



Electronic Design & Research Co. Inc.

Diversification is our name

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Web Site: www.vsholding.com

EDR Inc.'s declaration of conformity (in accordance with ISO/IEC 17050-1)

- 1) No. 2006223
- 2) Issuer's name: Electronic Design & Research Inc.
Issuer's address: 7331 Intermodal Drive, Louisville KY 40258
- 3) **The object of the declaration above in conformity with the requirements of the following documents: Self Declaration of QMS AS 9003**

Document No.	Title	Edition/Data of Issue
4) AS9003	Inspection and test Quality System	2001-10
- 5) **Additional information:**
Internal Audit summary

Singed for and on behalf of:

.....
Brooke A Dozer

Place and date of issue

12/24/2010

.....
Brooke Dozer/QMS Manager

.....
Signature

.....
date



AS9003 Internal Audit Report (12/15/2010)

Date: December 20, 2010
Auditor: Brooke Dozer
Title: Quality Manager

A complete and thorough audit of QMS documentation was performed on the AS9003 compliant Quality System at Electronic Design & Research Inc.

Areas of the Quality System requirements that were audited are as follows:

1. Management Responsibility
2. Quality System
3. Contract Review
4. Design Control
5. Document and Data Control
6. Purchasing
7. Control of Customer Supplied Product
8. Product Identification and Traceability
9. Process Control
10. Inspection and Testing
11. Control of Inspection, Measuring and Test Equipment
12. Inspection and Test Status
13. Control of Non-Conforming Product
14. Corrective Action
15. Handling, Storage, Preservation and Delivery
16. Control of Quality Records
17. Internal Quality Assessment
18. Training
19. Servicing
20. Statistical Techniques



Findings and Resolutions of the audit:

Although all sections of the quality manual and procedures were thoroughly reviewed and audited, only those areas where discrepancies were identified are listed below.

Quality System:

- 4.2.2 Availability of quality system procedures: The quality manual calls for the procedures to be readily available to employees responsible for ensuring compliance.

Copies of the quality manual and procedures have not been distributed to all employees who are responsible for ensuring compliance.

Corrective Action #033 has been issued to generate and distribute the quality manual and procedures to those employees who require them. The due date for this CAR is October 7, 2006. **COMPLETED**

4.6 Purchasing:

- 4.6.1 Procedure for Verification of Purchased Product:

A new employee Mr. Jeff Parr was hired to carry on responsibilities for purchasing material and components and insure completeness and compliance. **IN PROGRESS**

4.6.7 Supplier Evaluation and Approval;

Although a list of suppliers exists, currently, there is no approved suppliers list. **Explanation:** All components and supplies have purchased only from the major OEM companies with established ISA 9001:2000 and we consider that are automatically approved suppliers. **IN PROGRESS**

Once designed completed and a product went through major approval qualifications, such as, the EDR's and later a customer field tests the OEM company which supplied components for that particular product became the approved supplier for that specified product.

If for whatever reasons a supplier (OEM) stopped manufacturing component and the components became unavailable or other company bought a production license for that components and start manufacturing it than EDR's product will again go through the field tests.

4.11 Control Of Inspection, Measuring and Test Equipment

Calibration procedure QA002 that is referenced in this section of the manual requires that a vendor survey be performed on the calibration house.

Corrective Action #036 has been issued to complete a vendor survey. The due date for this CAR is October 30, 2006. **COMPLETED**

4.17 Internal Quality Assessment:

Quality manual requires that internal quality audit be performed regularly.



Corrective Action #037 has been issued to generate the process and procedure to perform and document the internal audit process. The due date for this CAR is November 30, 2006. **COMPLETED**

Electronic Design & Research is an organization that manufactures Solid State Modules and its facility includes manufacturing, R&D, engineering, finance and its corporate offices.

Although EDR Inc. is now self-declaring its conformity to AS9003, it has for several years implemented and adhered to the guidelines and directives of this quality system. Engineering, production, quality, purchasing and sales all work closely together to minimize and eliminate errors or missteps that lead to a reduction in product quality, late deliveries and rework. The teamwork and camaraderie, which is openly displayed at Electronic Design & Research, is one of the factors that lends itself to the smooth work flow from the front office, through production and onto shipping.

EDR's product and its customers

Electronic Design and Research Inc/VS Holding Inc. is approaching the end of the fiscal 2010 (04/31/2011) year with a number of exciting new products and widely expanded list of customers. Here is a small list of products and customers who bought them.

1. A new type charge-and-add DC/DC converter made for converting a 48VDC (four batteries) into 220VDC for an electrical car shipped for a field test.
2. A new type DC-3 phase AC converter to drive AC motor for electrical manufactured and shipped for a field test



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Auditor: Brooke Dozer
Title: Quality Manager

A complete and thorough audit of QMS documentation was performed on the AS9003 compliant Quality System at Electronic Design & Research Inc.

Areas of the Quality System requirements that we re audited are as follows:

21. Management Responsibility
22. Quality System
23. Contract Review
24. Design Control
25. Document and Data Control
26. Purchasing
27. Control of Customer Supplied Product
28. Product Identification and Traceability
29. Process Control
30. Inspection and Testing
31. Control of Inspection, Measuring and Test Equipment
32. Inspection and Test Status
33. Control of Non-Conforming Product
34. Corrective Action
35. Handling, Storage, Preservation and Delivery
36. Control of Quality Records
37. Internal Quality Assessment
38. Training
39. Servicing
40. Statistical Techniques



Findings and Resolutions of the audit:

Although all sections of the quality manual and procedures were thoroughly reviewed and audited, only those areas where discrepancies were identified are listed below.

