

# Rose Electronics Distributing Co., Inc.

## Quality Manual

MAN-07-5

PRODUCT REALIZATION			
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<b>Operations</b>			

### GENERAL POLICY

Product and process information and appropriate work instructions are established and are communicated to relevant personnel. Operations and production processes are monitored and controlled, and are validated where appropriate. Machines and equipment used in production and for monitoring and measurement activities are maintained. Methods for product release and delivery are defined.

Materials, components, parts, subassemblies, and finished products are identified. When required, traceability of materials and processes are recorded and maintained. Inspection and test status of product is identified to ensure that only product that has passed the required inspections is used, installed, or dispatched.

Customer-supplied products are normally controlled in the same manner as are purchased products. Customer-owned tools, equipment, software, or other property are marked to indicate ownership. Loss, damage, or unsuitability of a customer's product is recorded and reported to the customer.

Appropriate handling, storage and preservation methods are implemented to prevent product damage or deterioration. Receipt and dispatch to and from storage areas are controlled. The condition of products in stock is regularly assessed. Product packaging materials and methods are specified and controlled.

### PROCEDURAL POLICIES

#### 1. OPERATIONS CONTROL

##### 1.1 Product and process information

1.1.1 Information specifying product characteristics is communicated to production in the form of drawings, specifications, samples, instructions, work orders, and product-specific templates and other tooling. This information is controlled in accordance with Operational Procedure QOP-42-04, Control of Documents. Engineering, Production and Quality Assurance determine the scope, form, and distribution of product specifications.

1.1.2 Product and process information required by process operators is communicated through the work order or is included in work instructions. Where required for custom products,

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engineering drawings and specifications may be enclosed with the work order. Operational Procedures MOP-75-01, Production Control, and work instructions WI-75-01C, Master Document File Generating, and WI-75-01D, Master Document Generating for ESD Sensitive Assemblies, explain how to establish and use these documents.

### 1.2 Work instructions

- 1.2.1 Work instructions and workmanship standards may be in the form of manuals, procedures, sheets, posted signs, or samples. They instruct on how to carry out a process or perform an operation or task. The need for work instructions is evaluated on the basis of criticality, importance and complexity of the process; the ability to verify results of the process; operator qualifications; and history of quality problems associated with the process. Workmanship standards are provided when acceptability of the process output can only be determined by comparison with a standard sample.
- 1.2.2 Operational procedure MOP-75-02, Manufacturing Process Control, specifies criteria for determining when work instructions are needed, and provides guidelines for issuing, authorizing and controlling work instructions.

### 1.3 Equipment maintenance

- 1.3.1 Maintenance of key process equipment, machines, hardware, and software are addressed in Section 6.3 of this manual and in Operational Procedure QOP-63-01, Equipment Maintenance.

### 1.4 Measuring and monitoring equipment

- 1.4.1 Production and Quality Assurance determine requirements for measuring and monitoring equipment. This is in accordance with process control and product verification programs defined in product realization planning (refer to Section 7.1 of this manual).
- 1.4.2 Control system for measuring and monitoring equipment is defined in Operational Procedure QOP-76-01, Measuring and Monitoring Equipment.

### 1.5 Process monitoring and control

- 1.5.1 Processes are monitored and controlled through a variety of approaches, activities and techniques. The system is designed to control:
- Information, material and human (operator) input into the process;
  - Technology, tools and equipment used;
  - Process environment and performance; and
  - Process output.

Process monitoring activities are further defined in Section 8.2 of this manual. Activities

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related to process control are defined in operational procedures QOP-75-01, Production Control and applicable work instructions

### 1.6 Product release and delivery

- 1.6.1 Products are released for delivery only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Operational Procedure QOP-82-11, Final Inspection, define the system for final product verification and release.

## 2. VALIDATION OF PROCESSES

### 2.1 Special processes

- 2.1.1 Processes where the resulting output cannot be verified by subsequent measurement or monitoring is designated as special processes.
- 2.1.2 Production and Quality Assurance are responsible for identifying, validating, and documenting special processes. Where applicable, Engineering may assist with establishing validation specifications and testing of samples.

