5.3](#).

7.5.4 Customer property

We identify, verify, and maintain customer property for use or incorporation into the product as outlined in Quality Procedure [QP 7.5.4 Customer Property](#). The Engineering Manager and Quality Manager have primary responsibility for implementing and maintaining the requirements of customer supplied materials/property with assistance from the Materials Manager as required. The Quality Manager ensures that lost, damaged, or unsuitable customer property is recorded on a corrective/preventive action request and immediately reported to the customer; see [QP 8.3](#). Customer property may include intellectual property or confidential health information.

7.5.5 Preservation of product

The Materials Manager, Production Manager and the Quality Manager share in the responsibility for establishing and implementing a product handling system that ensures product conformity is preserved during internal processing and delivery to the intended destination. This system includes the handling, storage, packaging, delivery, and protection of final product as well as the in-process raw materials of the final product. 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 adequately packed to prevent deterioration or damage during storage and delivery. For detailed responsibilities and additional information see [QP 7.5.5](#).

7.6 Control of monitoring and measuring devices

The Engineering Manager has the overall responsibility for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measurement devices used to provide evidence of product conformance to established requirements. Related procedures are detailed in [QP 7.6](#) and summarized below:

We determine the measurements to be made and the accuracy required to assure conformity of our product to specified requirements. We identify and select monitoring and measurement devices and verify their capability of meeting such requirements prior to use; see [QP 7.1](#).

Monitoring and measuring devices are used and controlled in a manner that ensures continuing suitability; this includes ensuring that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out. We also define the processes employed for the on-going calibration, control and maintenance of monitoring and measuring devices including their identification, location, frequency/method of checks, uses/acceptance criteria and the action to be taken when results are unsatisfactory.

7.6. a All monitoring and measuring devices that can affect product quality are identified and

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calibrated at prescribed intervals against certified equipment having a known valid relationship to internationally or nationally known standards. Where no such standards exist, the basis used for calibration is documented.

7.6. b When monitoring and measuring devices are found to be out of calibration (or when calibration status is not known), they are adjusted or re-adjusted as necessary and the validity of previous measuring results is documented; actions taken are documented, including appropriate corrective/preventive actions to prevent recurrence; see [QP 8.5](#).

7.6. c Appropriate calibration records are maintained to document results of calibration activities (see [QP 4.2.4](#)) and suitable indicators are used to show current calibration status.

7.6. d All monitoring and measuring devices are safeguarded from adjustment that would invalidate the calibration.

7.6. e All monitoring and measuring devices are handled, maintained and stored in a manner that ensures accuracy and fitness for use is maintained.

8. Measurement, Analysis and Improvement

8.1 General

We have defined, planned, and implemented the monitoring, measurement; analysis and improvement processes needed to demonstrate conformity of the product, to ensure conformity of the quality management system and to maintain its overall effectiveness. *See Quality Procedure for [QP 8.1](#) details* procedures governing the selection and use of statistical techniques in measurement, analysis, and improvement.

8.2 Monitoring and measurement

8.2.1 Feedback

Gowanda Electronics measures the performance of the QMS and monitors information relating to meeting customer requirements as defined in *Quality Procedure [QP 8.5](#)*.

8.2.2 Internal audit

Internal audit results are critical inputs to aid in assessing the effectiveness of our Quality System and in identifying opportunities for improvement. Their purpose is to: determine whether the QMS conforms to ISO13485:2003 and ISO 9001:2000 requirements; to determine whether the process has been effectively implemented and maintained; and to identify opportunities for improvement.

The Quality System process, function, or quality system element under review is effective if it is

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achieving the desired results or established objectives; see [section 5.4.1](#). In addition, employee ideas for improving process effectiveness or efficiency are sought during internal audits. Internal audit results are also used to determine the scope, nature and frequency of future internal audits. Accordingly, the internal audit process is a key method for communicating with and involving employees in continuous improvement. Responsible managers may also request that the audit be used to gather “value added” data serving as input to aid in monitoring, measurement, and improvement of QMS processes and systems; see [sections 8.2.3](#) and [8.5](#).