1.1 Management Responsibility:

- 1.1.1 Quality Policy: Manual calls for the quality policy to be accessible to all employees, but was not posted in the facility.

Generated copies of the quality policy and posted them in the main production area and in the break room. **Completed**

Quality System:

- 4.2.3 Availability of quality system procedures: The quality manual calls for the procedures to be readily available to employees responsible for ensuring compliance.

Copies of the quality manual and procedures have not been distributed to all employees who are responsible for ensuring compliance.

Corrective Action #033 has been issued to generate and distribute the quality manual and procedures to those employees who require them. The due date for this CAR is October 7, 2011

4.6 Purchasing:

- 4.6.2 Procedure for Verification of Purchased Product:

Until the replacement will be hired, temporarily Mr. V Shvartsman carries on purchasing procedure and then re-audited the process to ensure completeness and compliance. **In progress**

- 4.6.7 Supplier Evaluation and Approval;
Although a list of suppliers exists, currently, there is no approved suppliers list.

Explanation: All components and supplies have purchased only from the major OEM companies with established ISA 9001:2000 and we consider that are automatically approved suppliers.

4.11 Control Of Inspection, Measuring and Test Equipment

Calibration procedure QA002 that is referenced in this section of the manual requires that a vendor survey be performed on the calibration house.

Currently, we do not have a completed vendor survey on the calibration house.

Corrective Action #036 has been issued to complete a vendor survey. The due date for this CAR is December 15, 2011

4.17 Internal Quality Assessment:

Quality manual requires that internal quality audit be performed regularly.



There is no documented procedure or process in place to accomplish this requirement.

Corrective Action #037 has been issued to generate the process and procedure to perform and document the internal audit process. The due date for this CAR is November 30, 2011

Electronic Design & Research is an organization that manufactures Solid State Modules and its facility includes manufacturing, R&D, engineering, finance and its corporate offices.

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Electronic Design & Research Inc.

Quality Manual

PREPARED BY: **Mr. Jeff Parr**
Production Manager

APPROVED: Brooke Dozer
QA Manager

APPROVED: _____
Vladimir A. Shvartsman, Ph.D.
President & CEO

November 2010



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Purpose

The purpose of this manual is to define and document the quality system of: Electronic design & Research, Inc. (EDR Inc. herein below) at 7331 Intermodal Drive, Louisville, KY 40258.

SCOPE

This manual describes the Quality Assurance Systems established and implemented by Electronic Design & Research, Inc. in accordance with the Quality Policy, and with the requirements specified in the standard for Inspection and Test Quality System, SAE AS9003, 2001-10.

Business description and background

Electronic Design & Research, Inc. provides OEM products 50/60Hz filters, DC/DC converters, Solid State Relays, Solid State Breakers, Solid State Drivers, Isolated Video Switches, High-voltage (up to 20 kV) push-pull switches, iUPS, Universal Electronic Load, Super-High Resolution Electrocardiograph, Cardio-Stimulators, Life Alert 1000 and 1001 emergency warning systems, Precision Phase detectors, F-to-V converters, “n”-shape filters, ripple-free high-pass filters, neural processor, power boosters, etc. It offers a turnkey product development and manufacture. It also offers redesigning and remanufacturing old and obsolete electronic controls, such as a PC Boards, modules, devices, DC/DC and AC/DC converters, etc. In addition, it is a leading repair service provide for a many manufacture companies, worldwide. Electronic Design & Research, Inc. is a small, diversified high-tech company. It holds several patents covering a multi-channel signal processor, pulse-width detector, neural-cell, solid-state relay and few more inventions are patent pending.

Electronic Design & Research Co., Inc. was founded in 1984 and operates since in Louisville, KY. It is regular, registered corporation and EIN # is 61-1020481

Electronic Design & Research, Inc. is a small company functioning like many other companies based in USA. It has no external or additional financial support and in the order to survive and compete on the open market operates like the best organized and financed one. All functions of a large corporation performed and carried a small corporation by their employees though; they are not as defined as it is accustomed in a large corporation to a specific employee. In other words, responsibilities and duties are attached to a job and title but actual work and task can be performed by other employee when and if the time permits.

Review, approval and revision

It is the responsibility of the current management representative to ensure that this manual is reviewed for accuracy and ongoing compliance. Updates to this manual require approval by the President and the Quality Control Manager.



MANUAL UPDATES

When required, updates to this manual will be performed by Quality Control Manager in accordance to the requirements specified in the Documentation Control procedure (see section 4.5, below).

Quality system Requirements

MANAGEMENT RESPONSIBILITY

The Management of EDR Inc. has defined its policy for quality, including objectives for quality and commitment to quality. They also ensure that the policy is implemented, maintained at all levels of the organization, and accessible to all employees.