### 2.2 Validation

- 2.2.1 Special processes are validated and controlled by applicable methods, such as destructive testing of product samples, equipment and personnel qualification, and work instructions and process procedures.
- 2.2.2 Production and Quality Assurance are responsible for selecting and implementing appropriate process validation and control measures for each special process. At a minimum, all special processes are documented in work instructions.
- 2.2.3 Special process records are established and maintained as appropriate. Depending on the control measures implemented, these records may include process qualification and validation reports, equipment qualification and maintenance records, first article inspections and tests, operator qualification and training records, and so forth.

## 3. IDENTIFICATION AND TRACEABILITY

### 3.1 Product identification

- 3.1.1 Purchased products are identified with unique numbers, codes, or names. The identification is the same as, or is cross-referenced with, the designations used in drawings, specifications, bills of materials, parts lists, purchase orders, etc. Purchased products are identified by marking, labeling, or tagging the products or their packaging, or by identification of the area where the products are held.

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- 3.1.2 During all stages of production, products are usually identified by work orders and other documents that accompany them through the production cycle. Parts and components may also be identified by labels or tags, or the containers in which they are held.
- 3.1.3 Final products are identified by their name and model number, which is labeled or marked on the products and/or is printed on the primary product packaging.
- 3.1.4 Rules and activities related to identification of products are governed by Operational Procedure MOP-75-03, Product Identification and Traceability. Additional relevant procedures are MOP-75-01, Production Control; MOP-74-03, Verification of Purchased Product; QOP-82-11, Final Inspection; and MOP-75-09, Packaging, Labeling and Shipping.

### 3.2 Traceability

- 3.2.1 When required by contracts, laws and regulations, or voluntary standards traceability is implemented to the extent specified. Traceability may also be implemented for internal reasons, to facilitate corrective action.
- 3.2.2 As required, traceability may apply to materials, components, parts, production processes, environmental conditions, inspection and testing, and personnel responsible for processing and verification of products. The scope of traceability is documented in product manufacturing specifications or the production work order.
- 3.2.3 Activities related to establishment and maintenance of traceability are regulated by Operational Procedures MOP-75-03, Product Identification and Traceability, and MOP-75-01, Production Control.

### 3.3 Inspection status identification

- 3.3.1 Following every inspection or test, products are identified to indicate whether they have passed or failed the inspection. This is to prevent nonconforming product from being used or dispatched. Physical location of product can only be used as inspection status identification when the location is designated and contained, and in automated production transfer processes.
- 3.3.2 QC inspectors, receiving clerks and production personnel authorized to carry out inspections and testing are responsible for identifying product inspection status. All personnel handling products are responsible for maintaining the identification.
- 3.3.3 Products that have passed the receiving inspection are moved to the material warehouse. Where intermingling with other product is a possibility, the inspected items are also appropriately tagged or labeled. Detailed rules for identifying inspection status of purchased products are provided in procedure POP-74-03 Verification of Purchased Product.
- 3.3.4 Status of an in-process inspection is usually identified by a sign-off in the work order

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accompanying the product. The status may be also identified by tagging or labeling, or holding products in designated containers. Operational procedure QOP-82-10, In-process Inspections, provides more detailed instructions.

3.3.5 Products that pass the final inspection are placed in the finished product area that is designated and used only for this purpose. Rules for identifying inspection status of finished products are provided in procedure QOP-82-11, Final Inspection.

3.3.6 Products that fail any inspections or tests are segregated and/or quarantined. Whenever a nonconforming product is identified, the nonconformity is documented using a product nonconformity report. Procedure QOP-83-01, Control of Nonconforming Product, instructs on how to identify and process nonconforming product.

### 4. CUSTOMER PROPERTY

#### 4.1 Receiving

4.1.1 Customer-supplied products are received and inspected following the same procedure that applies to purchased products, i.e., Operational Procedure POP-74-03, Verification of Purchased Product. In the event the supplied products fail receiving inspection, or are not suitable for any other reason, the customer is contacted.

#### 4.2 Marking, storage, and handling

4.2.1 Marking, storage, handling, and preservation of customer supplied products follow the same procedures that apply to purchased products. The applicable procedures are MOP-75-03, Product Identification and Traceability; MOP-75-04, Product Handling and Preservation; and MOP-75-08, Storage Areas.

