	Document: QM – AS9100 AEROSPACE QUALITY MANUAL	
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Electronics

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Introduction

Gowanda Electronics has developed and implemented a Quality Management System in order to document the company's best business practices, to better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Gowanda Electronics meets the requirements of the international standard SAE AS 9100. This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correspond to the Quality Management System sections of the ISO 9001:2000 format and AS 9100. Each section begins with a policy statement expressing Gowanda's obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

In addition this manual describes the Quality Management System, identifies interdepartmental relationships and responsibilities of the personnel responsible for performing the system requirements. The manual also provides procedures or references for all activities used within the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used both internally to guide the employees of Gowanda Electronics through the various requirements of the AS9100 standard and externally to familiarize or customers with our Quality System practices and controls.

Quality Policy

The Quality Policy adopted by Gowanda Electronics is to supply superior Quality Products and services to our customers that will meet or exceed their requirements both real and perceived recognizing that every employee must share in the responsibility of producing a Quality Product.



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 and is also ISO9001:2000 certified.

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



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.

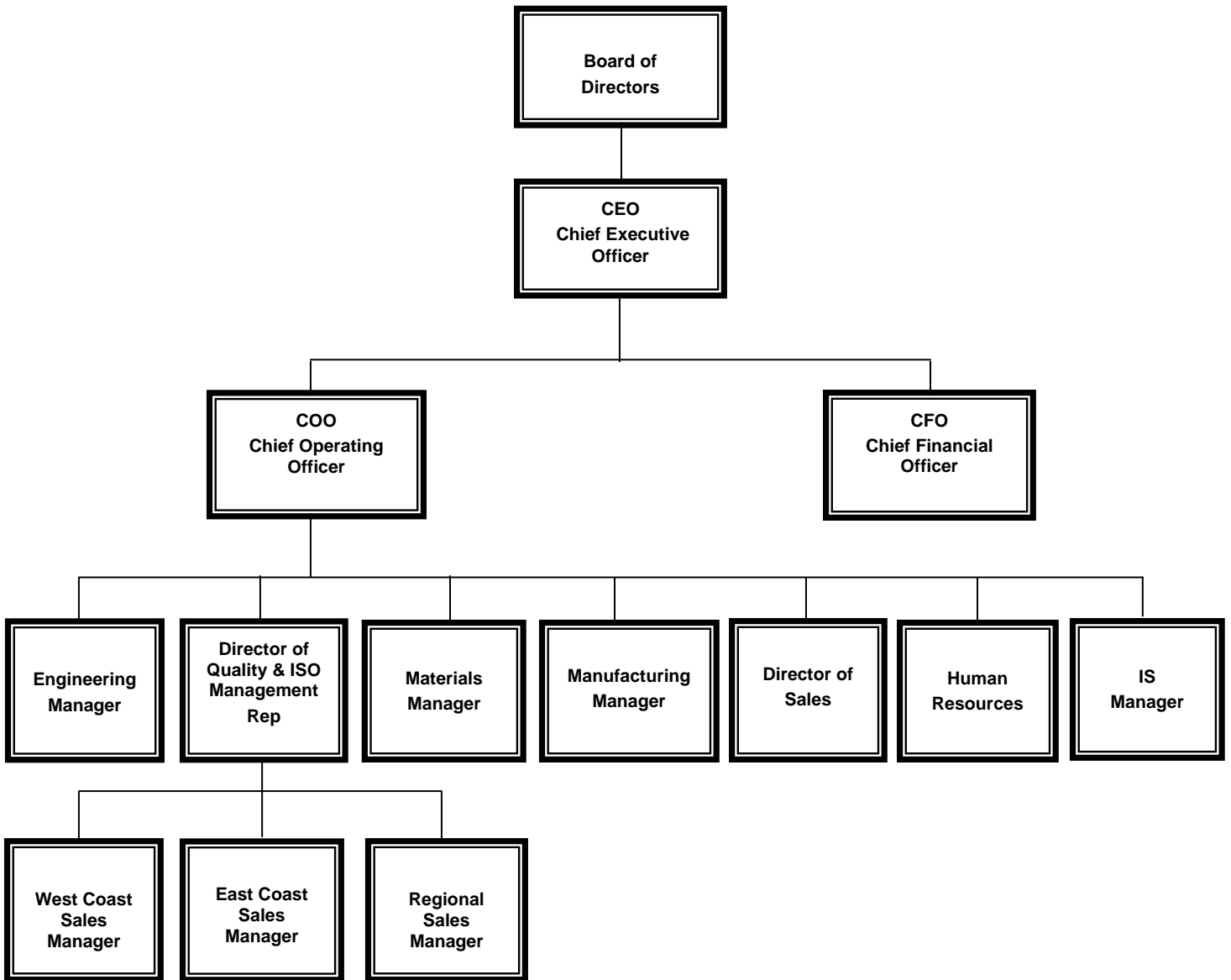
RoHs Policy

In its ongoing commitment in supplying superior quality products and meeting the ever changing global environmental regulations Gowanda Electronics offers RoHs compliant products that meet the requirements as defined in the EU Directive 2002/95/EC. Details of specific RoHs products, solder finishes, marking and packaging methods can be found at www.gowanda.com



GOWANDA ELECTRONICS ORGANIZATIONAL CHART

(Senior Management Staff)





Section 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 AS9100, AS9100:2004, 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 AS9100, 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 the latest revision of AS9100 requirements not applicable to our organization and provides a brief explanation justifying their exclusion from the scope of our QMS:

Gowanda Electronics has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

AS9100 Requirements EXCLUSION TABLE

Clause or Sub-clause	Exclusion	Justification
7.5.1.5	Control of service operations	Gowanda Electronics does not perform any service operations
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.



Section 2: Normative Reference

2.0 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- American National Standard ANSI/AS 9001/ASQ Q9000-2000, Quality Management Systems - Vocabulary.
- American National Standard ANSI/AS 9001/ASQ Q9001-2000, Quality Management Systems – Requirements
- American National Standard ANSI/AS 9001/ASQ Q9004-2000, Quality Management Systems – Guidelines for performance Improvements
- Society of Automotive Engineers SAE AS 9100B - Quality Management Systems – Requirements

Section 3: Definitions

3.0 Quality Management System Definitions

