



ENPAC
CORPORATION

Quality Control Manual

This Quality Control Manual
has been reviewed and
approved by:

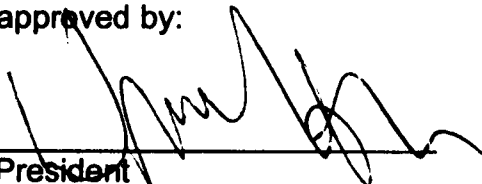


 _____ President	<u>11/26/02</u> _____ Date
 _____ Engineering	<u>11/26/02</u> _____ Date
 _____ Quality Control	<u>11-26/02</u> _____ Date

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PURPOSE OF THE QUALITY ASSURANCE MANUAL

The purpose of this Quality Assurance Manual is to outline the methods and procedures used to assure continuous improvement and the Quality of the products produced by ENPAC Corporation.

Procedures have been included to insure compliance with national codes and standards as well as customer requirements.

This manual and the procedures governed by this manual will be reviewed annually and revised when necessary, with re approval.

1 INTRODUCTION:

The management of ENPAC CORPORATION is in full agreement with the principles set forth in the Quality Control manual. Control of all phases is essential in order to produce secondary containment systems and all other products that will comply with the applicable codes and other requirements per ENPAC Data sheets and specifications. It is our intent to produce all products in strict accordance with this program.

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2 QUALITY ASSURANCE PROGRAM:

- 2.1 The Quality Assurance Program as defined in this manual has been established to provide a uniform and systematic method for control of quality, safety, and reliability in finished products. Procedures have been established to insure compliance with national codes and standards as well as customer requirements. The organization chart has been established and areas of responsibility defined thereon. All personnel involved in Quality Control related activities shall receive initial training and periodic retraining in the Quality Control Program requirements. All Quality related activities, Personnel training, Document Control and Transmittal, Material transfer, etc. shall be documented and records must be maintained by the Quality Control Manager.**
- 2.2 The Quality Assurance Program has been reviewed by the management of ENPAC CORPORATION and shall be revised to incorporate all changes in applicable codes and other requirements which have been management approved. Management shall review the Quality Assurance Program annually to determine the full implementation and adequacy of the Quality Control Procedures.**
- 2.3 The Quality Control Manual is under the control of the Quality Control Manager.**

2.4 The Quality Control Manual shall consist of three types,

1. Master Manual: This manual shall be complete, having all sections and revisions therein. The Quality Control office shall maintain this manual in its office at all times.

2. Controlled Manual: This is a registered manual that is sent a controlled group of recipients. All revisions and addenda as they are issued are transmitted to holders of the Controlled Manual. The Controlled Manual Log is reviewed every six months for accuracy and the current status. When a Controlled Manual Status is changed, the recipient of the manual is so notified.

3. Uncontrolled Manual: This manual is a non-registered manual and is not continually updated with revisions and addenda. This manual may not be complete, but a portion of the complete manual. A Register shall be maintained of all outstanding Uncontrolled Manuals.

3 ORGANIZATION:

- 3.1 The Quality Control Department is under the supervision of the Quality Control Manager, who is responsible for the effective functioning of the Department and all interdepartmental liaison between the other departments of ENPAC CORPORATION.**
- 3.2 The Quality Control Manager has the authority and capability to identify quality problems, initiate and verify implementation of solutions and control further processing until the unsatisfactory conditions have been corrected.**
- 3.3 The Quality Control Manager controls all the operations of inspection procedures at the production level, as well as incoming and outgoing products.**
- 3.4 The Quality Control Manager reports directly to the General Manager (see Organization chart). The Quality Control Manager will function in a similar manner between ENPAC CORPORATION, its customers and vendors.**