The Quality Manager has overall responsibility for managing the internal audit process in accordance with [QP 8.2.2](#) as summarized below:

Internal audits are conducted in accordance with a published schedule that identifies the audit scope and frequency. The schedule is developed on the basis of status and importance of the activity to be audited and previous audit results. Each of our key QMS processes is reviewed at least once annually.

Audits are carried out by trained personnel who do not have direct responsibility for the activity being audited. Audit checklists are prepared and used to aid in ensuring audit consistency and comprehensiveness. 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 plans to eliminate detected non-conformances and their causes and also initiate other appropriate improvement actions that may have been identified during the audit. Follow-ups are conducted to verify timely and effective implementation of the proposed action.

The Quality Manager maintains all internal audit records, including audit results and related follow-ups actions. Audits are periodically reviewed as well as corporate level objectives aimed at improving the overall QMS. (see [section 5.4.1](#)); Audit results are also reviewed during annual management review meetings; see [QP 5.6](#).

8.2.3 Monitoring and measurement of processes

We apply suitable methods for monitoring and measuring all QMS processes. Quality system processes depicted in [DFC 4.1](#) are documented, measured, controlled and evaluated to ensure they are effective and to identify opportunities for improvement. The manager with overall responsibility for the process develops key process measures used to verify process effectiveness and/or efficiency:

A process is effective if the desired results are achieved. Effectiveness can be measured in terms of product quality, process accuracy, delivery/schedule performance, cost/budget performance, employee/function performance against established objectives, and/or customer satisfaction.

A process is efficient when resource utilization is optimal. Efficiency can be measured in terms of total resource utilization, productivity indicators, and or waste/rework costs or hours.

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As previously discussed, we primarily utilize the internal audit process (see [OP 8.2.2](#)) to assess QMS process effectiveness.

Also as previously stated, production personnel monitor and report on the quality of their own work; see [OP 7.5.1](#).

Further, the Quality Manager is responsible for planning and implementing formal in-process inspection activities, including those using statistical techniques to ensure process control at the product, project, or contract level as required; see [OP 7.1](#), [OP 8.1](#) and [OP 8.2.4](#).

8.2.4 Monitoring and measurement of product

The Quality Manager has overall responsibility for planning and implementing effective product monitoring and measurement systems including receiving, in-process and final inspection and test activities and the use of appropriate statistical techniques needed to ensure process control at the product, project, or contract level; see [OP 7.1](#), [OP 8.1](#) and [OP 8.2.4](#).

Receiving inspection is performed to ensure quality of purchased product; see [OP 8.2.4](#).

Process monitoring is performed by production/service personnel throughout all product/service realization processes; see [OP 7.5.1](#). Formal in-process inspections are performed by floor line operators and or Quality Control personnel as required in accordance with the quality plan and procedures in [OP 8.2.4](#). All finished product and completed service is verified by final inspections/tests specified in the quality plan and procedures in [OP 8.2.4](#).

Products are not released for further processing or delivery until we have objective evidence that all requirements have been met.

8.2.4.1a Evidence of Conformity. Test and inspection records are maintained for a minimum of three years. These records include final inspection authority and identify and confirm that all critical parameters are in accordance with established requirements and specifications. Additionally, product samples are stored for a minimum of 3 years.

8.2.4.1b Product Release and Delivery. Product is not normally released or delivered until all planned inspections and tests have been completed and final lot acceptance documented. In rare cases (due to customer demands and or emergencies) unverified product may be released or delivered under controlled conditions of positive recall documented and authorized by the Quality Manager. No such release would be granted unless otherwise authorized by the customer. Nonconforming or suspect product is identified and controlled to prevent its inadvertent use; see [OP 8.3](#).