Our QMS uses the same internationally recognized terms, vocabulary and definitions given in both the ISO: 9000 and AS9100 Standards.

- Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
- Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
- Product – The end item result of meeting all contract terms and conditions. (eg: manufactured goods, merchandise, services etc.)
- Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable
- Key Characteristics- The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.



- Acronyms: DFC - Deployment Flowchart,
QMS - Quality Management System
GEC - Gowanda Electronics Corporation

Section 4 Quality Management System

4.1 General requirements

Gowanda Electronics has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of AS 9100. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS Gowanda Electronics has:

- Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- Determined the sequence and interaction of these processes, as depicted deployment flow chart 4.1 in Appendix A
- Determined criteria and methods needed to ensure that the operation and control of it's processes are effective and routers and work instructions, quality inspection plans, see QP8.2.4
- Ensured the continuing availability of resources and information necessary to achieve planned results and continuous improvement of these processes
- Established systems to monitor, measure and analyze these processes, and
- Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes, see Appendix B for a list of key system documents.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy, ref. pg 2
- This Quality Manual
- Documented Procedures



- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records
- Records required by regulatory authorities.

Gowanda Electronics ensures that personnel have access to quality management system documentation and are aware of relevant procedures. We also provide customer or regulatory authority's access to quality management system documentation as required. A list of the QMS documentation structure can be seen in Appendix C.

4.2.2 Quality manual

This Quality Manual has been prepared to describe Gowanda Electronics's QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The deployment flow chart listed in Appendix A provides a description of the interaction between the processes and functions of the QMS system. The relationship between the AS 9100 standard and documented procedure has been indicated by use of a numbering system that correlates to the AS 9100 standard.

4.2.3 Control of documents

All of the QMS documents are controlled according to the Document Control Procedure (QP 4.2.3). This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified and their distribution controlled
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose and
- Obtaining customer / regulatory agency approvals when required by contract or regulatory requirements
- Coordinating document changes with customers or regulatory authorities in accordance with contract or regulatory requirements.



4.2.4 Control of quality records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records, including those created by or maintained by suppliers, are maintained according to the Control of Quality Records Procedure (QP4.2.4). This procedure requires that quality records remain legible, readily identifiable and retrievable. Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records. Records are made available to customers / regulatory agencies when required by contract or regulatory requirements.