Quality Policy:

Electronic Design & Research, Inc. team will provide Customers with *dependable*, cost effective, on-time products and services; we expect our products to perform without interruption to stated specifications. Every employee is committed to implementing quality processes to identify and meet customer expectations and ensure mutual profitability. Quality plans with measured quality objectives ensure continual improvement of processes and products

Electronic Design & Research, Inc. continuously improves its products, services, and environment to better satisfy customers, shareholders, and employees. We employ our quality management systems, the basis of which are the ISO 9000 standards, to measure and analyze trends in product quality and provide positive feedback internally on process effectiveness.

Responsibility and Authority

The functional responsibilities and lines of communication for the management, direction and execution of activities affecting quality are defined in the paragraphs below. Electronic Design & Research is a small high-tech company where many employees are responsible for a several functions. (See Appendix A for a graphical representation.)

President & CEO – as in many small companies is the central figure. The president's responsibilities extended beyond the major company's key-responsibilities, such as a product conceiving, financial management, the company's product development and production, hiring a personal, development a product description and data sheets, etc. The responsibility is also including of developing with the EE Manger the quality control testing requirements and developing a quality control procedure and test fixture. He is responsible for managing all personal involved in production, quality control and delivery of the final product.

Production Manager – is responsible for producing a product on a timely basis. Manufacturing a high quality product on time and on budget are the major functions and responsibilities of the Production Manager. The responsibility is close interacted with a quality control personal. In some cases a testing of a product is complicate and lengthy

and the Production Manager must adjust the production schedule with a time required for testing and certifications. Responsibility included programming of a peak-and-plate equipment and training assemblers with operation and specifics. The PM insures assemblers learn and understand some production specifics and getting involve in all productions steps in cases of an assembler's absence or a "RUSH" ordered. Production Manager responsible for training and qualification of a newly hired assemblers.

EE Manager – the responsibilities are broad and covers most aspects of R&D, production, prototyping, test equipment maintenance and development of a test procedure and fixtures for a quality control testing. It is included and not limited to providing and organizing all requested by the president support in prototyping, testing, developing and implementing a quality test procedure that was discussed and approved by the president. Perform a rivers engineering, developing an artwork, assembling a pre-production sample and insure its product ability.

Quality Control Manager – Responsibilities are included scheduling and organizing testing of a produced product, gathering and analyzing information of the testing, communicating with a production manager the result of testing. The QCM is responsible for ordering components from a trusty suppliers and maintaining the inventory. The QMC works close with the EE manager on a new quality control procedure and writing a notes and recommendation.

Marketing/Sales Manager – Responsible for marketing the company's products, signing for an exhibition and directing the Webmaster about the company's website.

QUALITY SYSTEM

Quality Manual and Flow Down

The quality system documented by this Quality Manual is intended to ensure that product conforms to specified requirements. This manual contains a reference list of all quality system procedures in Appendix B.

Availability of Quality System Procedures

The quality system procedures listed in Appendix B are readily available to all employees responsible for ensuring compliance with requirements, and to customer and/or regulatory agency representatives.

CONTRACT REVIEW

The documented procedure for contract review, Document Number, used by Electronic Design & Research insures that the following are accomplished before acceptance of a contract, contract change notice or other required change:

- a. Requirements are determined to be adequately defined and documented.
- b. Capacity and capability to meet all contract requirements is ensured.
- c. Records of contract reviews are properly controlled and maintained.



DESIGN CONTROL

Not applicable to AS9003.

DOCUMENT AND DATA CONTROL

Control of Documents

Procedure, Document Number, describes EDR's process that controls all documents and data and ensures that only approved, released, pertinent revisions are available, including those in electronic format.

Document Review, Distribution, Implementation and Maintenance

Document number, Document Number (May be the same as that of 4.5.1), ensures the timely review, distribution, implementation, and maintenance of all authorized and released drawings, standards, specification, planning and changes. Electronic Design & Research maintains a record of change incorporation, and, when required, coordinates these incorporations with the customer and/or regulatory authority.

PURCHASING

Procedure for Verification of Purchased Product

Document Number describes EDR Inc.'s process for ensuring that purchased product meets specified requirements.

Purchase Document Requirements

EDR Inc.'s purchase documents clearly define the product ordered, including the applicable drawings, specifications, processing requirements, and other relevant data.

Location of Purchased Product Verification

Purchased product is verified upon receipt or at the supplier's facility before shipment.

Right of Entry Provision

EDR Inc. includes right-of-entry provisions in any subcontract. These provision allow the representatives of EDR Inc., our customers and regulatory agencies to determine and verify the quality of work, records, and material at any place, including the plant of the supplier.

Supplier Performance Review

EDR Inc. regularly reviews and evaluates the quality performance of its suppliers and takes appropriate actions.

Customer-Approved Special Process Sources

EDR Inc. ensures, when required, that EDR Inc. and our suppliers use customer-approved special process sources.

Supplier Evaluation and Approval

EDR Inc. maintains a process for evaluating and approving our suppliers. A list of approved suppliers is maintained.

CONTROL OF CUSTOMER-SUPPLIED PRODUCT

Document number, Document Number, explains EDR Inc.'s process for the control, verification, storage, and maintenance of customer-supplied products.

PRODUCT IDENTIFICATION AND TRACEABILITY

A procedure, 2006331, has been established for identifying a product or lot by suitable means from receipt and during all stages of production, delivery, and installation.