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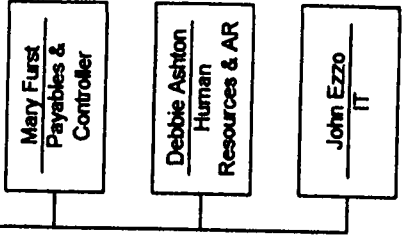
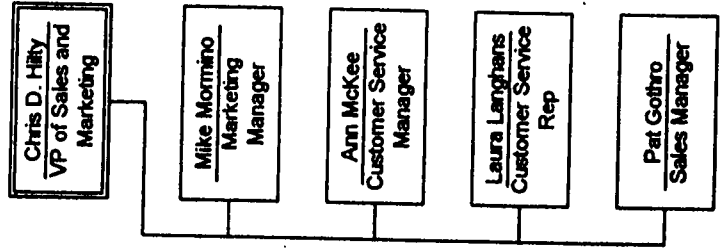
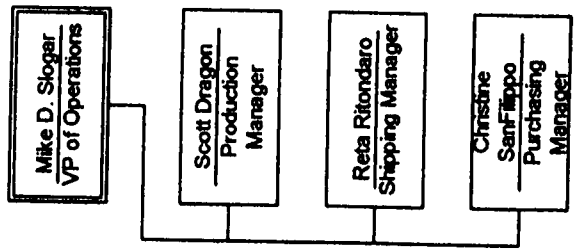
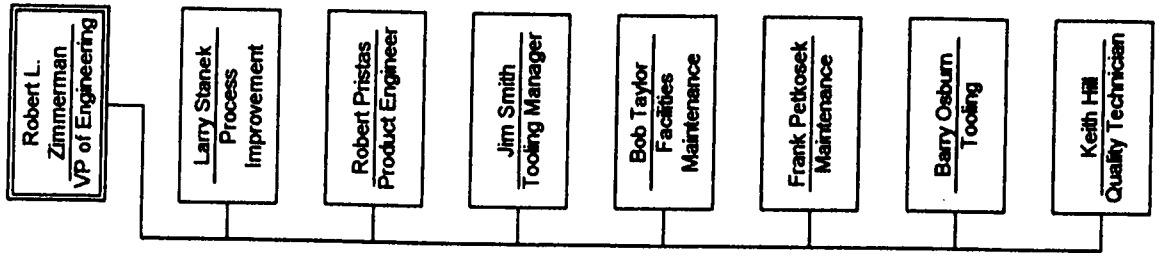
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4 DOCUMENT CONTROL:

- 4.1 This section establishes policies and responsibilities for control of documents, e.g., drawings, specifications, procedures, procurement papers, etc.
- 4.2 The Quality Manager, or a designee, shall assure that a numbering system adequate for the documents generated in the categories noted above is established.

A document control system shall be used to assign all numbers and maintain sequential logs for all documents in the above categories to prevent redundant numbers.
- 4.3 All Quality related documents shall be reviewed and/ or prepared by the Quality Department and approved, when acceptable, based on written and established criteria. All Quality Related documents pertaining to ENPAC products shall be officially issued prior to their use.
- 4.4 No document in this category shall be noted as officially issued until an authorized Quality Signature is placed on the document approval block.
- 4.5 All documents shall be revised via the same approval procedures as the original issue. All superceded and obsolete documents shall be immediately removed from active use.

5 PROCUREMENT DOCUMENT CONTROL:

- 5.1 It shall be the responsibility of the Quality Control Manager to compile an Approved Vendor List. Approved Vendors shall be subject to an initial Evaluation and reevaluation every three years, or less, to determine the Vendors Quality Assurance Program. The vendor evaluation shall be by Vendor Rating Program, Vendor Survey, or past history records.**
- 5.2 Material Procurement by the Purchasing Department shall be limited to Vendors as listed on the Approved Vendors List. Purchase Orders and Revisions shall be reviewed and signed by the Quality Control Manager to assure inclusion of all Quality Control Requirements and use of an Approved Vendor.**
- 5.3 The Quality Control Manager shall insure the maintenance of all procurement documents, requirements, specifications, purchase orders, change orders, and drawings. These files are to be kept up to date and available for inspection and audit.**