4.3 Configuration Management:

The organization has established, documented and maintains a configuration management process that is appropriate to the product.

Related Procedures

Document Control	QP 4.2.3
Control of Quality Records	QP 4.2.4
Configuration Management	QP 4.3.0



Section 5 Management Responsibility

5.1 Management commitment

Senior management is actively involved in implementing the quality management system (QMS). It has provided the vision and strategic direction for the growth of the company and QMS, and established quality objectives and the quality policy. An interaction or interdepartmental responsibilities and associated procedures can be seen in Appendix A.

To continue to provide leadership and show commitment to the improvement of the QMS, management will perform the following as required:

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct annual management reviews.
- Ensure the availability of resources.

5.2 Customer focus

Gowanda strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations. Senior management also holds weekly meetings to review any customer concerns and or needs.

Senior management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization (QP 7.2).



5.3 Quality policy

Senior management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy (reference page 2) at each management review meeting to determine the policy's continuing suitability for our organization in accordance with QP 5.6 management review.

5.4 Planning

5.4.1 Quality objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed *annually* for suitability. Quality objectives will be reviewed in accordance with Management Review QP 5.6. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the AS 9100 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located on page 5 of this manual.

5.5.2 Management representative

The Quality Manager has been appointed by senior management as the QMS management representative and has the following responsibility and authority; to:

- Ensure that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.



- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS and
- Resolve matters pertaining to quality issues
- Have the organizational freedom to resolve matters pertaining to quality.

5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit results, and other routine business communication.

5.6 Management review

5.6.1 General

Senior management reviews the QMS annually at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting in accordance with QP 5.6 and QP 4.2.4.

5.6.2 Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Customer feedback
- Process performance and product conformity
- Company level quality data
- Status of preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement

5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:



- Improvement of the effectiveness of the quality management system and its processes
- Improvement of product related to customer requirements
- Resource needs

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

Related Procedures:

Customer Related Processes	QP 7.2
Management Responsibility	QP 5.6
Planning of Product Realization Processes	QP 7.1
Control of Quality Records	QP 4.2.4



Section 6 Resource Management

6.1 Provision of resources

Gowanda Electronics has implemented a Quality Management System that complies with the AS 9100 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides the necessary resources.

6.2 Human resources

6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. Human resources maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the training procedure as outlined in QP 6.2.2.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.3 Infrastructure

To meet quality objectives and product requirements Gowanda Electronics has determined the infrastructure needed, ref QP 6.3. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be reviewed and implemented as necessary. Existing infrastructure is maintained to ensure product conformity. Maintenance requirements are documented as required in:

- Preventive maintenance plans
- Building maintenance plans



6.4 Work Environment

A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

Related Documents

Competence, Awareness and Training	QP 6.2.2
Facilities infrastructure	QP 6.3

Section 7 Product Realization

7.1 Planning of product realization

Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Planning of Product Realization procedure (QP 7.1). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product,
- Processes, documentation and resources required
- Verification, validation, monitoring, inspection and test requirements, and
- Criteria for product acceptance
- Resources necessary to support operation and maintenance of the product
- Resources to support operation and maintenance of the product.

The output of quality planning includes documented quality plans, processes, procedures and design outputs.



7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Gowanda Electronics determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by Gowanda Electronics

Customer requirements are determined according to the Customer Related Processes Procedure. (QP 7.2)

7.2.2 Review of requirements related to the product

Gowanda Electronics has a process in place for the review of requirements related to the product (QP 7.2). The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- Gowanda Electronics has the ability to meet the defined requirements
- Records are maintained showing the results of the review and any actions arising from the review
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, Gowanda Electronics communicates changes to relevant personnel and amends relevant documents
- Risks (e.g., new technology, short delivery time scale) have been evaluated; see QP 7.1.1 Risk Analysis Procedure.



