



# QUALITY MANUAL



**Document Number: Q01.0.00**

**Revision: M**

**Date: 6 April, 2016**

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| <b>REV.</b> | <b>DESCRIPTION OF CHANGE</b>   | <b>RELEASED DATE</b> | <b>RELEASED BY</b>  |
|-------------|--|----------------------|---------------------|
| F           | Updated all main sections to include more details  | 6/2/2006             | <i>Linda Berger</i> |
| G           | Updated Organizational Chart   | 1/12/2007            | <i>Linda Berger</i> |
| H           | Updated General Manager & added sales flow charts  | 10/4/07              | <i>Linda Berger</i> |
| I           | Update to include Sterling Heights facility  | 4/01/09              | <i>Linda Berger</i> |
| J           | Updated to Remove Sterling Heights   | 6/1/2010             | <i>Linda Berger</i> |
| K           | Updated to correct safety training on sections 5.5.3 and 6.4 to a minimum once a year and corrected type error of 9000 vs 9001 | 7/3/2012             | <i>Linda Berger</i> |
| L           | Updated Manual to correct error in environmental policy and to remove flow charts  | 7/31/2013            | <i>Linda Berger</i> |
| M           | Minor Changes to the Quality Policy  | 4/6/2016             | <i>Linda Berger</i> |

## **Authorization**

This Quality Manual is published to document and communicate the quality policies of IMPCO Technologies, Inc to all of it's employees and customers. It provides policy direction for the development of procedures and work instructions for activities and operations affecting quality, production, engineering, purchasing and sales. It is the intent of this manual to ensure that systems are defined and documented, records maintained and evidence of product and process conformance recorded.

This document is controlled and maintained by the Quality Assurance Organization, with direct content responsibility assigned to the Management Staff. It is reviewed periodically and updated as necessary to appropriately reflect the current quality plan.

IMPCO's Quality Management System is established in accordance with the EN ISO9001:2008 standard.

This manual has been authorized by:

*Jim Mitchell*  
Director, Quality Assurance  
Impco Technologies

07/03/2012  
Date



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### **Our History**

Imperial Machine Products Company, later changed to IMPCO (an acronym from the original name), was founded in 1957 by Herbert V. Hills and Richard Baverstock in a small Quonset hut in South Gate. The first product developed and sold was the CA300A carburetor, known as the "IMPERIAL", which is still sold today.

In 1967, the company was moved to Cerritos and became a wholly owned subsidiary of AJ Industries (Alaska Juneau Mining Company). IMPCO purchased BEAM Products Company in 1986, Garretson Equipment Company in FY1997, J & S Products and Algas Carburetion in FY1998. Along the way, several of IMPCO's distributors, such as Technisch Bureau Media in The Netherlands, Mikuni in Japan and Ateco PTY in Australia were purchased, becoming global affiliate locations. The company name was changed to IMPCO Technologies in the early 1990's.

### **IMPCO Today**

IMPCO Technologies, Inc., hereafter referred to as IMPCO, located in Santa Ana California and Sterling Heights Michigan, designs, manufactures and markets engines, products and systems that allow on-highway and off-highway engines to operate on clean burning, gaseous fuels such as propane and natural gas. We've been in the gaseous fuels business for fifty years, but that does not keep us from creating innovative solutions. Looking at situations from a different vantage point and originating exceptional solutions is what we do best. We bring new perception and technology to the table. IMPCO Technologies has grown to become a truly global business with offices on every major continent. With our Spectrum® Fuel Management Systems and Certified Engines Systems in addition to our traditional gaseous fuel carburetion components, IMPCO Technologies is poised for unprecedented growth.

Our products, and just as important, our integration expertise, enable Original Equipment Manufacturers (OEMs) to satisfy both customer specifications and government emissions regulations for application in the transportation, industrial and power generation markets.

With offices and manufacturing facilities around the world, and a distributor network that reaches every corner of the globe IMPCO Technologies is definitely part of the solution to the global air pollution and environmental challenges we face. As such, we work with governments around the world on initiatives to clean up the air in their major cities through the use of clean burning gaseous fuels.

## **MISSION STATEMENT**

At IMPCO, we develop, manufacture and market products that enable internal combustion engines to operate cleaner for our environment and more economically for the owner. We strive to remain market leaders by providing high quality, reliable, and cost effective products that bring value to our customers.