4.2.2 Customer-owned tooling and returnable packaging are permanently marked so that ownership of each item is visually apparent.

4.2.3 Customer's software, documents, and other intellectual property are protected to the same extent as would internal ROSE's documents of similar content, unless there are contractual requirements for special measure to protect customer's intellectual property.

#### 4.3 Special requirements

4.3.1 When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures.

#### 4.4 Loss or damage

4.4.1 Customers are contacted in the event of loss, damage, deterioration, or unsuitability of their products.

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### 5. PRESERVATION OF PRODUCT

#### 5.1 Product handling and preservation

5.1.1 Production and Warehouse are responsible for product handling and preservation; and in particular for ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage. Procedure MOP-75-04, Product Handling and Preservation, describes in detail how these policies are implemented.

#### 5.2 Storage

5.2.1 Warehouse staging and holding areas are controlled by the department that brings in new stock or uses the area. Only products that are properly identified and that have passed required inspections are authorized to enter and leave the warehouse. Every six months the stockrooms are inspected to assess the condition of stock.

5.2.2 When special storage conditions are specified (for example, temperature or humidity), products are stored in special rooms, boxes, or containers where the specified conditions can be continuously maintained. These special conditions are monitored to ensure that they are maintained without interruption and that the product is not compromised at any time.

5.2.3 Products with limited shelf life are identified with the manufacturer's date codes. These products are used first-in, first-out (FIFO) to ensure that the oldest product is used first.

5.2.4 Material is controlled using an inventory management system. The system can report available in stock quantities and turnover times. The system is used to optimize and minimize inventory levels.

5.2.5 Procedure MOP-75-08, Storage Areas, governs the operation of the warehouse, staging and holding areas.

#### 5.3 Packaging and labeling

5.3.1 Primary packaging are boxes, bags or other packaging in which products are presented to the end users.

5.3.2 Secondary packaging are cardboard boxes, crates, or other additional packaging intended to contain and protect products for shipping and transportation.

5.3.3 Primary packaging and labeling operations are controlled following the same policies and procedures that apply to production operations and processes. Product packaging and labeling are defined in drawings, specifications and artwork. These documents are issued and controlled in the same manner as other engineering documents. When appropriate, personnel

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involved with these processes are provided with work instructions and/or special training.

- 5.3.4 Shipping department is responsible for establishing specifications for secondary packaging and labeling. The specifications are compatible with requirements of commonly used carriers and for intended means of delivery (ground, sea, air). Packaging specifications may be documented in drawings, written standards, and/or packaging instructions. Secondary packaging specifications are maintained and controlled by Shipping.
- 5.3.5 Packaging and labeling activities are governed by Procedure MOP-75-09 Packaging, Labeling and Shipping.

### 5.4 Shipping and delivery

- 5.4.1 Shipping of finished products is initiated by the shipping order. The order identifies the shipping consignee address, shipping due date, products to be shipped, labeling requirements, and transportation mode or carrier. Before products are dispatched, the shipping clerk verifies that the shipment contains the same products and quantities as specified in the shipping order, and that packaging and labeling conform with customer and/or carrier requirements. Only orders that have been verified and signed off by the Shipping department can be loaded for shipment.
- 5.4.2 Activities related to shipping and delivery operations are regulated by Procedure MOP-75-09, Packaging, Labeling and Shipping.

### ASSOCIATED DOCUMENTS

- Operational Procedure QOP-63-01: Equipment Maintenance
- Operational Procedure MOP-75-01: Production Control
- Operational Procedure MOP-75-02: Manufacturing Process Control
- Operational Procedure QOP-75-03: Product Identification and Traceability
- Operational Procedure MOP-75-04: Product Handling and Preservation
- Operational Procedure MOP-75-08: Storage Areas
- Operational Procedure MOP-75-09: Packaging, Labeling and Shipping
- Operational Procedure POP-74-03: Verification of Purchased Product
- Operational Procedure QOP-82-10: In-process Inspections
- Operational Procedure QOP-82-11: Final Inspection
- Operational Procedure QOP-83-01: Control of Nonconforming Product