7.2.3 Customer communication

Gowanda Electronics has implemented an effective procedure (QP 7.2) for communicating with customers in relation to:

- Product Information
- Inquiries, contracts and order handling, including amendments
- Customer Feedback, including customer complaints

7.3 Design and Development

7.3.1 Design and development planning

The design and development procedure (QP 7.3) outlines the process for controlling the design and development process. The Engineering department plans design and development according to this procedure. The design plan includes:

- Design and development stages including organization, task sequence, mandatory steps, significant stages and method of configuration control,
- Required design reviews, verification and validation appropriate to each design stage
- Responsibilities and authorities for design and development.
- Where appropriate, due to complexity, the organization gives consideration to the following activities:
 - Structuring the design effort into significant elements;
 - For each element, analyzing the tasks and the necessary resources for its design and development. This analysis considers an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element is reviewed to ensure consistency with requirements.
- Verification and validation methods appropriate to each design and development stage
- Responsibilities and authorities for design and development
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses
- The different design and development tasks to be carried out, defined according to specified safety or functional objectives of the product in accordance with customer or regulatory authority requirements.



7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Design and Development procedure (QP 7.3). All inputs are reviewed for adequacy and completeness, and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development

7.3.3 Design and development outputs

Outputs of design and development are documented according to the Design and Development Procedure (QP 7.3). They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs:

- Meet the input requirements
- Provide appropriate information for purchasing, production and for service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.
- Identify key characteristics in accordance with design or contract requirements (QP 7.3)

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained is defined by the organization according to the Design and Development Procedure (QP 7.3)

7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfill requirements
- Identify any problems and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed to authorize progression to the next stage.



7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Design and Development procedure (QP 7.3).

7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the design and development procedure.

7.3.6.1 Documentation of Design and/or Development Verification and Validation

At the completion of design and/or development, the organization ensures that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

7.3.6.2 Design and/or Development Verification and Validation Testing:

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following:

- Test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria
- Test procedures describe the method of operation, the performance of the test, and the recording of the results
- The correct configuration standard of the product is submitted for the test
- The requirements of the test plan and the test procedures are observed
- The acceptance criteria are met

7.3.7 Control of design and development changes

The design and development procedure defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review. This procedure provides for customer or regulatory authority approval of changes, when required by contract or regulatory requirement.



7.4 Purchasing

7.4.1 Purchasing process

A documented procedure (QP 7.4) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records. The organization is responsible for the quality of all products purchased from suppliers, including customer-designated sources.

7.4.2 Purchasing information

Purchasing information describes the product to be purchased, including where appropriate:

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements outlined in the Purchasing Procedure (QP 7.4)

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

7.4.3 Verification of purchased product

The Purchasing procedure (QP 7.4) describes the process used to verify that purchased product meets specified purchase requirements. Purchased product is not used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure. If test reports are used to verify purchased product, the data must meet applicable specifications. Test reports for raw material are periodically validated.

When verification activities are requested from the supplier the requirements are defined, and a register of the activities will be maintained in accordance with QP 7.4.

If Gowanda Electronics or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information. Where specified in the contract, the customer or the customer's representative is given the right to verify at the suppliers premises and organization's premises that product conforms to specified requirements



7.5 Production and Service Provision

7.5.1 Control of production and service provision

Gowanda Electronics plans and carries out production and service provision under controlled conditions according to documented procedure (QP 7.5). Planning considers, as applicable:

- The establishment of process controls and development of control plans where key characteristics have been identified,
- The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization,
- The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- Special processes (see 7.5.2).

Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring devices
- The implementation of monitoring and measurement
- The implementation of release, delivery and post-delivery activities
- accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product), part accountability to ensure bad parts have been destroyed
- evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
- provision for the prevention, detection, and removal of foreign objects,
- monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality, and criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

7.5.1.1 Production Documentation

Production operations are carried out in accordance with approved data. This data contains as necessary:



- Drawings, parts lists, process flow charts including inspection operations, production documents and inspection documents
- A list of specific or non-specific tools and numerical control (NC) machine programs required and specific instructions associated with their use.

7.5.1.2 Control of Production Process Changes:

Authorized people for approving changes to production processes are identified in the Procedure QP 7.5. Gowanda Electronics identifies and obtains acceptance of changes that require customer or regulatory authority approval in accordance with contract or regulatory requirements. Changes affecting processes, production equipment, tools and programs are documented and procedures are available to control the implementation of changes.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs

Production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification. Storage requirements, including periodic preservation/condition checks, have been established for production equipment or tooling in storage.