PROCESS CONTROL

Process Control Procedure

EDR Inc. has created a documented procedure, Document Number, which defines the method for controlling manufacturing, applicable service, production and installation processes.

Work Instructions

Work instructions are prepared, maintained and monitored. These instructions reflect requirements and may include manufacturing plans, travelers, routers, work orders, or process cards.

Configuration Control

EDR Inc. maintains accountability and configuration control of all parts during all phases of production.

Split Order Quantities

EDR Inc. documents and maintains control of split order quantities.

Customer Approval of Process or Processor

When customer approval of a process or processor is required, EDR Inc. uses only customer-approved sources.

Tooling Control Procedure

EDR Inc.'s tooling control procedure, Document Number specifies the care and control of tooling, including customer-supplied tooling. EDR Inc. maintains records in compliance with procedure, Document Number.

INSPECTION AND TESTING

Inspection and Test Procedure

The procedure, Document Number, describes EDR Inc.'s process for verification of product compliance with specifications. Detail instruction may be found in authorized work instructions for the inspection/test activity.

Product Inspection

EDR Inc. inspects the product to ensure that it conforms to the purchase order or contract, drawing, and specifications.

Certification Test Reports

When certification test reports are utilized to accept material, EDR Inc. ensures that data in said reports are acceptable per applicable specifications. EDR Inc. validates test reports periodically.

Final Inspection

EDR Inc. performs final inspections and verifies that all inspections and tests have been completed.

First Article Inspection

EDR Inc. performs inspection, verification, and documentation of the first production article, as appropriate.

First article inspection documentation is retained and includes a list of the characteristics required by the design data and any required tolerances, the actual results, and when testing is required, the results of the test.

The First Article Inspection is updated to include changes to production processes or product configuration.



CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

Calibration Procedure

EDR Inc.'s calibration process is defined by document Document Number. The scope of the procedure includes the control, calibration and maintenance of all inspection, measuring, and test equipment that can affect product quality, including test software and personally owned equipment, and customer-supplied equipment.

Calibration Traceability

Calibrations are traceable to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration is documented.

Identification of Calibration Status

Equipment is identified with suitable indicators or an approved identification record of the calibration status.

Precautions for Out of Calibration Equipment

EDR Inc. assesses the validity of previous inspection results when equipment is found to be faulty or out of calibration and recalls the product for re-inspection when the assessment indicates the result may be nonconforming product.

INSPECTION AND TEST STATUS

Identification of Inspection and Test Status

EDR Inc. maintains a documented procedure, Document Number, for the identification of inspection and test status.

Identification of Conforming and Nonconforming Product

The inspection and test status of a product is identified by suitable means, which indicate the conformance or nonconformance of a product with regard to the inspection and tests performed.

Inspection and Test Status Traceable to Individual

The inspection and test status of a product is traceable to the individual performing the acceptance.

CONTROL OF NONCONFORMING PRODUCT

Control of Nonconforming Product Procedure

EDR Inc.'s procedure for the control of nonconforming product is Document Number. This procedure requires and specifies the identification, documentation, evaluation, segregation, disposition, and notification to concerned parties of a nonconforming product.

Allowable Dispositions

The procedure described in 4.13.1, above, restricts the application of preliminary review on dispositions to "rework", "regrade", "scrap", "return to supplier". The procedure further requires that nonconforming product be submitted to the customer for authorization when a disposition to "repair" or "use as is" is requested.

No "Regrade" Disposition on Products of Customer-Proprietary Design

The document of 4.13.1 prohibits the use of "regrade" dispositions on products of customer proprietary design.

Regrading Material

Product dispositioned for regrade requires a change in product identification to preclude

the product's original use. Adequate test reports and certifications reflect the regrading.

Disposition of EDR Inc. -Design Nonconforming Product

Unless otherwise restricted in the contract, a product designed by EDR Inc. that is controlled by means of a customer specification may be dispositioned by EDR Inc. as "use as is" or "repair", provided the nonconformity does not result in a departure from customer-specified requirements nor affect form, fit, function, reliability or maintainability.

Re-inspection of Repaired or Reworked Product

All products that have been repaired or reworked are re-inspected in accordance with documented instructions.

Identification of Scrap Product or Material

Scrap product or material is conspicuously and permanently marked or separated from production material until physically rendered useless for the original production.

Notification of Customer Upon Discovery of Delivery of Discrepant Product

It is EDR Inc.'s policy to promptly notify the customer when it is discovered that discrepant material or product has already been delivered. Notification includes the concise description of discrepancy, parts and serial numbers affected, lot numbers, delivered quantities, and delivery dates.

CORRECTIVE ACTION

Corrective Action Procedure

EDR Inc. has implemented procedure number Document Number for the processing of corrective actions.

Corrective Action Response

When written corrective action is required, the response addresses immediate correction of the discrepancy, root cause, root cause correction, corrective action verification plan, and follow-up and includes a restatement of the finding.

HANDLING, STORAGE, PRESERVATION AND DELIVERY

Document number, Document Number, describes the steps taken by EDR Inc. to prevent damage or deterioration due to handling, storage, packaging, preservation, and delivery of a product.

CONTROL OF QUALITY RECORDS

EDR Inc.'s quality records meet the following conditions:

Maintained

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

Retained

Quality records are retained as specified by contract.