6 DESIGN CONTROL:

- 6.1 The Engineering Department shall prepare the drawings which shall include all dimensional data requirements, as well as dimensional tolerances, bills of material, finishing instructions, packaging, shipping instructions, testing requirements, etc., either with notes or referring to specifications.**
- 6.2 The Engineering Department shall prepare the calculations as required and the preliminary sketches for drafting purposes. Any changes or deviations from specified design requirements or quality standards shall be reviewed, documented, and controlled by the Managers of Engineering, Production, and Quality Control.**
- 6.3 Engineering calculations, drawings, and specifications shall be checked and verified for accuracy by an Engineer other than the originator.**

7 INSTRUCTIONS, PROCEDURES, AND DRAWINGS:

- 7.1 All important activities which shall be performed per specifications and requirements shall be documented through work instructions, specifications, operating and procedure manuals, shop construction drawings, or any other type of forms.**
- 7.2 The completed file containing drawings, specifications, job flow sheets, procurement documents, and any specific instruction sheets shall be reviewed by the Quality Control Manager and released for production if all requirements are satisfied.**

8 CONTROL OF PURCHASED ITEMS:

- 8.1 The Receiving Department checks all the material received against the information listed on their copy of the Purchase Order.**
- 8.2 Test Reports, Laboratory Analyses, etc., are to be identified with the material and securely attached thereon. The material shall then be placed in the Hold Area for final acceptance by the Quality Control Department.**
- 8.3 Quality Control shall inspect all incoming material and complete the Incoming Materials Inspection check list. The Inspector shall review the material certifications with applicable specifications and certify their compliance.**
- 8.4 Rejected material shall be identified with a Reject Tag, then placed in a segregated Hold Area, a Discrepancy Report is to be filled out and a copy attached to the defective Material.**
- 8.5 Raw Material suppliers will send Certification on each Lot of Material and all Statistical Process Control charts from the production of each Lot produced.**

9 IDENTIFICATION AND CONTROL OF ITEMS:

- 9.1 This section is to delineate requirements and procedures for assuring identification, traceability, handling, storage, protection and inventory of material utilized in ENPAC products.**
- 9.2 The Quality Manager, or a designee, shall assure compliance with the material control requirements of this Quality Policy.**
- 9.3 The material control functions may be delegated to other ENPAC employees or suppliers. However, the responsibility for verification of adherence to the material control requirements will remain with the Quality Manager.**
- 9.4 Materials and equipment utilized in ENPAC products shall be inventoried after receipt and acceptance.**
- 9.5 Inventoried items shall be recorded to assure maintenance of material traceability, identity, storage location and condition control. All inventoried items shall be staged in an appropriate and controlled location.**

10 INSPECTION:

- 10.1 All inspection Personnel are assigned by the Quality Control Manager to whom they shall report all discrepancies.**
- 10.2 The inspection system has been established to verify conformance of production activities to documented instructions, procedures, and drawings. Inspection activities are conducted on a random sampling basis.**
- 10.3 All incoming material is inspected upon receipt for condition, quality of work, quantity, etc., against the purchase order. Acceptance or rejection of the material is documented and the Quality Manager, Production Manager, and Engineering Manager notified. Material Certificates shall be kept in the Quality Control Managers file.**
- 10.4 The Quality Control Manager shall advise the Quality Control Inspector at which stages of the production flow he is to perform his inspection. The manufacturing plan and inspection instructions shall clearly show these positions, tests, and data.**
- 10.5 Upon completion of the molding operation the operator has to weigh the product and record the data on the appropriate X and R chart. Shot weight control is a critical factor in control of the process and products ENPAC produces.**