8.2.4.2 When applicable Gowanda Electronics maintains the identity of any personnel assigned to inspecting or testing implantable devices. Evidence will be maintained in the device history record and stored in accordance with *Quality Procedure* [OP 4.2.4](#).

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8.3 Control of nonconforming product

We ensure that nonconforming purchased product, in-process materials and finished product is identified and controlled to prevent inadvertent use. The Quality Manager has the overall responsibility for implementing an effective process for identifying, documenting, segregating, evaluating, and disposing of nonconforming product in accordance with [QP 8.3](#) as summarized below:

Identification. Identification of nonconforming product originates from inspection, internal testing, or customer complaint. Employees clearly mark or otherwise identify nonconforming product.

Where required by contract, responsible Sales or Customer Service personnel will notify the customer.

Documentation. The Quality Manager and or authorized Quality Control personnel, may enter the nonconformance into the corrective action system if required (see [QP 8.5](#)) identifying the nonconforming product and lot number if applicable, description of nonconformance, and location where the nonconforming product is being held pending further review or disposition.

Segregation. Nonconforming product is segregated pending evaluation and disposition.

Evaluation. The Quality Manager and or authorized Quality Control personnel will perform the initial evaluation of nonconforming product in accordance with approved test and inspection procedures. Where needed, Engineering, Production and other technical personnel may become involved in the evaluation and recommendation for disposition.

Disposition. The results of the evaluation and inspections will be documented. Dispositions resulting from the evaluation of nonconforming product may include:

- rework to meet specified requirements
- regrade for an alternative application
- use as is (under customer concession or other required approval authority)
- obtain (from relevant authority) a waiver of or deviation from requirements
- return to supplier
- scrap or other disposal (in accordance with applicable environmental controls)

8.3. a Correction and Re-verification. Reworked nonconforming product is re-verified after correction to demonstrate conformity to original requirements.

8.3. b Product Recall. In the event nonconforming product is detected after delivery or use has started, the Quality Manager and or Sales personnel will notify the customer and initiate action appropriate to the effects, or potential effects, of the nonconformity. Where appropriate, product recall will be initiated based on trace and recall data and records; see [QP 7.5.3](#).

8.3. c Nonconformance Reporting. Records of the nature of nonconformities and any

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subsequent actions taken, including concessions obtained, will be maintained in accordance with *QP 8.3*, applicable inspection and test procedures, and [QP 4.2.4](#).

8.3. *d* When applicable, acceptance of nonconforming material is accepted by concession only if regulatory requirements are met. Records will be maintained of personnel authorizing the concession in *Quality Procedure QP 4.2.4*.

8.3. *e* When applicable, product rework will be documented and maintained as identified in *Quality Procedure QP 8.3*.

8.4 Analysis of data

Senior management and staff along with floor supervisors collect and analyze appropriate data using statistical techniques (see [QP 8.1](#)) to determine the suitability and effectiveness of elements of the QMS applicable to their area(s) of responsibility and to identify opportunities for improvement. At a minimum, data is analyzed to assess achievement of the corporate level quality objectives such as those related to: Customer feedback, Supplier Performance, Internal Audit results, Overall QMS Effectiveness, Competency and Training Effectiveness, and Product/Service Performance; see [section 5.4.1](#).

Results of data analysis together with related recommendations are presented to senior management for review and action during management reviews; see [QP 5.6](#).

8.5 Improvement

8.5.1 General

At Gowanda Electronics, the continuous improvement process begins with the establishment of our quality policy (see [section 5.3](#)) and objectives for improvement based on key measures established by senior management (see [section 5.4.1](#)). Customer feedback, internal audit, process and product performance data is then collected, analyzed and monitored to assess progress against established objectives; see [section 8](#). Corrective actions are initiated when desired results are not achieved and preventive actions are initiated to prevent the repeat occurrence of problems or to implement other improvement actions.

