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1 INTRODUCTION

PROFACTURE Corporation recognizes its responsibility as a provider of quality products/services. To this end, PROFACTURE Corporation has developed and documented a quality management system. The quality system complies with the international standard ISO 9001:2000, Quality management systems - Requirements. This manual provides comprehensive evidence to all customers, suppliers and employees of what specific controls are implemented to ensure product/service quality.

This manual also governs the creation of quality related documents. It will be revised, as necessary, to reflect the quality system currently in use. It is issued on a controlled copy basis to all internal functions affected by the quality system and on an uncontrolled copy basis to customers and suppliers. It may be issued to customers on a controlled copy basis upon customer request.

1.1 QUALITY POLICY

PROFACTURE Corporation accepts responsibility for the complete satisfaction of its customers. We exercise this responsibility through adequate training of our employees, adherence to proven procedures, and total commitment to meeting and exceeding customer requirements, and to maintaining an organizational culture that fosters continuous improvement.

Matthew E. Burns

Matthew Burns, Quality Control Officer (**QCO**)

2 MANAGEMENT RESPONSIBILITY

2.1 Management Commitment

The management of PROFACTURE Corporation is committed to implementing, and maintaining a documented quality system. This commitment includes: ensuring that customer, regulatory and legal requirements are understood and appropriately addressed, the quality policy is understood and implemented at all levels of the organization, quality objectives and plans are established as necessary and that the responsibilities of all functions affecting quality are clearly defined. Management will make provisions for the necessary resources and personnel to maintain the system, including a management representative, who will ensure that the requirements of this manual are met. Management will review the system annually to determine its effectiveness.

2.2 PLANNING

2.2.1 QUALITY OBJECTIVES

The management of PROFACTURE Corporation establishes annual key initiatives, which include quality objectives. The objectives are established via the Management Review Procedure and communicated to all levels of the organization for use in establishing each function's and employee's annual key objectives. Quality objectives are measurable, include business performance indicators reflecting requirements for products/services, and are consistent with the quality policy including the commitment to continuous improvement.

2.2.2 QUALITY MANAGEMENT SYSTEM PLANNING

The management of PROFACTURE Corporation ensures that the resources needed to achieve the quality objectives are identified and planned. All quality plans are documented and include: the required resources; the processes of the quality system, permissible exclusions; continuous improvement of the quality system.

3 PRODUCT REALIZATION

3.1 PLANNING OF PRODUCT REALIZATION

PROFACTURE Corporation has established and maintains documented procedures to ensure that the sequence of processes is conducted in a controlled manner. Planning of the realization processes is consistent with other requirements of the organization's quality system. Plans of product and service realization determine the following:

- quality objectives for the product/service, project or contract;
- the need to establish processes and documentation, and provide resources and facilities specific to the product/service;
- verification and validation activities, and the criteria for acceptability;
- the records that are necessary to evidence conformity of the processes and resulting product/service to specified requirements.

4 MEASUREMENT, ANALYSIS AND IMPROVEMENT

4.1 GENERAL

PROFACTURE Corporation has established and maintains a documented Continuous Improvement Procedure to define, plan and implement the measurement and monitoring activities needed to assure conformity and achieve improvement. This includes the determination of the need for, and use of, applicable methodologies including statistical methods.

4.2 MONITORING AND MEASUREMENT OF PROCESSES

PROFACTURE Corporation applies suitable methods for measurement and monitoring of those realization processes necessary to meet customer requirements. These methods confirm the continuing ability of each process to satisfy the intended purpose.

4.3 MONITORING AND MEASUREMENT OF PRODUCT

PROFACTURE Corporation measures and monitors the characteristics of the product/service to verify that requirements for the product/service are met. This is carried out at appropriate stages of the product/service realization process. Evidence of conformity with the acceptance criteria is documented. Records include the authority responsible for release of the product/service.

5 INSPECTION AND TEST PROCEDURES

5.1 RECEIVING INSPECTION AND TEST

All purchased material which influences the manufacture of, or is intended for use as part of, deliverable products is subject to inspection and/or testing by Receiving Inspection. Upon receipt of products, receiving personnel verify the quantity of delivered units, check marking and identification of packages, and inspect all packages for any signs of tampering or damage. If all these checks and inspections are satisfactory, receiving personnel signs the delivery receipt. If not, any shortages or damages are noted on all copies of the delivery receipts.

The received containers are then moved to the designated inspection area, a copy of the purchase order is retrieved, and the packing slips are removed from the containers. Upon opening the containers, the goods are verified against the purchase order and the

5.1 RECEIVING INSPECTION AND TEST....*Continued*

packing slip, and are examined visually for any signs of damage. The purchase order is stamped "RECEIVED" and is signed and dated by the receiving inspector. All receiving inspections are logged in the Receiving Inspection Log.

On critical parts and components, as determined by the Quality Manager, a precision inspection/test is performed. This type of inspection includes:

- Review of material certificates, supplier inspection records, compliance certificates, and any other relevant documentation delivered with the product
- Random sampling based on statistical technique specified
- Visual inspection to detect any damage or other visible problems
- Performing measurements and testing against specified requirements as required
- Recording the sample size, actual measurements, and inspection test results on the Inspection/Test & Audit Report

Where it is not practical to perform receiving inspection upon receipt, provisions are made to perform source inspection at the supplier's facility.

The Quality Manager determines the extent and scope of receiving inspection based on the importance of the item and the suppliers' control methods and performance. The Quality Manager may request that suppliers provide objective evidence of conformance (i.e., material certifications, certificates of conformance, test data, first article inspection, and SPC data). Objective evidence provided by suppliers may be used as the basis for reducing/waiving receiving and source inspection.

Upon acceptance, products are identified with an "ACCEPT" tag [green sticker] and moved to stock. In the event that product which is designated for receiving inspection is released to production due to urgency, it shall be positively identified and recorded in receiving inspection records.

5.2 IN-PROCESS INSPECTION AND TEST

In-process inspection/testing is conducted to ensure that the product/process conforms to specified requirements. The inspection/testing is normally carried out by production personnel. Random audits of the in-process inspection/testing process are conducted by quality control personnel.

The Quality Manager determines the extent and scope of in-process inspection/testing based on the importance of the item, control methods, and previous performance.

5.3 FINAL INSPECTION AND TEST

For acceptance of completed products, final inspection/testing is utilized. This includes a verification of satisfactory receiving and in-process inspections/tests, as well as completion of the remaining inspections/tests to assure that the finished products/processes conform to specified requirements. Products are not released, and processes are not approved until all inspection/test activities have been satisfactorily completed and the appropriate documentation is available and authorized. All final inspections are logged in the Final Inspection Log. On critical parts and components, as determined by the Quality Manager, a Final Inspection/Test & Audit Report is completed.

The Quality Manager determines the extent and scope of final inspection/testing based on the importance of the item, control methods, and previous performance.

5.4 INSPECTION AND TEST RECORDS

Inspection/test records, which show clearly whether the product/process has passed or failed the defined acceptance criteria, are established and maintained.

5.5 NONCONFORMING MATERIAL/PRODUCTS

All material/products that are found to be nonconforming are identified and segregated and/or quarantined, and appropriately dispositioned per the Control of Nonconforming Product Procedure.