Our activities are supported by a set of values that all IMPCO people are asked to respect:

- We put the customers first
- We deliver on our commitments
- We are professional
- We respect each other
- We work as one team
- We are committed to continuous improvements

## **QUALITY POLICY**

IMPCO Technologies, Inc. is committed to producing products which provide customer value, contribute to a better environment and are;

- high quality
- reliable
- cost effective
- delivered on time
- designed to meet or exceed all applicable customer or regulatory requirements,

Our Quality Management System (QMS) has been established to achieve these objectives and to embrace the principles of continuous improvement

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## **IMPCO TECHNOLOGIES ENVIRONMENTAL POLICY**

IMPCO Technologies, Inc. is dedicated to a better world through cleaner air, and we have committed ourselves to improving global environmental quality, preventing pollution and protecting the environment.

We demonstrate this commitment through our development of technologies and products aimed at better utilizing alternate fuel resources such as natural gas and propane and minimizing traditional fuel sources via idle reduction and auxiliary power technologies.

Our policy encompasses:

- Providing products to OEM customers for use in all combustion engine applications that exceed customer and governmental emissions regulations.
- Working with government regulators worldwide in support of technically and financially responsible environmental legislation, and supporting such legislation with technology development to provide product solutions to meet those environmental requirements.
- Continuously assessing the impact of our plants, products and processes on the environment, to ensure we fulfil all legal and other compliance obligations.
- A goal to continuously assess our environmental management system to identify opportunities for improvement, and to implement those changes with the full commitment and support of management at all levels.



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## **4. Quality Management System**

**4.1 General requirements**

**4.2 Documentation requirements**

#### **4.1 General Requirements**

The Organization has established and documented the Quality Management System.

The Impco quality system has the priority to meet the Customer's expectation by assuring the product conformity with the specified requirements and a continuous improvement of products, services and IMPCO's processes.

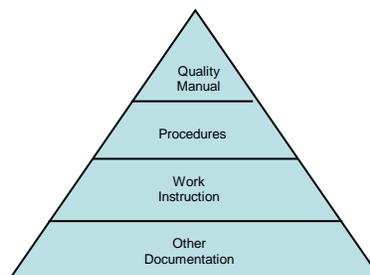
In order to attain this purpose, the management intends to apply the eight quality management principles:

1. **Customer Focus:** The organization intends to understand the customer's current and future needs to meet their requirements in order to exceed all expectations.
2. **Leadership:** The Managers have establish the organizations goals and objectives and have involved all personnel to achieve them.
3. **Employee Involvement:** Our employees are the essence of our organization. Their involvement and awareness of their importance allows us to obtain their maximum benefit.
4. **Process approach:** Impco uses a process approach to manage activities and resources.
5. **System approach to management:** Impco uses a system approach which aligns our policies and procedures which enables us in achieving our goals and objectives.
6. **Continual Improvement:** Impco has adapted the methodology know as Plan-Do-Check-Act (PDCA) which allows us to continual improve our processes.
7. **Factual approach to decision making:** All decision are based upon facts and data.
8. **Mutually beneficial supplier relationships:** Impco believes in supplier partnership which aligns with our mission statement to work as one team.

## 4.2 Documentation Requirements

This Quality Management System includes provisions for ensuring continual improvement and measuring effectiveness of procedures and processes.

IMPCO has established and maintains a Quality Management System as a means of ensuring that products conform to specified requirements and that all processes affecting quality are identified, documented and monitored. IMPCO's Quality Management System is comprised of Quality Policy, Quality Manual, procedures, forms, work instructions and records.



IMPCO's Quality Policy is stated on page 6 of this document.

The Director of Quality Assurance is responsible for maintaining this Quality Manual as an outline of IMPCO's overall Quality Plan.

IMPCO has prepared documented procedures consistent with the requirements of EN ISO9001:2008 and the company's stated Quality Policy and Quality Manual. The procedures that form this Quality Management System correspond with the company's operational processes.

The range and detail of these procedures is dependent upon the complexity of the work, the methods used and the skills and training needed by personnel involved in carrying out the activity. The documented procedures may make reference to work instructions that define how an activity is performed. Implementation of this Quality Management System is supported with records of training and satisfactory compliance of products and processes.