Available

Quality records are available for customer and regulatory agency examination.

INTERNAL QUALITY ASSESSMENT

Electronic Design & Research performs scheduled, documented assessments that



include its quality procedures and records in order to determine the effectiveness of its quality system. As appropriate, personnel independent of the function being assessed perform the assessments.

TRAINING

Personnel performing specific assigned tasks are qualified on the basis of appropriate education, training, and/or experience. Training records for personnel affecting quality are maintained.

SERVICING

Not applicable to AS9003.

STATISTICAL TECHNIQUES

Implementation of Statistical Techniques

Electronic Design & Research considers the use of statistical techniques and maintains documented records where such techniques are implemented.

Customer-Approved Acceptance -Sampling Plan

When required by contract, EDR Inc.'s acceptance sampling in accordance with a customer-approved acceptance-sampling plan.

Appendix

Forms or other attachments that are applicable to the document are attached in the appendix.

APPENDIX A: ORGANIZATION, RESPONSIBILITY AND AUTHORITY

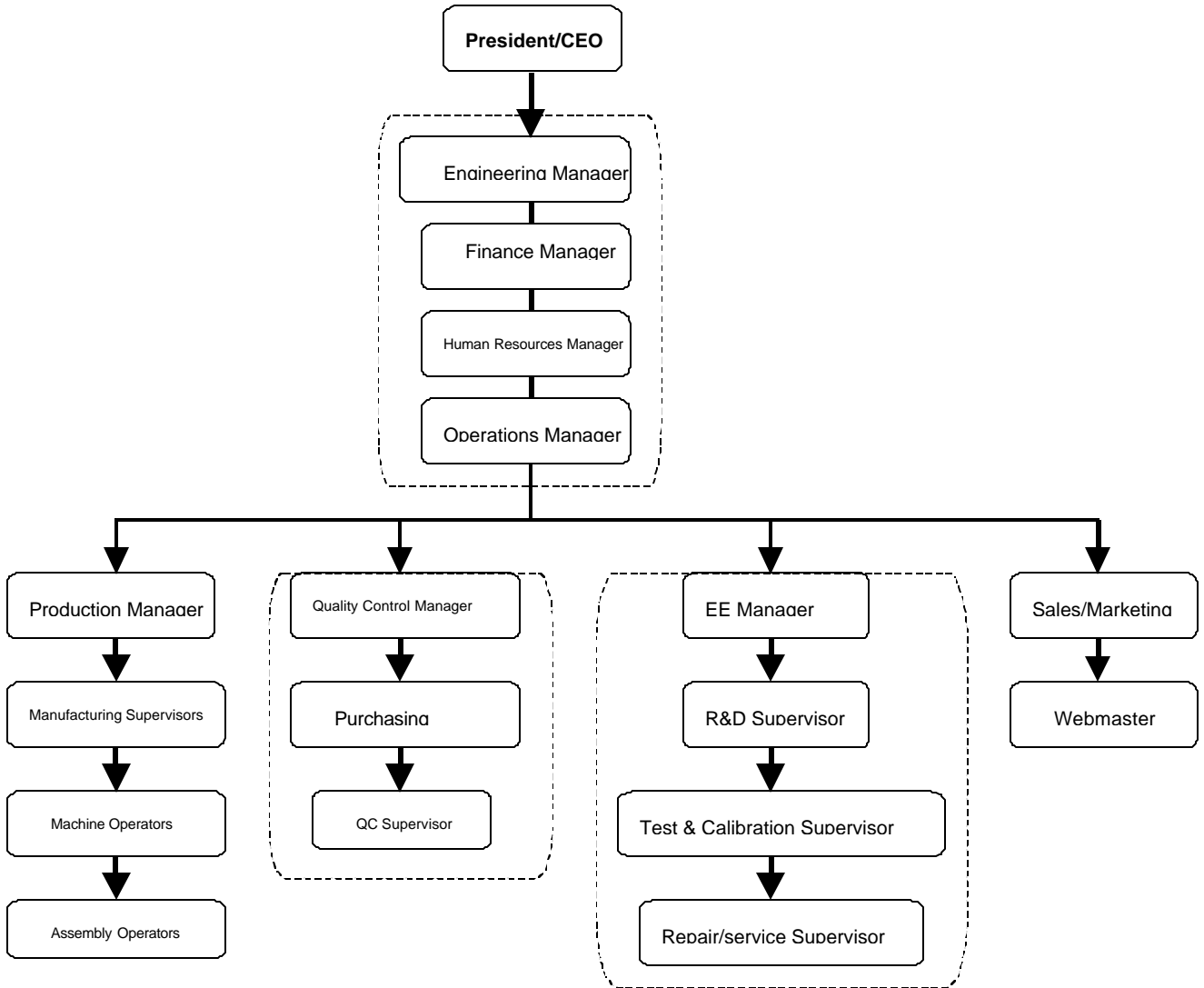
APPENDIX B: LIST OF SUPPORTING QUALITY DOCUMENTS

APPENDIX C: to EDR Inc. suppliers



Appendix A

ORGANIZATION, RESPONSIBILITY AND AUTHORITY of Electronic Design & Research Inc.