11 TEST CONTROL:

- 11.1 All production testing shall be performed in accordance with written test procedures. Testing shall be performed by the inspector under direct supervision of the Quality Control Manager.**
- 11.2 Standard test procedures shall be prepared by the Engineering Department or the Quality Department and approved by the Quality Control Manager prior to use. Any specific test requirements per customer specifications shall be reviewed by the Quality Control, Engineering, Production Managers.**
- 11.3 Results of all tests shall be documented and evaluated by the Quality Control Manager to assure that test requirements have been satisfied.**
- 11.4 At this time, thickness gauging (panametric testing) pressure/ leakproofness, static load, drop, leak, stacking, impact, volume and fit/ dimensioning are the major tests routinely performed by ENPAC Corporation.**

12 CONTROL OF MEASURING AND TEST EQUIPMENT:

- 12.1 All test equipment shall be selected by the Engineering Department and approved by the Quality Control Manager prior to use. It shall be a joint responsibility to assure that the equipment is suitable for the purpose intended.
- 12.2 Panametric gauges used for thickness testing shall be calibrated every six months against certified equipment. All production scales will be calibrated and certified every month, by a certified outside source, traceable to the National Bureau of Standards or other nationally recognized standard.
- 12.3 ALL other precision measuring devices, micrometers, verniers, etc. shall be checked against standard calibrated gauge blocks with traceability to the National Bureau of Standards. Non-precision measuring devices, rulers, straight edges, tapes, etc. shall be checked against shop standards every six months.
- 12.4 All precision measuring devices shall be permanently identified with a serial number by tagging or etching. A permanent file shall be maintained in the Quality Control Office of each measuring device and its calibration record.
- 12.5 It shall be the responsibility of the Quality Control Manager to assure that all measuring devices used are within calibration. Calibration measuring devices which are found to be out of calibration shall be removed from service. All production records of material checked by the faulty device shall be evaluated for acceptability or for retest.

13 HANDLING, STORAGE, AND SHIPPING:

- 13.1 Shipping requirements include all operations necessary for proper handling, storage, shipping, cleaning, preserving, and packing of all material. It shall be the responsibility of the Shipping Department Supervisor to use and maintain the appropriate tools and equipment for loading and securing shipments.**
- 13.2 The shipping Department shall be responsible for all shipping and marking requirements as specified on drawings, purchase orders, or specification. Any deviations from the requirements must be approved by the Engineering Manager, the Quality Control Manager and Customer, if required.**
- 13.3 All shipments shall be tagged or marked adequately to identify the item. If any special handling is required, the marking should so indicate to prevent damage. The description of the material shipped and any special storage or handling shall be itemized on the packing slips. .**
- 13.4 The Shipping Department shall be responsible for the handling and storage of incoming material. All incoming material shall be placed in the Hold Area and checked for compliance with the purchase order. Material that is checked and found correct, will then be moved to the in process area for production use.**

14 CONTROL OF PROCESSES:

- 14.1 Partlow graphs are utilized in Process Control of the molding machine. This chart identifies correct length of cycle and the temperature during the cycle. Shot weights are controlled for reliability and consistency in the molding operation.**
- 14.2 X bar R Charts are used to help control material wall thickness as well as X bar R Charts used in shot weight control. These two areas are Critical To Quality therefore these are the items utilized in S.P.C. by the Machine Operator (shot weight) and by the Quality personnel (panametric readings), are charted and controlled to produce the most cost effective and reliable part possible.**
- 14.3 All testing procedures where required shall be performed by trained and qualified personnel or by a qualified testing service using qualified procedures.**

15 INSPECTION, TEST, AND OPERATING STATUS:

15.1 A Hold Tag shall be attached to non-conforming materials to prevent their use.

All non-conforming materials or assemblies shall be placed in the Hold Area.

15.2 Quality Control Approval is required prior to final release to assure that all required inspections have been performed and found to be satisfactory.

