

7

PRODUCT REALIZATION

GENERAL POLICY

Solon Manufacturing Company considers various requirements when carrying out product realization steps. These include the planning of product realization, customer-related processes, purchasing and production provision. Each process is documented with procedures and/or work instructions.

PROCEDURAL POLICIES

7.1 Planning of Product Realization

- 1.1 Solon Manufacturing Company plans and develops the processes needed for product realization as outlined in P-ENG D+D – Engineering, Design and Development and P-SCS Sales Customer Service. Planning of product realization is consistent with the requirements of the other processes of the quality management system.
- 1.2 In planning product realization, Solon Manufacturing Company determines the following, as appropriate:
 - a) quality objectives and requirements for the product;
 - b) the need to establish processes, documents, and provide resources specific to the product;
 - c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
 - d) records needed to provide evidence that the realization processes and resulting product meet requirements.
- 1.3 The output of this planning is recorded on F7101 Planning of Product Realization. P-SCS Sales Customer Service (P-ENG D+D – Engineering, Design and Development).

7.2 Customer-Related Processes

- 1.1 Solon Manufacturing Company determines, as outlined in P-SCS Sales Customer Service,
 - a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
 - b) requirements not stated by the customer but necessary for specified use or known and intended use,
 - c) statutory and regulatory requirements applicable to the product, and
 - d) any additional requirements considered necessary by Solon Manufacturing Company
- 1.2 Solon Manufacturing Company reviews the requirements related to the product. The review is

conducted prior to Solon Manufacturing Company's commitment to supply a product to the customer. P-SCS Sales Customer Service outlines these reviews. It ensures that

- a) product requirements are defined
 - b) contract or order requirements differing from those previously expressed are resolved
 - c) Solon Manufacturing Company has the ability to meet the defined requirements.
- 1.3 Records of the reviews and actions arising from the reviews are maintained as outlined in P-SCS Sales Customer Service.
- 1.4 Where the customer provides no documented statement of requirement, Solon Manufacturing Company confirms all customer requirements prior to acceptance. Methods used are outlined in P-SCS Sales Customer Service,
- 1.5 Where product requirements are changed, Solon Manufacturing Company ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements. Specific methods used are outlined in P-SCS Sales Customer Service.
- 1.6 As outlined in P-SCS Sales Customer Service, Solon Manufacturing Company determines and implements effective arrangements for communicating with customers in relation to
- a) product information,
 - b) inquiries, contracts or order handling, including amendments,
 - c) customer feedback, including customer complaints.

7.3 Design and Development

- 1.1 Solon Manufacturing Company plans and controls the design and development of product. P-ENG. D+D. – Engineering, Design and Development outline these processes.
- 1.2 During design and development Solon Manufacturing Company determines
- a) the design and development stages
 - b) the review, verification and validation that are appropriate to each design and development stage
 - c) the responsibilities and authorities for design and development.
- 1.3 Solon Manufacturing Company manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
- 1.4 Planning output is updated, as appropriate, as the design and development progresses.
- 1.5 Inputs relating to product requirements are determined and records are maintained.

They include

- a) functional and performance requirements
 - b) applicable statutory and regulatory requirements
 - c) where applicable, information derived from previous similar designs
 - d) other requirements essential for design and development.
- 1.6 The inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.
- 1.7 The outputs of design and development is provided in a form suitable for verification against the design and development input and is approved prior to release.
- 1.8 Design and development outputs
- a) meet the input requirements for design and development,
 - b) provide appropriate information for purchasing, production and service provision,
 - c) contain or reference product acceptance criteria
 - d) specify the characteristics of the product that are essential for its safe and proper use.
- 1.9 At suitable stages, systematic reviews of design and development are conducted in accordance with planned arrangements
- a) to evaluate the ability of the results of design and development to meet requirements, and
 - b) to identify any problems and propose necessary actions.
- 1.10 Participants in these reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of these reviews and any necessary actions are maintained. (P-ENG D+D – Engineering, Design and Development)
- 1.11 Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.
- 1.12 Records of the results of the verification and any necessary actions are maintained as outlined in P- ENG D+D – Engineering, Design and Development.
- 1.13 Design and development validation is performed in accordance with planned arrangements to ensure that resulting product is capable of fulfilling the requirements for the specified or known intended use or application.
- 1.14 Wherever practicable, validation is completed prior to the delivery or implementation of the product.
- 1.15 Records of the results of validation and any necessary actions are maintained (P-ENG D+D – Engineering, Design and Development).



