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QUALITY MANUAL

1.0 PURPOSE

To define DPS policies and procedures concerning Quality Management, in general agreement with ISO 9001, Quality System, Model for Quality Assurance in Design, Development, Production, and Servicing.

2.0 POLICY

DPS shall document, maintain and review policies and procedures as outlined in this Quality Manual.

3.0 MANAGEMENT COMMITMENT

Management shall continually demonstrate commitment to:

- Ensure that all DPS personnel understand and implement the policies and procedures outlined in this Quality Manual.
- Following up on the implementation of the quality policies and procedures.
- Providing adequate resources and training to support the quality system development, implementation and improvement.

4.0 RESPONSIBILITY AND AUTHORITY

The responsibility, authority and the interrelation of the key personnel that manage, perform and verify work affecting quality are defined in paragraph 4.1 of this document. These personnel shall have the organizational freedom and authority to:

- Initiate action to prevent the occurrence of any nonconformity relating to the quality system.
- Identify and record any problems relating to the quality system.
- Initiate, recommend or provide solutions concerning quality issues.
- Verify the implementation of solutions to quality issues.

In addition, the overall quality process is the responsibility of every employee at DPS. The work performed by each employee is inspected by at least one other employee with knowledge and training in the same work area.

4.1 JOB DISCRPTIONS

President – David Pierce

Oversees the daily operations of the manufacturing facility.

Engineering Management Teams –

Electronics – John Iest

Mechanical – Darius Kelley

Software – Dan Beadle

Applications – David Pierce

Quality Management Team –

Meets weekly to discuss work in progress, special applications and requirements, and update other team members on new projects, revisions, and enhancements to products.

5.0 RESOURCES

Management shall identify resource requirements and provide adequate resources, including the assignment of trained personnel, to perform verification of policies and procedures including internal quality audits.

Adequate resources shall include but are not limited to the following:

- Adequate training.
- Schedules that include time for design verification, inspections and testing.
- Appropriate tools and equipment.
- Documented polices, procedures and work instructions, as appropriate.

6.0 REVIEW PROCESS

Management shall review the Quality System twice a year to include as a minimum the review of the Quality Manual, Procedures, and adherence to compliance requirements. Such review shall be documented and maintain in a Quality System Review File.

7.0 RECORDS

Compliance records shall be maintained for ten years. Other records shall be maintained for minimum of two years unless otherwise specified in the applicable procedure.

8.0 DESIGN CONTROL

DPS shall design, develop, verify, and validate all products in accordance with the procedures outlined herein:

- A primary design team will be defined for each new product.
- The design must comply with the requirements of the customer, or application.
- The instrument will be tested against the application performance requirements.
- The instrument must also pass the standard final test and inspection criteria.
- Appropriate operation, installation, and service documentation will be generated and added to the instrument manual.

8.1 DESIGN CHANGES

Prior to the implementation of design changes, such changes shall be identified, reviewed and approved by the same functions/organization that performed the original review. All such changes shall be considered for notification to the applicable compliance agencies.

9.0 DOCUMENTATION

DPS shall keep on file records pertinent to: design, purchasing, work execution, quality standards, inspection of materials compliance, and all quality system documents.

10.0 PURCHASING

DPS shall maintain records of approved parts and associated vendors. All parts and supplies defined in the technical construction document will be checked to assure that they have the appropriate rating, marking, etc. upon delivery.

10.1 EVALUATION OF SUBCONTRACTORS AND VENDORS

DPS has a policy of procuring parts and components that meet compliance requirements and check incoming parts against compliance requirements. We do not evaluate or audit individual subcontractors or vendors.

11.0 PROCESS CONTROL

DPS shall produce all products, under controlled conditions, in accordance with the applicable procedures. These procedures shall include the following:

- Use of safe and suitable working environment.

- Compliance with national recognized standards, codes, and compliance agreements.
- Acceptance criteria for workmanship.
- Maintenance of equipment.
- Special procedures and the associated material/equipment.
- Required records.

12.0 INSPECTION AND TEST

These procedures shall include the following:

- Incoming product is not used or processed until it has been inspected or otherwise verified as conforming to the applicable specifications.
- All sub-assemblies shall be checked by at least one other employee with suitable training and experience.
- Final assembly shall complete the “Final Assembly Checklist” and have another final assembly employee verify their work.
- The instrument test department employees shall test, complete and sign the “Quality Control Inspection & Testing” form. Any non-conforming part shall be recorded on the work order and repaired or replaced. Another test technician shall inspect and verify the performance and completeness of the final testing procedure. Performance records shall be maintained for each instrument.
- No instrument will be released from the test department unless it meets all quality standards. We shall not produce any non-conforming instruments.
- Shipping will once again check the original purchase order and verify that the final product included all items listed. A copy of the final test form and performance data are inserted in the instrument manual and shipped with the instrument.

12.1 TESTING EQUIPMENT

These procedures shall include the following:

- Ensure that the environmental conditions are suitable for the inspection/test.
- Ensure that the handling and storage of the test equipment is adequate.
- Safeguard the test equipment from adjustments or damage.
- Ensure that the calibration program is traceable to NIST or National standards, and maintain a record and schedule for re-calibration.

14.0 SHIPPING

Instruments shall be packaged and verified against the appropriate “Shipping Check List”.

14.0 TRAINING

Every DPS employee affects the quality of our products. Consequently, every employee is responsible for the quality of each product we produce. Every new employee is trained by an experienced employee. Each step of the manufacturing process is cross checked by a trained employee, and the final product is subjected to a series of functional and performance tests.

15.0 INTERNAL QUALITY AUDITS

These procedures shall include the following:

- Instrument performance audits are performed on a random basis by DPS in Germany.
- Audit results are discussed by the Quality review team.
- Corrective action.
- Follow-up audit activities.

16.0 SERVICING

Service activities are handled by each distributor. We have designed our products to be installed by the end user and serviced over the telephone. When additional service or upgrades are requested, they are handled through our central service center in Germany. Our service center:

- Assumes the authority and responsibility for servicing the instrument.
- Documents the work performed.
- Feeds back critical information to the Quality management team.