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# **Quality Assurance Manual**

**Version 3.5.2**

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## 1.0 INTRODUCTION

911EDA, Inc. was formed in 2000 to satisfy customer requirements for PCB design services. This business has developed well and is expanding successfully.

Additional capabilities have been added to the organization to include electronic engineering services, and PCB manufacturing services.

This Quality System relates to the full range of company activities.

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## 2.0 POLICY and OBJECTIVES

911EDA, Inc.'s quality policy is to:

- Support the company's policy to continuously improve our products, services, and operations so that we constantly offer customers superior value
- Meet all defined requirements, including those defined by our customers, statutory and regulatory requirements, industry associations, etc. Our management is committed to continually improve the effectiveness of our quality management system.
- Communicate our quality policy to all employees within our organization and takes appropriate steps to ensure it is understood by everyone.

This level of quality is achieved through adoption of a system of procedures that reflect the competence of the Company to existing customers, potential customers, and independent auditing authorities.

Achievement of this policy involves all staff members who are individually responsible for the quality of their work, resulting in a continually improving working environment for all. This policy is provided and explained to each employee by the Managing Director or Quality Manager.

To achieve and maintain the required level of assurance, the Managing Director retains responsibility for the Quality System with routine operation controlled by the Quality Manager.

The objectives of the Quality Assurance System are:

- To achieve and maintain a level of quality which enhances the Company's reputation with customers.
  - To ensure compliance with relevant statutory and safety requirements.
  - To endeavor, at all times, to maximize customer satisfaction with the services provided by 911EDA, Inc.
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## **3.0 DEFINITIONS**

The terms and descriptions used in this Manual are generally defined within ISO9001 - Quality Systems.

Additional definitions apply for items not covered by the documents:

Site: Any location, other than the Company's established premises, where work is undertaken as part of a formal contract

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## **4.0 QUALITY SYSTEM**

The Quality Assurance System applies to all activities of the Company, and has been developed in accordance with ISO9001. The Quality Assurance System is fully documented and structured in 3 levels:

### **Level 1 : Quality Manual**

This document details the corporate quality policy and structure of the Company and references appropriate Operating Procedures.

### **Level 2 : Operating Procedures**

These documents describe the actual process, and controls applied, to all activities concerned with the attainment of a quality assured contracting service.

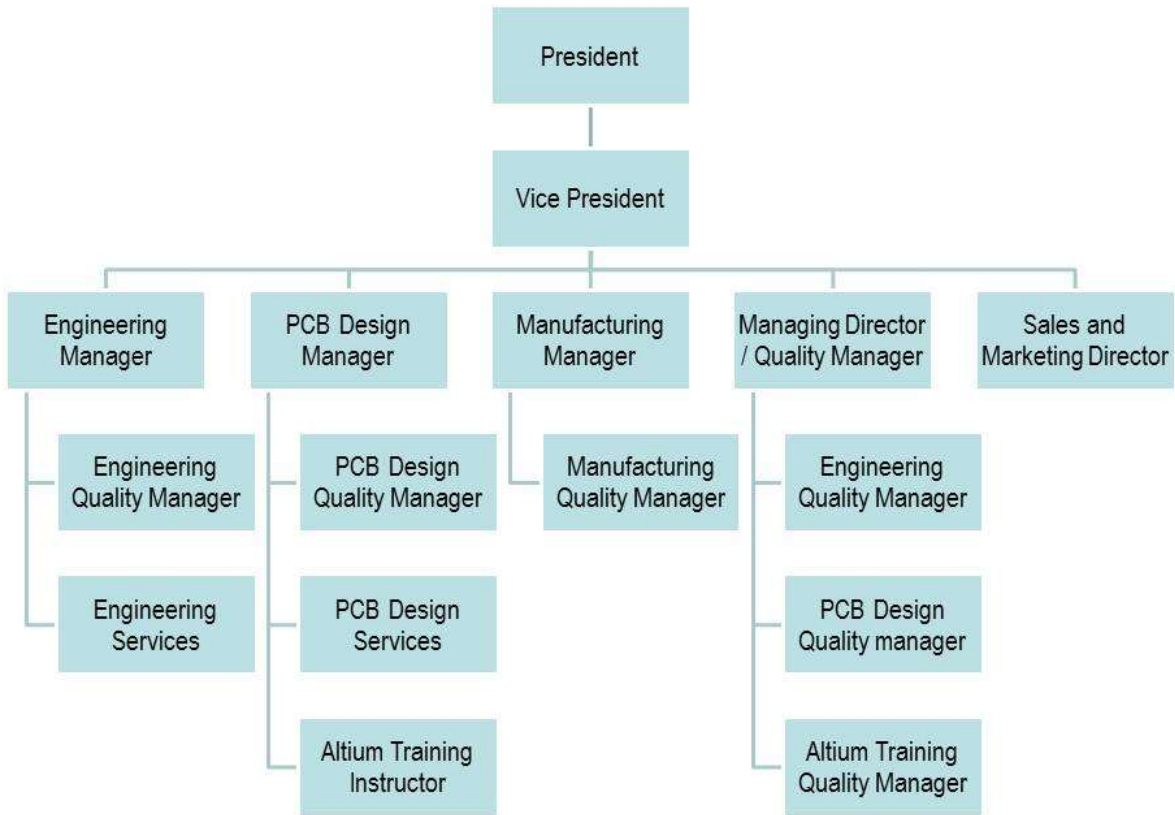
A list of Operating Procedures is given in the Index Section of this Quality Assurance Manual.