7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities

When planning to temporarily transfer work to a location outside the organization's facilities, the organization defines the process to control and validate the quality of the work.

7.5.1.5 Control of Service Operations

Where servicing is a specified requirement, service operation processes provide for:

- A method of collecting and analyzing in-service data,
- Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements,
- The control and updating of technical documentation,



- The approval, control, and use of repair schemes, and
- The controls required for off-site work

7.5.2 Validation of processes for production and service provision

Gowanda Electronics validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

Gowanda Electronics has documented the process for validation including:

- Defined criteria for review and approval of the processes, qualification and approval of special processes prior to use
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures,
- Control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto
- Requirements for records
- Revalidation

7.5.3 Identification and traceability

Gowanda Electronics identifies the product throughout product realization according to the Identification and Traceability procedure (QP 7.5.3).

- Gowanda Electronics maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.
- Product is identified with respect to monitoring and measurement requirements.
- When acceptance authority media such as stamps, electronic signatures or passwords are used Gowanda Electronics establishes and documents controls for the media.
- According to the level of traceability required by contract, regulatory, or other established requirement, our system provides for:
 - Identification to be maintained throughout the product life;
 - All the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;



- For an assembly, the identity of its components and those of the next higher assembly to be traced;
- For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

Gowanda Electronics controls and records the unique identification of the product where ever traceability is a specified requirement.

7.5.4 Customer property

Gowanda Electronics exercises care with customer property while it is under the organization's control or being used. A procedure (QP 7.5.4) outlines the Identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained. NOTE Customer property can include intellectual property, including customer furnished data used for design, production and/or inspection.

7.5.5 Preservation of product

Gowanda Electronics preserves the conformity of product during internal processing and delivery to the intended destination per procedure (QP 7.5.5). This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Preservation of product also includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- Cleaning;
- Prevention, detection and removal of foreign objects;
- Special handling for sensitive products;
- Marking and labeling including safety warnings;
- Shelf life control and stock rotation;
- Special handling for hazardous materials.

The organization ensures that documents required by the contract or order to accompany the product are present at delivery and are protected against loss and deterioration.

7.6 Control of monitoring and measuring devices

Gowanda Electronics has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure (QP7.6) outlines the



process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

- a) All monitoring and measuring devices that can affect product quality are identified and 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.
- 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.
- 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.
- d) All monitoring and measuring devices are safeguarded from adjustment that would invalidate the calibration.
- e) All monitoring and measuring devices are handled, maintained and stored in a manner that ensures accuracy and fitness for use is maintained.
- f) If in the event equipment needs to be recalled due to an out of tolerance condition the guidelines in QP 7.6 will be followed.

In addition, Engineering and or Quality assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. We also take appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

Gowanda Electronics maintains a register log of all monitoring and measuring devices. The process used for their calibration is defined in procedures, work instructions and equipment manuals and includes details of equipment type, unique identification, location, frequency of checks, inspection methods and acceptance criteria.

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

Gowanda Electronics ensures that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.



Related Documents

Planning of Product Realization Processes QP 7.1

Customer Related Processes QP 7.2

Design and Development QP 7.3

Purchasing QP 7.4

Control of Production and Service Provision QP 7.5

Identification and Traceability QP 7.5.3

Preservation of Product QP 7.5.5

Control of Monitoring and Measuring Devices QP 7.6



Section 8 - Measurement, Analysis and Improvement

8.1 General

Gowanda Electronics plans and implements the monitoring, measurement, analysis and improvement processes as needed

- To demonstrate conformity of the product,
- To ensure conformity of the quality management system, and
- To continually improve the effectiveness of the quality management system.

These processes are identified in documented procedures and include determination of applicable methods, including statistical techniques, and the extent of their use.

NOTE

According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- design verification (e.g., reliability, maintainability, safety);
- process control:
- selection and inspection of key characteristics;
- process capability measurements;
- statistical process control;
- design of experiment;
- inspection - matching sampling rate to the criticality of the product and to the process capability;
- failure mode and effect analysis.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Gowanda Electronics monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Related Processes (QP 7.2) and the Management Responsibility procedures (QP 5.6).



8.2.2 Internal Audit

Gowanda Electronics conducts internal audits at planned intervals to determine whether the quality management system

- Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization
- Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (QP 8.2.2).