Appendix B

LIST OF SUPPORTING QUALITY DOCUMENTS

Quality Manual Paragraph	Record(s)	Document(s) Description	Document Number	Document Title
4.1.1		Quality Policy		
4.1.2		Who's responsible for Quality		
4.2.1		Quality Manual		
4.3		Contract Review Procedure		
4.3	Contract Review Records			
4.5.1		Document Control Procedure		
4.5.2	Change Incorporation Record			
4.6.1		Procedure for Verification of Purchased Product		
4.6.7	List of Approved Suppliers			
4.7		Procedure for Control of Customer-Supplied Product		
4.8		Procedure for Product Identification and Traceability		
4.9.1		Process Control Procedure		
4.9.2		Work Instruction, Traveler ...		
4.9.6	Tooling Control Records	Tooling Control Procedure		
4.10.1		Inspection/Test Procedure		
4.10.5	First Article Inspection Documentation			
4.11.1		Calibration Procedure		
4.11.3	Calibration Tags or Records			
4.12.1		Identification of Inspection/Test Status Procedure		
4.13.1		Nonconforming Material Control Procedure		
4.14.1		Corrective Action Procedure		
4.15		Handling, Preservation, Packaging Procedure		
4.16	Quality Records			
4.17	Internal Audit Schedule and Result Records			
4.18	Training Records			
4.20.1	Records of Implementation and Application of Statistical Control Methods Used			

Attention: to Suppliers

Electronic Design & Research is a self-declared of compliance with quality system AS9003. We expect all suppliers to conduct their worldwide operations in a socially and environmentally responsible manner. Our goal is to work collaboratively with our suppliers to encourage compliance with:

- Local, state, federal and international standards and laws.
- We encourage all suppliers to have continual improvement programs that integrate environmental, occupational, health and safety into their business and decision making process.
- Suppliers to maintain effective management systems that are based on sound business and scientific principals. Which include establishing appropriate objectives and targets regularly assessing performance and practicing continued improvement.

PREPARED BY: (Signature On File)
Originator

APPROVED: (Signature On File)
Engineering

APPROVED: (Signature On File)
Manufacturing

APPROVED: (Signature On File)
Quality Assurance



PRODUCT IDENTIFICATION AND TRACEABILITY

All products assembled will have a unique identifier or part number. This identifier is correlated to corresponding drawings, specifications, software, hardware and other project specific technical material. The identifier will also encompass different levels of the project evolution process. However, consumables (e.g. Solder, wires' for wire-wrapping etc.) used during the project manufacturing process do not require a unique identifier. Quality Assurance Manager shall be responsible for maintaining Product Identification and Traceability.

All finished products will be identified by a part number, unique name and a serial number Picture 1 (or by a lot number, Picture 2.)



Picture 1



Picture 2

4.8.1 Definition

The word " Product" as used in this section of the Quality Manual, is defined to be any :
Modules (encapsulated, designed to perform a specific function, assembled device, e.g.: Solid State Relay, High-Pass Filters, iUPS, iSSR, 50/60Hz Comb Notch Filter, Ultra-low noise pre-Amplifiers, Phase-Detectors, F-to-V converters, Drivers, etc.)
Equipment (a device, designed to perform a complicate tasks and as usually assembled inside an enclosure (e.g.: Universal Electronic Load, Power Line Filter, Cardio-stimulators, H-ECG, Life alert 1000, Life Alert 1001, etc.)

Software (e.g.: Life Alert 1001's Operating System, APA-4's operating software, CAD Tool, etc.)

Documentation (e.g.: Data Sheet, Operating Manual, Design / Progress Reports, etc.).

4.8.2 Part and Product Identification

All products being developed or assembled shall have a unique part, if appropriate a name, and product identification. The finished product shall be categorized with a serial number or a lot number.

4.8.3 Product Identification Code Format

All product identification codes (PIC) shall follow a strict format. The format may only be changed in the instance where a product cannot be uniquely identified under the current structure. In this case, the Quality Manager is notified of the problem, and appropriate corrective action sought.

Part Number, Unique name, and serial number

Example:

EDR82366/4
D3G40D10/24
Lot#0306

Which is interpreted as :

Part Number : EDR82366

Unique Name (description): D3G40D10/4

Serial Number: absent

Lot #: 0306

Part Numbers and Unique Name are assigned to all devices manufactured since 1984. These numbers are a part of the Product Identification Code (PIC) for purchased/received goods. A product can be identified and ordered by a Part Number and/or Unique Name.

8.4 Identification Number Record (INR)

Electronic Design and Research maintains an Identification Number Record (INR) for every project it under-takes. The INR file includes and maintains all unique Product Identification Codes, Serial Numbers for finished products as well as Part Numbers for purchased/received goods. The INR shall be maintained by the QA Manager and updated at any change or modification made and authorized by the President and/or EE Engineering Manager.



PROCEDURE

1.0 Identification of Purchased Products

- 1.1 Purchased materials and parts are identified with unique numbers, codes, or names. The identification is the same as used in drawings, specifications, bills of materials, part lists, purchase orders, etc.
- 1.2 Whenever possible, suppliers are required to identify the products they supply with our part numbers. The receiving clerk verifies that products are properly identified (refer to procedure, Verification of Purchased Product). If the original identification is not appropriate or adequate, the Receiving function is responsible for marking purchased products, or the packaging, with our company's part numbers.
- 1.3 Materials and parts are identified by marking, labeling, or tagging the packaging or containers holding them and, when appropriate and practical, by labeling the products themselves. Products may be also identified by general identification of the area dedicated for storage of particular product (a dedicated shelf in the material stockroom or in the material staging area, for example).
- 1.4 Materials and parts identification is maintained while the products are in storage and/or are staged for production.