### **Quality Planning**

As the Company operates a standard type and range of services, customer satisfaction and quality are achieved by operation in accordance with the documented quality system. Specific customer requirements are identified and documented during the contract review process, allowing these requirements to be communicated and achieved, ensuring satisfaction of all customers' declared needs.

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## 5.0 ORGANIZATION



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## 6.0 AUTHORITY & RESPONSIBILITIES

### 6.1 Authority

6.1.1 All staff are allocated with authority to perform their allocated responsibilities. The following provides a summary of the principal responsibilities of each job role, and these are clarified in greater detail within the Operating Procedures.

6.1.2 All staff share the authority and responsibility of identifying non-compliances or possible improvements, and recording these instances such that corrective action can be taken, both to rectify the immediate situation and to prevent recurrence.

6.1.3 The Managing Director continually reviews the company's resources to ensure that adequate staff, equipment and materials are available to meet customer requirements.

## **6.2 Responsibilities**

### **6.2.1 President**

- Company management and support

### **6.2.2 Vice President**

- Management and coordination of sales and support functions
- Contract review
- Project management
- Control of contract documentation
- Planning and organization
- Supplier selection and purchasing

### **6.2.3 Sales and Marketing Director**

- Management and coordination of sales and support functions
- Contract review
- Sales order processing
- Design control
- Estimating
- Project management
- Control of contract documentation
- Planning and organization
- Supplier election and purchasing

### **6.2.4 Managing Director / Quality Manager**

- Management of Quality Control
  - Quality Assurance Manual
  - Quality Policy
- Achieve and maintain a level of quality which enhances the Company's reputation with customers
- Ensure compliance with relevant statutory and safety requirements
- Maximize customer satisfaction with the services provided by the Company

### **6.2.5 Engineering Manager**

- Management of engineering projects
- Engineering project quoting
- Project management
- Design control
- Planning and organization

## **6.2.6 Support Engineers**

- Engineering services
- Customer support

## **6.2.7 PCB Design Manager**

- Management of PCB design projects
- PCB design project quoting
- Project management
- Design control
- Planning and organization
- Altium Training Class instruction

## **6.2.8 PCB Designers**

- PCB layout services
- PCB library services
- Customer support

## **6.2.9 Manufacturing Manager**

- Management of manufacturing services
- Manufacturing quoting
- Project management
- Planning and organization

## **6.2.10 Quality Managers**

- Internal Audit
  - Resolution of Quality Assurance System Discrepancies
  - Control & Maintenance of the Quality Assurance System
  - Documentation & Change Control (Quality System Documents)
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## **7. COMPLIANCE WITH ISO9001**

This Quality System is structured with policy statements relating to each area of activity being within the relevant Operating Procedure. However, the following items of ISO9001 are not addressed within the operating procedures as they are not applicable to this Company:

- Statistical Techniques
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## **8. MANAGEMENT REVIEW and INTERNAL AUDIT**

Management review of the suitability and effectiveness of the Quality System take place at least twice per year. During the management meetings actions are allocated and minuted to record the development of the Company's management system.

The objectives of Management Review are:

- a) To establish that the Quality (Management) System is achieving the expected results and meeting the Company's requirements, continuing to conform to the Standard, continuing to satisfy the customers' needs and expectations, and functioning in accordance with the established Operating Procedures.
- b) To expose irregularities or defects in the System, identify weaknesses and evaluate possible improvements.
- c) To review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the Company.
- d) To review any complaints received, identify the cause and recommend corrective action if required.
- e) To review the finding of internal/ external audits and identify any areas of recurring problems or potential improvements.
- f) To review the reports of nonconforming items and trend information to identify possible improvements.

Internal audits of the Quality System are undertaken at least once per annum to confirm that the function concerned is adhering to the Company's Procedures. A comprehensive Audit Program is compiled at least a year in advance. However, should particular needs be identified the frequency of audit may be increased at the discretion of the Quality Manager.

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## **9. CONTRACT REVIEW**

The Company offers specialist services to meet each customer's needs. Specialist service requirements differ from one customer to another (and from one contract to another), therefore each tends to be quoted for the specific contract.

Once a proposal is accepted by the customer, or an order is placed, it is recorded and reviewed to establish that the requirements of the order are adequately defined and documented, any differences from the proposal are resolved, and the Company is capable of fully satisfying the customer's requirements.

In addition to the original order/ contract specification the customer may also request addition/ variation work to be undertaken by the Company. In these circumstances the work content is documented and agreed with the customer prior to execution to ensure that no ambiguity exists.

The Company operates on a computerized order processing system to ensure rapid fulfillment of customer orders.