The departmental manager is responsible for the area being audited and responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Detailed tools and techniques such as checksheets, process flowcharts, or any similar method to support audit of the quality management system requirements are developed, maintained and used according to the Internal Audit Procedure (QP 8.2.2). The acceptability of the selected tools is measured against the effectiveness of the internal audit process and overall organization performance.

Internal audits meet contract and/or regulatory requirements.

8.2.3 Monitoring and measurement of processes

Gowanda Electronics applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. In the event of process nonconformity, the organization:

- Takes appropriate action to correct the nonconforming process,
- Evaluates whether the process nonconformity has resulted in product nonconformity, and
- Identifies and controls the nonconforming product in accordance with clause 8.3.

The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Monitoring, Measuring and Analysis of Product Realization Processes (QP 8.2.4) and Management Responsibility procedures (QP 5.6).



8.2.4 Monitoring and measurement of product

Gowanda Electronics monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Monitoring, Measuring and Analysis of Product Realization Processes (QP 8.2.4).

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

When key characteristics have been identified, they are monitored and controlled.

When the organization uses sampling inspection as a means of product acceptance, the plan is statistically valid and appropriate for use. The plan precludes the acceptance of lots whose samples have known nonconformities. When required, the plan is submitted for customer approval.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

8.2.4.1 Inspection Documentation

Measurement requirements for product or service acceptance are documented. This documentation is part of the production documentation, and includes:

- Criteria for acceptance and/or rejection,
- Where in the sequence measurement and testing operations are performed,
- A record of the measurement results, and
- Type of measurement instruments required and any specific instructions associated with their use.
- Test records shall show actual test results data when required by specification or acceptance test plan.
- Where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements. (see applicable QPIS form Quality Inspection Planning Sheet)

8.2.4.2 First Article Inspection

The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or



following any subsequent change that invalidates the previous first article inspection result.

8.3 Control of Nonconforming Product

Gowanda Electronics ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (QP 8.3).

The term “nonconforming product” includes nonconforming product returned from a customer.

Responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions is defined in the procedure.

The organization does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if

- The product is produced to customer design, or
- The nonconformity results in a departure from the contract requirements.

Unless otherwise restricted in the contract, organization-designed product which is controlled via a customer specification may be dispositioned by Gowanda Electronics as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.

Product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

In addition to any contract or regulatory authority reporting requirements, Gowanda Electronics system provides for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification includes a clear description of the nonconformity, which includes as necessary parts affected, customer and/or organization part numbers, quantity, and date(s) delivered.

8.4 Analysis of Data

Gowanda Electronics determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in the Management Responsibility procedure (QP 5.6). Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:



- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

8.5 Improvement

8.5.1 Continual improvement

Gowanda Electronics continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

Gowanda Electronics takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QP 8.5) defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing corrective action taken.
- Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and specific actions where timely and/or effective corrective actions are not achieved.

8.5.3 Preventive action

Gowanda Electronics determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedure (QP 8.5) defines requirements for:

- Determining potential nonconformities and their causes



- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing preventive action taken

