

Rose Electronics Distributing Co., Inc.

Quality Manual

MAN-07-1

PRODUCT REALIZATION			
Section 7.1	Section Rev.: 0001	Rev. Date: 08/01/02	Section Page 1
Planning of Product Realization			

GENERAL POLICY

Planning of product realization processes includes determination of requirements and quality objectives for products; development of required processes and process documentation; and establishment of product verification and validation programs. The plan also defines requirements for records necessary to demonstrate process and product conformity.

PROCEDURAL POLICIES

1. Product requirements and quality objectives

- 1.1 Product requirements and quality objectives for product are defined and communicated in drawings and specifications, contract documents, internal and external standards, product samples and workmanship standards, and applicable legal and regulatory requirements.
- 1.2 For custom products manufactured to customer design, product requirements and quality objectives are specified in the technical documentation provided by the customer. Sales, Production Control and Quality Assurance review these specifications before acceptance of the contract and commencement of production, as instructed in Sales Operational Procedure SOP-72-02, Contract Review for Custom Products.
- 1.3 For custom products provided by ROSE Electronics to meet customer-specified needs and performance requirements, product requirements and quality objectives are determined by the customer. Specifications are reviewed, verified and, when appropriate, validated in accordance with Operational Procedure SOP-72-02, Contract Review for Custom Products.
- 1.4 For standard products provided by ROSE Electronics Requirements are reviewed, verified and, when appropriate, validated in accordance with Sales Operational Procedure SOP-72-01, Contract Review for Standard Products.
- 1.5 Section 7.2 of this manual explains in more detail how customer and product requirements are determined and reviewed.

2. Product realization planning

- 2.1 Product realization planning includes, as applicable:

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Planning of Product Realization

- Definition and evaluation of manufacturing operations and processes,
 - Development of adequate and capable processes,
 - Identification of special processes and consideration of associated risks and consequences,
 - Establishment and implementation of appropriate process control measures,
 - Development of instructions and training for process operators, and
 - Requirements for records necessary to demonstrate process conformity.
- 2.2 Product realization plans are established in collaboration between Production, Engineering, and Quality Assurance. The plans are defined in various types of production documents, such as process flowcharts, production work orders, control plans, operator instructions, process validation reports, etc.
- 2.3 Operational procedures related to Section 7.5, Operations, explain how outputs of product realization planning are used.
- 3. Product verification and validation planning**
- 3.1 Product verification and validation plans determine the inspection and testing program for a product, and for materials and components incorporated into the product. This includes:
- Identification of inspection and testing points,
 - Inspection and testing scope, frequency, and method,
 - Acceptance criteria, and
 - Requirements for records necessary to demonstrate product conformity.
- 3.2 Quality Assurance and Engineering are responsible for development of product verification plans. The plans are defined in various types of documents, such as product drawings and specifications, production work orders, purchasing documents, inspection and testing procedures, and so forth. Documents defining the inspection and testing program for a product are collectively referred to as control plans.
- 3.3 Operational Procedures POP-74-03, Verification of Purchased Product; POP-82-16, In-process Inspections; and POP-82-18, Final Inspection, explain how outputs of product verification and validation planning are used.
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Planning of Product Realization

ASSOCIATED DOCUMENTS

- Quality Manual MAN-07-3: Design Control
- Operational Procedure MOP-71-01: Document Control - Manufacturing
- Operational Procedure SOP-72-01: Contract Review for Standard Products
- Operational Procedure SOP-72-02: Contract Review for Custom Products
- Operational Procedure QOP-74-03: Verification of Purchased Product
- Operational Procedure QOP-82-16: In-process Inspections
- Operational Procedure QOP-82-18: Final Inspection