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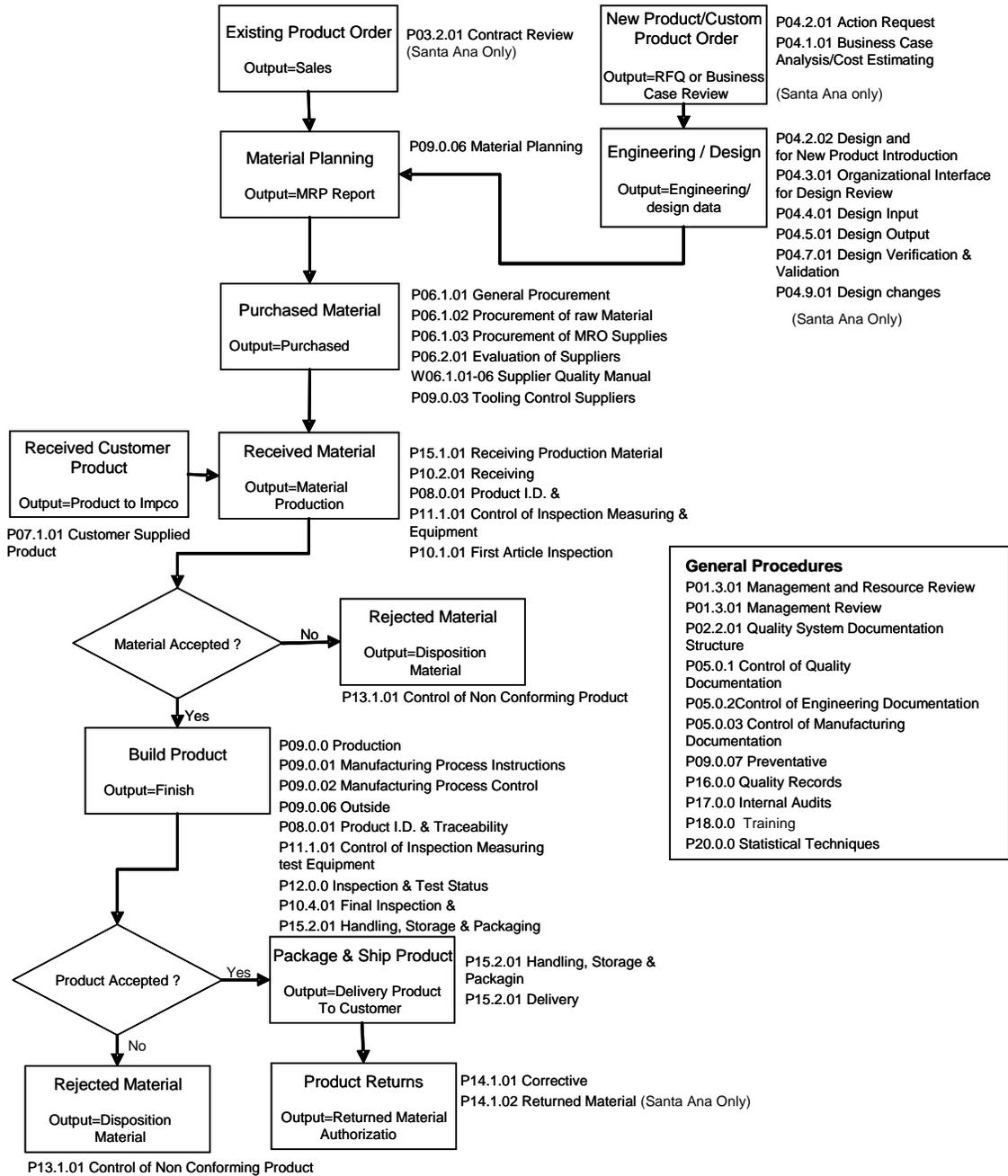
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**Reference Documents:**

Company Quality Manual Q01.0.00  
Company procedure P02.2.01 Quality System Documentation Structure  
Company procedure P05.0.01 Control of Quality System Documentation  
Company procedure P05.0.02 Control of Engineering Documentation  
Company procedure P05.0.03 Control of Manufacturing Documentation  
Company procedure P16.0.00 Quality Records

### 4.0 Quality System Operational Overview



## **5.0 Management Responsibility**

### **5.1 Management commitment**

### **5.2 Customer focus**

### **5.3 Quality policy**

### **5.4 Quality objectives**

#### 5.4.1 Quality objectives

#### 5.4.2 Quality planning

### **5.5 Responsibility, authority and communication**

#### 5.5.1 Responsibility and authority

#### 5.5.2 Management representative

#### 5.5.3 Internal communication

### **5.6 Management Review**

#### 5.6.1 General

#### 5.6.2 Review input

#### 5.6.3 Review output

### **5.1 Management Commitment**

IMPCO management with executive responsibility is committed to the development and improvement of the Quality Management System as described throughout this Quality Manual which include the following:

- Quality policy and objectives.
- Communication to the organization the importance of meeting customer, statutory and regulatory requirements.
- The establishment of appropriate workplace infrastructure and ensuring the availability of resources.
- Management reviews.