Related Documents

Management Responsibility QP 5.6

Risk Analysis Procedure QP 7.1.1

Customer Related Processes QP 7.2

Customer Satisfaction QP 8.2.1

Internal Audits QP 8.2.2

Monitoring and Measuring of Product and Realization Processes QP 8.2.4

Control of Nonconforming Product QP 8.3

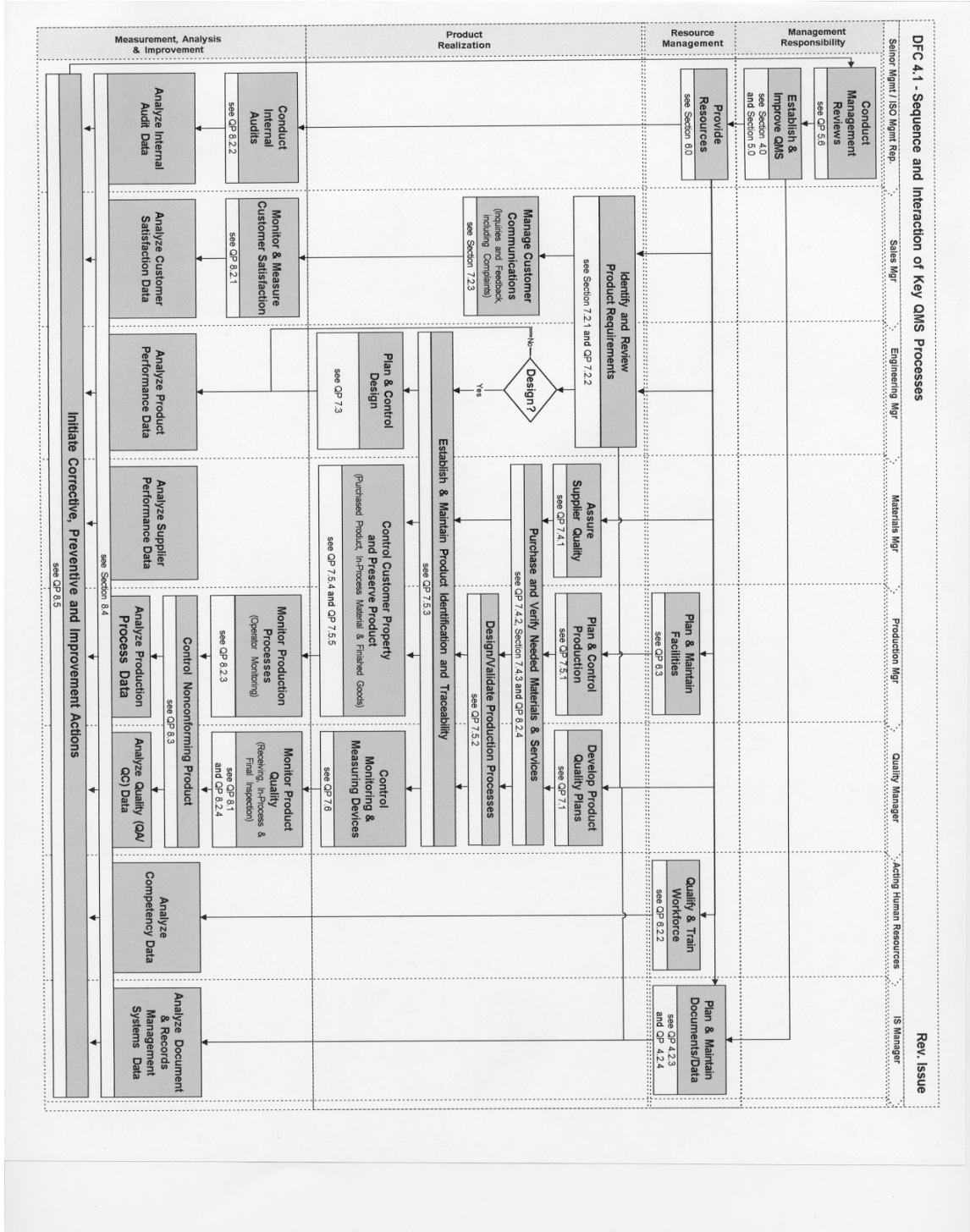
Corrective Action QP 8.5

Preventive Action QP 8.5

Statistical Techniques QP 8.1



Appendix A





Appendix B

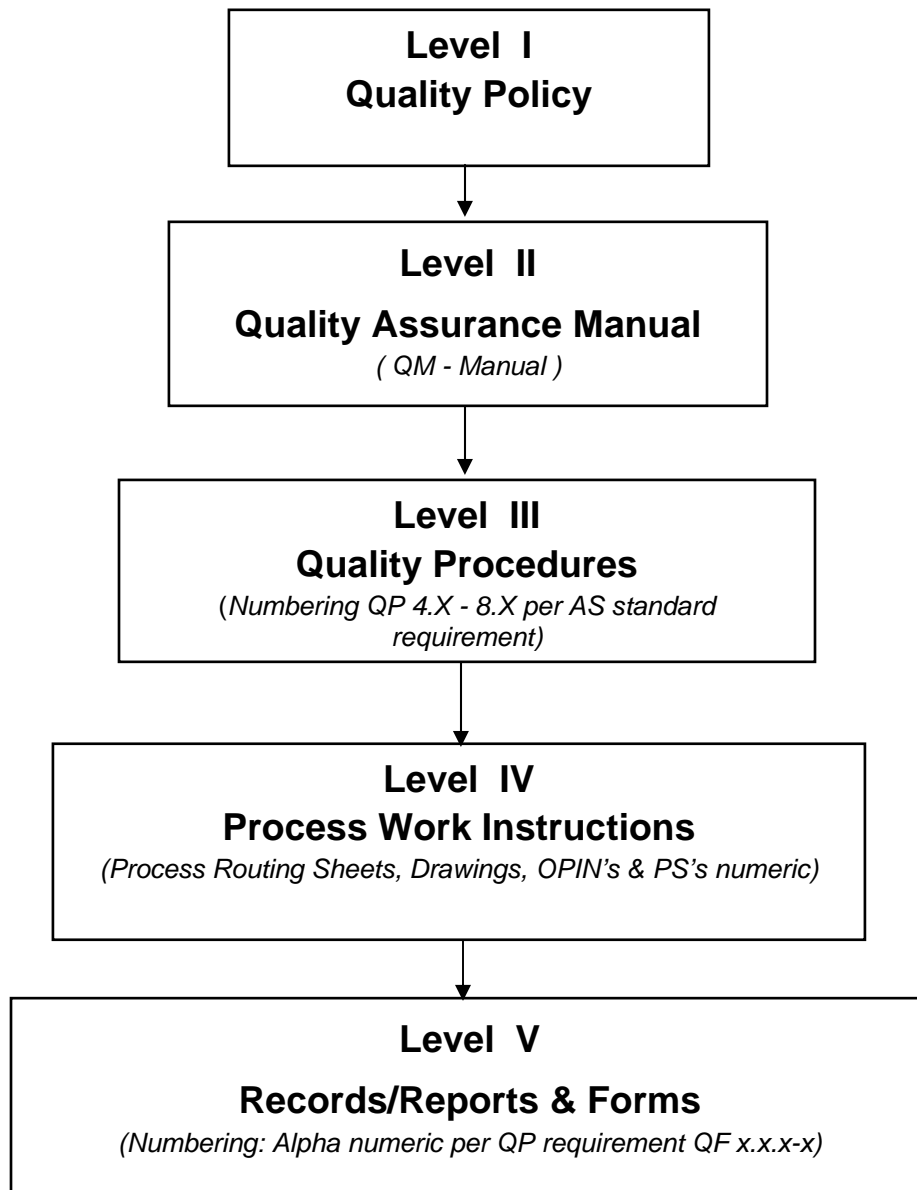
Key System Documents

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 4.3	Configuration Management
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 7.1.1	Risk Analysis Procedure
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'S	Quality Forms (<i>indexed QF 4.1-x – 8.5-x</i>)



Appendix C

QMS Document Structure





Quality Manual Distribution

The latest revision of the Quality Manual shall be controlled electronically and is available on the system network in the following path: Note, No hard copy formats will be distributed.

Network → Quality on Gowanda-01\ISO Quality Manuals\AS9100 QM

Additional Gowanda Quality System Certifications:

ISO9001:2000 February 2004

ISO13485:2003 May 2006



QUALITY MANUAL REVISIONS

Date	Rev.	DESCRIPTION OF CHANGE	AUTHORIZED BY, Title
1/9/95	A	Revised complete manual to ISO9001 requirements	Don Cotter QA Manager
3/6/95	B	Added Company History info	Don Cotter QA Manager
9/3/96	C	Modified Organizational chart	Don Cotter QA Manager
3/20/97	D	Modified mission statement	Don Cotter QA Manager
7/20/98	E	Modified organizational chart	Don Cotter QA Manager
9/21/00	F	Added applicable Quality Reference Procedures	Ken Hicks QA Manager
3/15/01	G	Modified design review procedure & updated Org. chart	Ken Hicks QA Manager
9/10/03	H	Rewrote entire manual to comply with new ISO9001:2000 reqmts. Also added reference to GEM quick reference guide in sections 1 & 2	Don McElheny, COO Ken Hicks, QA Mgr
8/3/06	I	Updated Organizational chart and deleted distribution listing	Ken Hicks QA Manager
11/9/06	J	Reformatted entire manual and updated to meet AS9100 system requirements	Don McElheny, COO Ken Hicks, QA Mgr