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## **10. DESIGN CONTROL**

All Design activities are strictly controlled to ensure that the design output information complies with customer/contract requirements and all design input data.

Design activities are planned and normally executed by specialists and are subject to regular management, review and verification by the Sales Director, and where relevant, agreement with the Customer.

The design input and output items are documented, and where ambiguity exists, will be clarified and documented. All items of design documentation and notes are recorded in a design project file. Design output documentation is produced and reviewed to ensure that it:

- Meets the design input,
- References the design input or appropriate criteria,
- Identifies all of the characteristics which are critical to the safe and effective operation of the system(s).

Design output is reviewed and approved by the Sales Director, and is also provided to the Customer for approval prior to use. Validation of the design is achieved during commissioning of the system to confirm compliance to the customer's requirements.

The designer is required to specify any inspections or tests which may verify the design, by practical means, at the earliest possible stage of development.

All changes to the design criteria, input or output are subject to strict review and documentation control procedures.

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## **11. DOCUMENTATION & CHANGE CONTROL**

All documentation utilized within the Company related to the management system itself, or to the execution of individual customer contracts is controlled to ensure that it is issued to the

appropriate personnel, under the correct level of authority, is revised and reissued as necessary, and all obsolete versions are removed from the point of use.

Such documentation typically includes:

Specifications, Customer Orders, Plans/ Drawings,  
Quality Assurance Manual/ Operating Procedures,  
National/ International Standards and Codes of Practice.

The Quality Assurance Manual, Procedures and Quality Plans are maintained by the Quality Manager who ensures that the appropriate items, at the correct revision levels, are issued to all who need them within the Company.

National/ International Standards, Codes of Practice are maintained by the Support Engineers who ensure that appropriate documents are available within the Company, and are issued at the correct revision levels. External suppliers of documentation are contacted regularly to ascertain that the documents held remain current.

The distribution of standard documents is controlled and recorded on Distribution Lists, which also show the current issue status. The Distribution Lists are reviewed and updated as changes occur.

All changes to documents are reviewed and approved by the person responsible for the original issue and, where appropriate, the nature of the change is indicated on the document. Master copies of the revised documents are retained as records of the changes and renewed as necessary to ensure clarity.

Each contract has a File which contains all relevant information. Information is also held on the company's computer system for ease of access and manipulation.

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## **12. PURCHASING**

Suppliers of products, materials and services, where unspecified by a customer contract, are selected on their ability to meet the Company's requirements given due consideration to the quality, statutory obligations, timescale and cost. A list of approved suppliers and sub-contractors is maintained which is compiled on the following criteria:-

- a) Previous performance in supplying to similar specifications and requirements.
- b) Compliance with an approved third party product/ quality registration scheme.
- c) Recommendation by other similar purchasers or manufacturers of equipment.

d) A trial order and evaluation of performance.

All supplies and sub-contracts are subject to an authorized Purchase Order providing full clarification of the type and extent of supply.

Should a supplier, not appearing on the Approved Suppliers List be proposed, they will be analyzed by capability and subject to acceptance on the authority of a Director.

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### **13. CUSTOMER SUPPLIED ITEMS**

Goods received from customers (i.e. free issue items or equipment being serviced) are always visually inspected at the receipt stage, with any undeclared non-conformance being immediately reported to the customer.

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### **14. PROCESS CONTROL**

All productive work is planned and undertaken in accordance with the company's procedures, and any specific documents agreed for individual contracts (e.g. contract specifications).

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### **15. NON-CONFORMING ITEMS, PREVENTIVE & CORRECTIVE ACTION**

Once non-conforming items have been noticed they are identified by location, associated documents, or specific markings to prevent their inadvertent use. All non-conforming items and customer complaints are subject to review and rectification by nominated personnel. The type and extent of non-conformity is documented in order to establish trends and identify possible areas for improvement.

The corrective action required to prevent recurrence is evaluated, documented, and its effective implementation is monitored. All rectification is subsequently re-inspected to ensure complete customer satisfaction.

All employees are encouraged to suggest improvements in methods, materials, suppliers, and sub-contractors. The Company has established procedures for review of all activities in order to identify and evaluate all possible improvements in methods/ materials and its procedures.

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## **16. HANDLING, STORAGE, PACKAGING, PRESERVATION & DELIVERY**

Materials and goods received, whether the property of the company or others, will, as far as practicable, be protected and their quality preserved until such time as they are transferred to a customer.

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## **17. RECORDS**

Storage facilities are allocated which ensure that all stored records are identifiable and retrievable.

Where records are maintained on computer magnetic media, and these are subject to "back-up" at regular intervals, with the "back-up" information being stored in a protected location to ensure security from loss/ damage of active data.

All records are retained for a minimum of 1 year.

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## **18. TRAINING**

The policy of the company is to ensure that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. The company generally procures and recruits employees capable of meeting the technical, skill, experience and educational requirements of the company's activities.

All staff and senior employees are responsible for recommending the training needs of others and for ensuring that all employees allocated specific tasks are suitably qualified and experienced to execute those tasks. Once training needs are identified these are provided under the responsibility of the Directors.

Full records are maintained of all training undertaken by employees.

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