

# Rose Electronics Distributing Co., Inc.

## Quality Manual

MAN-04-2

QUALITY MANAGEMENT SYSTEM			
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<b>Documentation and Records</b>			

### *GENERAL POLICY*

ROSE Electronics developed a quality management system to ensure the highest level of quality in our processes and our ability to meet customer needs. The quality system is designed to comply with the requirements of ISO 9001:2000.

The scope of the quality system documentation is defined. Establishment and revision of documents, and their distribution, are controlled. New documents and revisions are reviewed and approved prior to issue; and are identified with respect to their revision level. Appropriate documents are available at locations where they are used. Obsolete documents are removed from points of use. Documents of external origin are identified and their distribution is controlled.

Quality records are identified and indexed to facilitate their retrieval, and are stored in a suitable environment to minimize deterioration. Quality records are retained for a period of seven years.

### **PROCEDURAL POLICIES**

#### **1 Scope**

1.1 ROSE Electronics Quality Manual (MAN) uses : the following documentation prefixes to document operational procedures, forms, flowcharts, supplements, and work instructions

- Quality Operating Procedures (QOP)
- Sales Operating Procedures (SOP)
- Purchasing Operating Procedures (POP)
- Manufacturing Operating Procedures (MOP)
- Forms (FORM) used in the procedures follow the applicable procedures
- Flowcharts (FLOW) are provided to visual enhance the procedures
- Supplements (SUP) are documents to enhance the understand of manual elements, operational procedures and/or work instructions.
- Work Instructions (WI) provides instructions for specific task or operation

1.2 ROSE's quality system includes the following types of documents:

- Quality Manual

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Originated by : Sally J. Chun	This Revision Date : March 18, 2003

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## Documentation and Records

- Operational procedures
- Work instructions
- Product realization and control plans
- Forms
- Flowcharts
- Standards and other technical reference materials
- External Standards and regulations
- Engineering documents, including drawings, specifications, procedures, and other documents defining products
- Customer engineering documents

1.3 Purpose, scope, and responsibility for controlling various types of documents are defined in Operational Procedure QOP-42-03, Quality System Documentation.

### 2 Quality Manual

2.1 The top level document defining the overall quality management system is the Quality Manual. It includes:

- The scope of the quality system, including details of and justification for any exclusions (refer to Section 0.3);
- Description of quality system processes, their sequence, and interrelation; and
- References to documented procedures;

2.2 The Quality Manual Status and Update Listing (SUP-42-02) reflects changes and updates to the Quality Manual

### 3 Document control

3.1 ROSE Electronics is gradually transitioning from paper to electronic documentation. As this transition progresses, new categories of documents are transferred from paper to electronic document control system. Both systems are currently used, and are defined in Procedure QOP-42-04, Control of Documents.

3.2 New documents and document changes may be initiated by anyone in the organization, but may only be issued by an authorized function. The authorized functions and the rules governing the issue of documents are defined in procedures QOP-42-03, Quality System Documentation, and QOP-42-04, Control of Documents. All documents are reviewed and approved prior to issue.

3.3 A paper document is officially issued for use when it is approved by authorized function. An electronic document is issued by being placed in a public directory accessible from ROSE's intranet.

## Documentation and Records

- 3.4 Documents are distributed to personnel and locations where they are used. When appropriate and relevant, documents display a distribution list. Electronic documents are available on the intranet and are accessible at relevant computers. Document placement is regulated by Control of Documents (QOP-42-04).
- 3.5 Obsolete documents are removed from points of use. Retained masters or copies of obsolete documents are properly marked and are kept separate from active documents. Obsolete electronic documents are removed from the server and, if retained, are stored in directories that are only accessible to authorized personnel.
- 3.6 Document changes are reviewed and authorized by the same function that issued the original document. Revised documents are distributed with a brief summarizing the changes. The Quality department maintains a master list specifying the latest issues and revisions of all controlled documents. For electronic documents such list is not necessary, as only the latest issue and revision of a documents is available on the intranet. Electronic documents are password protected to prevent unauthorized changes.
- 3.7 The Master List of Controlled Documents (SUP-42-01) reflects revision level, date of revisions, department responsible for documents and comments regarding changes and updates to documents contained in the Quality Manual

### 4 Control of quality records

- 4.1 Quality records are established and maintained to provide evidence that:
- Product designs satisfy design input requirements;
  - Materials, components, and production processes meet specified requirements;
  - Finished products conform to specifications: and
  - The quality system is operated in accordance with documented procedures and that it is effective.

Where required, quality records also include traceability information.

- 4.2 Records are established by personnel performing the task, operation, or activity for which the results need to be recorded. Records are dated; and identify the product, person, or event to which they pertain.
- 4.3 Records are indexed and grouped to facilitate their retrieval. Cabinets, binders, computer disks, and other storage media containing records are clearly labeled with identification of their content.
- 4.4 Records are normally stored by the same department that initially established the record. Records are stored in dry and clean areas, and electronic records are regularly backed up. Quality records and documents may not be stored in private desk drawers, unauthorized computer drives, or other obscure locations that are not generally known.

## Documentation and Records

- 4.5 Retention periods for quality records are determined on the basis the lifetime of the product or the event to which the record pertains, and on regulatory and contractual requirements.
- 4.6 All categories of quality records maintained by ROSE Electronics are listed in Operational Procedure QOP-42-05, Control of Quality Records. The list identifies specific types of records for each category; their storage location; and retention period.

### ASSOCIATED DOCUMENTS

- Manual Supplement SUP-42-01: Master List of Controlled Documents
- Manual Supplement SUP-42-02: Quality Manual Status and Update Listing
- Operational Procedure QOP-42-03: Quality System Documentation
- Operational Procedure QOP-42-04: Control of Documents
- Operational Procedure QOP-42-05: Control of Quality Records
- Operational Procedure QOP-42-06: Data and Document-Backup
- Operational Procedure QOP-42-07: Data and Document-Virus Protection
- Operational Procedure QOP-42-08: Inspection and Test Records