2.0 Identification During Production

- 2.1 During all stages of production, in-house manufactured parts and subassemblies are usually identified by the work order, in-process inspection records, and other documents and/or electronic records created during manufacturing, assembly, and inspection or testing of a product. These documents and records are kept or made available electronically in the area where the product is being processed or is staged for the next processing step. Some parts and subassemblies are identified by permanently marked part numbers, or reside in marked containers.

3.0 Identification of Final Product

Final products are identified by their unique name, product identification number, and serial number (or a lot number). This identification is labeled or marked on the products and/or is printed on the primary product packaging. Example:

EDR82366/4
D3G40D10/24
Lot #0306

EDR82366/4 is an internal product identification number.

D3G40D10/24 is a product unique name and it is interpreted as: Single Pole, Single Throat (SPST) Solid State Relay.

"D" device functionality
"3" for a type of package,
"G" for a speed,
"40" for a maximum applied voltage,
"D" for a VDC voltage,

- “10” for a maximum applied current
- “24” for a control voltage.

Traceability is very important procedure that helped trace to origin of a problem if such raised and for that reason and determine a warranty period all manufacture products are identified with their serial or lot numbers. Using a serial number or a lot number for identification is determined by the President, the EE Manager and/or the Quality Control Manager. In most cases preferred a serial number and especially a product costs more than \$250.00 ea and there is available room to print (engrave a serial number). A product costs less than \$250.00 and especially it is a small size a lot number is a choice.

4.0 Part Number and Product Configuration Records

4.1 For in-house designed products, Engineering maintains records correlating each issued part number to corresponding drawings, specifications, technical data, and other documentation defining the part.

4.2 For products that are assembled from numerous parts, Production maintains product configuration records. The records correlate production periods, batches of products, or individual products with the bills of materials and parts lists used in their manufacture and assembly.

4.2.0 Traceability

4.2.1 Traceability is maintained when specified by customers, governmental regulations, or internal requirements. The extent of traceability is defined in accordance with the stated requirements.

5.2 When required, purchased products are traceable to their purchase orders — and thereby to their original inspection, testing, or lab analysis reports, or other such quality records supplied with the products.

5.3 When required, during production, traceability is maintained using bills of materials, work orders, inspection records, and other such documents and records established during the manufacture, assembly, inspection, and testing of a product. In these documents(records), process operators and inspectors record serial and batch numbers of materials and parts used; identify process and inspection equipment and their operators; note process parameters; identify personnel performing final labeling operations; and record other such information necessary to satisfy traceability requirements.

6.0 Traceability Records

6.1 When traceability is required, Production maintains (or coordinates) the traceability record. The record usually consists of purchase orders for materials, parts and components; material inspection and testing reports; process data and product inspection and testing reports. The exact scope of the required traceability record for a given product is documented in manufacturing specifications or the production work order.

6.2 Whenever possible and practical, traceability information is recorded directly on the work order. For each relevant operation, operators or inspectors record material batches, equipment, process parameters, environmental conditions, and when other such traceability information, as required.



Document and DATA control

- a. The Quality System Manual (QSM) policies & procedures are available for viewing on the company's INTRANET in an electronic format. Personnel requiring access to this information are either trained or are provided access via department leaders.
 - b. QSM policy / procedure documents contain the following verbiage under the header: "Uncontrolled copy when printed unless signed with an expiry date." To remain as a controlled document after being printed, these documents must be signed by an appropriate authority and issued a "Printout Expiry Date." The authorities include department trainers, Supervisors & Managers.
 - c. Printouts of OMNI 'CF-XX' forms / documents that will be used to control quality remain in a controlled status unless stamped "Reference Only".
 - d. Printouts of database reports / documents are considered uncontrolled unless they form part of a controlled paper document or will exist as a quality record.
 - e. Essential data for Purchasing, Inventory Control and Sales are generated through pertinent software databases. Authorized users have been granted password-protected access to the pertinent software by an issuing authority (*or designate*).
 - f. Computer source files are protected via a daily automated backup process that is scheduled to start and run automatically after business hours. The backup media is data cartridges that are rotated offsite each day to furnish the restoration of critical files in the event of equipment malfunction, fire, theft or other problem.
 - g. Externally-supplied forms, tags and other company-specific stationary that are currently in use at OMNI are grand-fathered in the Quality System. When revisions are required, they will incorporate a revision indicator as uniquely appropriate.
- a. Controlled documents are identified on Master Lists. The documents are reviewed & approved by authorities defined on the pertinent Master Lists for adequacy prior to issue or release.
 - b. Evidence of approval control is indicated according to the pertinent category:
 - i. Electronic & paper-based documents approvals are accomplished with the use of the paper-based Document Change Notice: CF-001 on which the approving authority and approval date are identified.
 - ii. Controlled data is considered approved after input or amendment by qualified users. Authorized users have been granted password-protected access to the pertinent software by an issuing authority (*or designate*).
 - a. Controlled documents are amended as per the following details. All company personnel can formally submit change / amendment requests to document issuing authorities using the Document Change Notice or by the following

system:

- i. Obtaining a copy of the document to change;
 - ii. Marking the document "Reference Only";
 - iii. Clearly & completely defining the change(s) requested on the document;
 - iv. Forwarding the document to the issuing authority (or designate) for review.
- b. The Document Change Notice: CF-001 has been developed to allow both the electronic and hand-written input of document change details. In both methods, CF-001 is accessed & printed from the corporate Intranet along with a copy of the document to be changed. The amended document is attached to CF-001 for use as a reference.
- c. The issuing authority has access to pertinent background information for the review & approval process. Document & data amendments are reviewed and approved by the issuing authority (or their designate) prior to implementation using the same control system as defined above in point #4.2.3.2.
- d. Amended paper-based documents are either physically distributed or electronically available at locations identified on the pertinent Master List. Amended electronic documents and data are available from a networked database, or from the Intranet website.
- e. The nature of amendment details are identified as per the following methods or as uniquely appropriate to help identify changes from the previous revision:
- . Changes to Quality System Manual (QSM) documents are identified by yellow shading as viewed on the Intranet) over the text in changed sections.
 - i. Changes to 'OMNI' procedures and controlled OMNI forms are identified on a Document Change Notice: CF-001 &/or in the right-hand column of the amended document as appropriate.
 - ii. When amended details are deemed by the issuing authority to not affect quality or are not practicable to identify, the changes are not highlighted.
- f. The issuing authority will notify pertinent users (or trigger a notification system) of changed documents and data that affect the quality system. Impact to other quality system documents & data (and resultant training needs) are to be considered during the amendment process and included in the notification process as required.
- a. Hand-written amendments are identified in a manner that is uniquely suitable for the particular application. The amended details are dated and initialed by the amending authority.
- a. Revision levels are updated at the source file for electronic data.
- b. Revision dates on Intranet-based Master Lists are updated for electronic & paper-based documents.

- c. Master locations for OMNI controlled documents is the company Intranet. Controlled data is distributed electronically on the computer network. Master locations for other quality system documents are defined on Master Lists.
- d. Department managers are responsible for ensuring that pertinent issues of appropriate documents, including access to Intranet-based documents & data, are available to personnel at pertinent locations in their department.
- a. All documents are handled using methods that retain their legibility and are stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage, deterioration or loss.

Documents of external origin that impact quality of product are typically customer-supplied engineering specifications & drawings. Documents that are updated from customer-supplied amendments are initially received by client services. The Production Mgr (*or designate*) distributes the changed documents to pertinent production department locations as uniquely appropriate.

Statutory and regulatory standards documents that apply to OMNI products are considered uncontrolled (unless they are a contractually specified requirement) and reside in a "Reference Only" area or are individually stamped with a "Reference Only" marking.

Issuing authorities (or their designate) are responsible to ensure that invalid or obsolete documents are removed, destroyed or physically separated from all points of issue to prevent unintended utilization.

When retained for legal or knowledge preservation purposes, controlled documents are separated from issue sources and suitably identified with a "Reference Only" or "Obsolete" marking as uniquely appropriate.



4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

4.15.1 General

Electronic Design & Research, Inc. shall establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.

Procedures shall be established to cover how product is handled, stored, packaged, preserved and delivered, in such a way to prevent damage or deterioration through all processes, including delivery of the product to its final destination.

4.15.2 Handling

Electronic Design & Research, Inc. shall provide methods of handling product that prevent damage or deterioration.

Procedures shall be established for the handling of materials with consideration given to the transport of product (such as containers, pallets, etc.) so that damage, deterioration, or contamination may be prevented.

4.15.3 Storage

Electronic Design & Research, Inc. shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

Procedures for suitable storage shall be established addressing physical security, controlled areas, proper identification and environmental conditions when necessary.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

Procedures shall be established for the periodic assessment of product and materials. These assessments shall be conducted and recorded to ensure that proper preservation is maintained.

4.15.4 Packaging

Electronic Design & Research, Inc. shall control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

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Packaging procedures shall be established for processes of packing, and marking, to the extent necessary to ensure conformance to specified requirements.

4.15.5 Preservation

Electronic Design & Research, Inc. shall apply appropriate methods for preservation and segregation of product when the product is under Electronic Design & Research, Inc.'s control.

Procedures shall be established as appropriate to identify, preserve, and segregate all products from time of receipt until the responsibility of *Electronic Design & Research, Inc.* is complete. Special storage requirements, when required, may include: a) part number, b) lot number, c) assigned location, d) segregation through a means of identification, and e) bonded and/or controlled storage.

4.15.6 Delivery

Electronic Design & Research, Inc. shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

Procedures shall be established to control the method of delivery after final inspection and test, where appropriate, that ensure product is received by the customer in a manner that is consistent with contract specifications. Consideration will be given to various types of delivery and the variations in environment which may be encountered.

Supporting Documents:

- Material Handling Procedure (4.15-1)
- Storage and Preservation Procedure (4.15-2)
- Packaging Procedure (4.15-3)
- Delivery Procedure (4.15-4)

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