- 1.16 Design and development changes are identified and records are maintained (P-ENG D+D – Engineering, Design and Development).
- 1.17 The changes are reviewed, verified and validated, as appropriate, and approved before implementation.
- 1.18 The review of design and development changes includes evaluation of the effect of the changes on constituent parts and delivered product.
- 1.19 Records of the results of the review and changes and any necessary actions are maintained (P-ENG D+D – Engineering, Design and Development).

7.4 Purchasing

- 1.1 Solon Manufacturing Company ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product. P-PUR Purchasing outlines steps used in applying control to the supplier.
- 1.2 Solon Manufacturing Company evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established in P-PUR Purchasing. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained in P-PUR Purchasing and P-4.2.4 Control of Records.
- 1.3 Purchasing information, as summarized in P-PUR Purchasing, describes the product to be purchased, including, where appropriate,
 - a) requirements for approval of product, procedures, processes and equipment,
 - b) requirements for qualification of personnel,
 - c) quality management system requirements.
- 1.4 Solon Manufacturing Company ensures the adequacy of specified purchase requirements prior to their communication to the supplier. Methods used are outlined in P-PUR Purchasing.
- 1.5 In P-Q Quality and P-R/S Receiving/Shipping, Solon Manufacturing Company has established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
- 1.6 Where Solon Manufacturing Company or its customer intends to perform verification at the supplier's premises, Solon Manufacturing Company states the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision

- 1.1 Solon Manufacturing Company plans and carries out production and service under controlled conditions. P-MFG Manufacturing and P-SCS Sales Customer Service outlines these controlled conditions. Controlled conditions include, as applicable

- a) the availability of information that describes the characteristics of the product,
 - b) the availability of work instructions as necessary
 - c) the use of suitable equipment,
 - d) the availability and use of monitoring and measurements equipment,
 - e) the implementation of monitoring and measurement, and
 - f) the implementation of product release, delivery and post-delivery activities.
- 1.2 As outlined in P-MFG (Manufacturing), Solon Manufacturing Company validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Solon Manufacturing Company's business processes requires the use of internal "special processes" for HEAT TREAT and SURFACE COATINGS. Validation demonstrates the ability of these processes to achieve planned results. Solon Manufacturing Company has established arrangements for these processes including, as applicable,
- a) defined criteria for review and approval of the processes
 - b) approval of equipment and qualification of personnel,
 - c) use of specific methods and procedures,
 - d) requirements for records, and
 - e) revalidation
- 1.3 Where appropriate, Solon Manufacturing Company identifies the product by suitable means throughout product realization. This includes the identification of product status with respect to monitoring and measurement requirements. Where traceability is a requirement, Solon Manufacturing Company controls and records the unique identification of the product. Specific methods utilized are outlined in P-MFG.
- 1.4 Solon Manufacturing Company exercises care with customer property while it is under the organization's control or Solon Manufacturing Company is using it. Solon Manufacturing Company identifies, verifies, protects and safeguards customer property provided for use or incorporated into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it is reported to the customer and records are maintained as described in P-SCS Sales Customer Service.
- 1.5 Solon Manufacturing Company preserves the conformity of the product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Specific methods utilized are outlined in P-R/S Receiving/Shipping and P-MFG. Manufacturing. Preservation also applies to the constituent parts of a product.

7.6 Control of Monitoring and Measuring Equipment

- 1.1 As outlined P-Q Quality, Solon Manufacturing Company determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.
- 1.2 Solon Manufacturing Company establishes processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with monitoring and measurement requirements as outlined in Control Plans, Work Orders, Work Instructions and various forms.
- 1.3 Where necessary to ensure valid results, monitoring and measuring equipment is:
 - a) calibrated or verified, or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded;
 - b) adjusted or re-adjusted as necessary;
 - c) identified in order to determine its calibration status;
 - d) safeguarded from adjustments that would invalidate the measurement result;
 - e) protected from damage and deterioration during handling, maintenance and storage.
- 1.4 In addition, Solon Manufacturing Company assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Solon Manufacturing Company takes appropriate action on this equipment and any product affected. Records of the results of calibration and verification are maintained.
- 1.5 If and when applicable, when used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and is reconfirmed as necessary.

DOCUMENTATION AND REFERENCES

- P-ENG D+D Engineering, Design & Development
- F7101 Planning of Product Realization
- P-SCS Sales Customer Service
- P-4.2.4 Control of Records
- P-TM Top Management
- P-PUR Purchasing
- P-Q Quality

ISO 9001:2008
Quality Manual – Product Realization



Page 7 of 7

- P-MFG Manufacturing PS
- P-MFG Manufacturing Washers
- P-R/S Receiving/Shipping

Date	Pg	Par.	Summary comments

Approved by: JT Dunn
Originated by: Gary Ault

Approval Date: 1-15-2010
Originated Date: 1-15-2010