### **5.2 Customer Focus**

IMPCO management has implemented a Quality Management System aimed at meeting the customer's requirements

### **5.3 Quality Policy**

IMPCO's Quality Policy is stated on page 6 of this document. The company's Quality Policy is issued and re-assessed by the management so that it can always be updated as changes devise in the market. The Quality Policy is communicated through out the organization and understood by all.

## **5.4 Quality Planning**

### **5.4.1 Quality Objectives**

- Establish and maintain a Quality Management System in compliance with the requirements of ISO9001:2008.
- Provide products that meet or exceed customer requirements and expectations.
- Continually improve products, processes and resources.

### **5.4.2 Quality Planning**

This Quality Manual and all of the supporting procedures is referred to as the Quality Plan.

The coordination and execution of the plan is the responsibility of the ISO9001 Steering Committee and the responsible functional area managers affected by the ISO9001:2008 standard. This Quality Plan is maintained in conjunction with executive management review that takes place on a yearly basis.

## **5.5 Responsibility, Authority and Communication**

### **5.5.1 Responsibility and Authority**

Top Management ensures that the responsibilities and authorities are defined and communicated throughout the organization. IMPCO has developed Organizational Charts to reflect the reporting structure of the organization and Job Descriptions which define employee responsibilities.

IMPCO's Quality Assurance Program is established at the direction of the Director of Quality Assurance.

### **5.5.2 Management Representative**

The Director of Quality Assurance with irrespective of other responsibilities, have defined authority for:

- Ensuring that a Quality Management System is established, implemented and maintained in accordance with this Quality Manual and ISO 9001:2008.
- Reporting on the performance of the Quality Management System to IMPCO management for review and as a basis for improvement of the system.

Responsibilities of the Management Representative also include liaison with external parties on matters relating to IMPCO's Quality Management System. In the event of absence of the Quality Assurance Director, the Chief Operating Officer serves as the alternate Management Representative.

The responsibility for execution of the Quality Program is assigned to the management staff. Their disciplines include Quality Assurance, Sales/Marketing, Engineering, Operations, Human Resources, Finance and Project Management. The management staff may delegate responsibility for the Quality Program, however, they retain the ultimate responsibility.

The primary responsibilities for the functional areas are as outlined below:

- Ensuring that orders for product are adequately reviewed, agreed to and communicated is the responsibility of Sales.
- Ensuring that designs are appropriate to the requirements, establishment of the testing criteria and the ability to meet new designs and design changes is the responsibility of Engineering.
- Ensuring the timely purchase of materials that conform to the specified requirements for incorporation into IMPCO products is the responsibility of Purchasing.
- Establishment of the manufacturing process, identification of suitable verification points and clarification of those acceptability standards within the manufacturing process is the responsibility of Manufacturing Engineering.

- Management of IMPCO's production planning system and inventories is the responsibility of Materials.
- Planning, set up and execution of the production process is the responsibility of Production.
- Ensuring that personnel are retained and properly trained is the responsibility of Human Resources.

Quality Assurance oversees IMPCO's Quality Assurance Organization. Quality Assurance has responsibility, directly or in conjunction with the operating organization, for:

- Incoming material inspection
- In-process and final inspection
- Control of inspection, measuring and test equipment
- Inspection and test status
- Control of nonconforming product
- Corrective and preventive action
- Returned materials
- Internal quality audits
- Statistical techniques

Quality Assurance has the organizational freedom and authority to prevent the occurrence of nonconformities, record problems, initiate corrective actions, verify solutions and, if necessary, stop those processes until such time as they fully comply.