The effectiveness of corrective and preventive actions taken as well as the overall progress towards achieving corporate level improvement objectives is assessed through our management review process. At GEC, our “baseline” performance begins with meeting customer and ISO13485 quality system requirements. All inputs to the management review process are used to establish new/changed improvement objectives and to initiate additional improvement actions; see [QP 5.6](#). When applicable advisory notices will be issued in accordance with *Quality Procedure QP 8.5*.

The Quality Manager has overall responsibility for establishing and implementing an effective corrective and preventive action system in accordance with [QP 8.5](#) as summarized in the

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following sections.

8.5.2 Corrective action

Evidence of nonconforming product, customer dissatisfaction, and ineffective processes is used to drive our corrective action system. Investigating and eliminating the root cause of these failures is a critical part of our continuous improvement process. We apply controls and follow-up measures to ensure that the corrective action plan is effective.

In addition, the Quality Manager summarizes and analyzes corrective action data to identify trends needed to assess overall effectiveness of the corrective action system and to develop related recommendations for improvement. The corrective action system is considered effective if specific problems are resolved or 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; see [QP 5.6](#).

8.5.3 Preventive action

Data from internal audits, customer feedback, and or employee suggestions is collected and analyzed (see [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 apply controls and follow-up measures to ensure that effective preventive action is taken to prevent future re-occurrences.

In addition, the Quality Manager summarizes and analyzes preventive action data to identify trends needed to assess overall effectiveness of the preventive action system and to develop related recommendations for improvement. 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 to evaluate its effectiveness; see [QP 5.6](#).

Appendix A

Master List of Key QMS Documents

Document No.	Document Title
QM	Quality Manual
DFC 4.1	Sequence and Interaction of QMS Processes
QP 4.2.3	Control of Documents
QP 4.2.4	Control of Records
QP 5.6	Management Review
QP 6.2.2	Competency, Awareness & Training
QP 6.3	Facilities and Equipment Maintenance
QP 7.1	Planning of Product Realization
QP 7.2	Customer Related Processes
QP 7.3	Design & Development
QP 7.4	Purchasing
QP 7.5.1	Control of Production & Service provision
QP 7.5.3	Product Identification & Traceability
QP 7.5.5	Preservation of Product
QP 7.5.4	Customer Property
QP 7.6	Control of Monitoring Measuring Devices
QP 8.1	Statistical Techniques
QP 8.2.1	Feedback
QP 8.2.2	Internal Audit
QP 8.2.4	Monitoring & Measurement of Product
QP 8.3	Control of Nonconforming Material
QP 8.5	Continual Improvement
OPIN'S	Operating Instructions (<i>indexed 1001 – 3002</i>)
PS	Process Specifications (<i>indexed 1000-9000</i>)
QF	Quality Forms (<i>indexed QF 4.1-x – 8.5-x</i>)

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Appendix B

Terms and Definitions

Acronyms:

CEO – Chief Executive Officer
CFO – Chief Financial Officer
COO – Chief Operating Officer
DFC – Deployment Flowchart
QMS – Quality Management System
GEC - Gowanda Electronics Corporation

Terms and Definitions. Terms and definitions contained in ISO13485:2003 apply; contact the Quality Manager (ISO Management Representative) to obtain or view a copy.

Deployment Flow Charting: A technique employed at Gowanda Electronics to visually depict responsibilities for and the sequence and interaction of one or more related processes; this technique can be used in conjunction with the corresponding Quality Procedure (QP) or other QMS document.

Appendix C

Quality Manual Controlled Distribution List & Approvals (See QA Manager for complete listing)

X	CEO	X	Quality Manager	
X	COO	X	Information Systems Manager	
X	CFO	X	Senior Design Engineer	
X	Sales Manager	X	East Coast Sales Manager	
X	Materials Manager	X	West Coast Sales Manager	
X	Production Manager			
X	Engineering Manager			

Quality Manual Revision History

<u>Date</u>	<u>Revision</u>	<u>Description</u>
2/20/06	Issue	Initial release of QM
3/12/07	A	Added reference to CFR 21 Part 820 Document