16 CONTROL OF NON-CONFORMING ITEMS:

- 16.1 Any non-conforming material shall be segregated from the normal production flow or storage areas, identified with a securely fastened Hold Tag, and placed in the Hold Area. The procedure for disposition of non-conforming material shall be documented by a Discrepancy Report, a release form or a scrap report.**
- 16.2 It shall be the responsibility of the Quality Control Manager to assure that Discrepancy Reports are completed and copies are distributed to the General Manager, Engineering, Production, and Quality Control Inspectors.**
- 16.3 Any material, part, or product in which one or more characteristic does not conform to the requirements, specifications, drawings, or other documents is nonconforming.**

17 CORRECTIVE ACTION:

- 17.1 The procured material which is not according to specification or drawing is called incorrect material. It shall be the responsibility of the Quality Control Manager to inform Purchasing and Engineering of the non-conforming material. This incorrect item may be returned to the vendor for replacement via Purchasing, or may be repaired "as is" with customer approval.
- 17.2 Non-conforming items may be incomplete, incorrect, defective, or incorrectly manufactured. Corrective Action may be directed at different stages of production flow depending upon the non-conformance.
- 17.3 The material with incomplete operation or missing parts is called incomplete material. This material may be reworked and returned to production with the approval of the Quality Control Inspector.
- 17.4 It shall be the responsibility of the Quality Control Manager to assure that the corrective action report is to be completed and that the corrective procedures are implemented by the following:
1. Rework and Reinspect
 2. Material Review Board-Control
 3. Return to Vendor
- 17.5 The Material Review Board shall consist of the Manager of Production, Engineering, and Quality Control. The Material Review Board shall convene monthly, or as required, to review all Non-Conforming and Corrective Action Reports.

17.6 The Material Review Board shall identify and institute corrective measures for all recurrent deficiencies. Material that is non-conforming after corrective action shall be referred to the Material Review Board for disposition by either:

1. Return to Vendor

2. Scrap out Material

18 QUALITY ASSURANCE RECORDS:

- 18.1 All records and duplicates shall be retained in controlled access files. These files shall be protected from fire, water, temperature extremes and theft.**
- 18.2 Records shall be retrievable via traveler number, purchase order number, shipping order number, or part number. This shall be achieved by use of a cross reference system.**
- 18.3 Copies of orders, receiving and shipping, etc. shall be kept in record files for a period of not less than two years. Also, copies of drawing, production orders, inspection reports, material certifications, and destructive and nondestructive testing records shall be filed by part names or numbers.**
- 18.4 It shall be the responsibility of the Quality Control Manager to keep and maintain these records and make them available for review if required.**

19 AUDITS:

- 19.1 The complete Quality Assurance Program shall be audited every twelve months, or sooner if required, to evaluate the performance of the Procedures set forth. The Auditing Committee shall be composed of trained or experienced personnel having no responsibility of the area to be audited.
- 19.2 The Auditing Committee shall complete the audit check list and submit its findings to the General Manager and the Managers of Engineering, Production, and Quality Control. Areas that have been found deficient shall be subject to re-audit within thirty days to ensure implementation of corrective action.
- 19.3 The Quality Control Audits shall be reviewed annually by the General Manager and the Quality Control Manager to assure the adequate implementation of the Quality Control Program.

20 EXHIBITS:

To be revised

<u>Form Number</u>	<u>Description</u>
QP-1	INSPECTION STICKERS
QP-IVF-2	INSPECTION VERIFICATION
QP-IVF-3	PANAMETRIC DATA SHEET
QP-IVF-4	ADHESION DATA SHEET
QP-5	DISCREPANCY REPORT
QP-6	VARIABLES CONTROL CHART
QP-7	PARTLOW GRAPH
QP-8	QUALITY MANUAL TRANSMITTAL
QP-9	QUALITY CONTROL MANUAL LOG
QP-10	QUALITY CONTROL MANUAL DISTRIBUTION CARD
MI-17	INCOMING MATERIAL INSPECTION SHEET