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| Responsibility<br>Procedure/Process |  | Quality | Engineering | Purchasing | Materials | Production | Sales | Human Resource | Accounting |
|-------------------------------------|--|---------|-------------|------------|-----------|------------|-------|----------------|------------|
|                                     |  |         |             |            |           |            |       |                |            |
| P01.3.01                            | Management and Resource Review   | X       |             |            |           |            |       |                |            |
| P02.2.01                            | Quality System Documentation Structure                                       | X       |             |            |           |            |       |                |            |
| P03.2.01                            | Contract Review  |         |             |            |           |            | X     |                |            |
| P04.1.01                            | Business Case Analysis/Cost Estimating                                       |         | X           |            |           |            |       |                |            |
| P04.2.01                            | Action Requests  |         | X           |            |           |            |       |                |            |
| P04.2.02                            | Design and Development Planning for New Product Implementation (NPI) Process |         | X           |            |           |            | X     |                |            |
| P04.3.01                            | Organizational Interface for Design Review                                   |         | X           |            |           |            |       |                |            |
| P04.4.01                            | Design Input   |         | X           |            |           |            |       |                |            |
| P04.5.01                            | Design Output  |         | X           |            |           |            |       |                |            |
| P04.7.01                            | Design Verification/Validation   |         | X           |            |           |            |       |                |            |
| P04.9.01                            | Design Changes   |         | X           |            |           |            |       |                |            |
| P05.0.01                            | Control of Quality System Documentation                                      | X       |             |            |           |            |       |                |            |
| P05.0.02                            | Control of Engineering Documentation   |         | X           |            |           |            |       |                |            |
| P05.0.03                            | Control of Manufacturing Documentation                                       |         | X           |            |           |            |       |                |            |
| P06.1.01                            | General Procurement  |         |             | X          |           |            |       |                |            |
| P06.1.02                            | Procurement of Raw Material  |         |             | X          |           |            |       |                |            |
| P06.1.03                            | Procurement of MRO Supplies  |         |             | X          |           |            |       |                |            |
| P06.1.04                            | Procurement of Capital Equipment   |         |             |            |           |            |       |                | X          |
| P06.2.01                            | Evaluation of Suppliers  |         |             | X          |           |            |       |                |            |
| P07.1.01                            | Control of Customer Supplied Product   |         |             |            | X         |            |       |                |            |
| P08.0.01                            | Product ID & Traceability  |         |             |            |           | X          |       |                |            |
| P09.0.00                            | Production   |         |             |            |           | X          |       |                |            |
| P09.0.01                            | Mfg. Process Instructions  |         | X           |            |           |            |       |                |            |
| P09.0.02                            | Mfg. Process Control   | X       |             |            |           |            |       |                |            |
| P09.0.03                            | Tooling Control - Suppliers  |         |             | X          |           |            |       |                |            |
| P09.0.05                            | Outside Processing of Inventory Items  |         |             | X          |           |            |       |                |            |
| P09.0.06                            | MRP  |         |             |            | X         |            |       |                |            |
| P09.0.07                            | Preventive Maintenance   |         | X           |            |           |            |       |                |            |
| P10.1.01                            | Internal/Customer First Article Inspection                                   | X       |             |            |           |            |       |                |            |
| W06.1.01-06                         | Supplier Quality Assurance Manual  | X       |             |            |           |            |       |                |            |
| P10.2.01                            | Receiving Inspection & Testing   | X       |             |            |           |            |       |                |            |
| P10.3.01                            | Machine Shop Inspection  | X       |             |            |           |            |       |                |            |
| P10.4.01                            | Final Inspection & Testing   | X       |             |            |           |            |       |                |            |
| P11.1.01                            | Control of Inspec., Measure., & Test Equip.                                  | X       |             |            |           |            |       |                |            |
| P12.0.00                            | Inspection & Test Status   | X       |             |            |           |            |       |                |            |
| P13.1.01                            | Control of Nonconforming Product   | X       |             |            |           |            |       |                |            |
| P14.1.01                            | Corrective and Preventive Action   | X       |             |            |           |            |       |                |            |
| P14.1.02                            | Returned Materials   | X       |             |            |           |            |       |                |            |
| P15.1.01                            | Receiving Production Materials   |         |             |            | X         |            |       |                |            |
| P15.2.01                            | Handling, Storage/ Packaging/Preservation                                    |         |             |            | X         |            |       |                |            |
| P15.3.01                            | Delivery   |         |             |            | X         |            |       |                |            |
| P16.0.00                            | Quality Records  | X       | X           | X          | X         | X          | X     | X              | X          |
| P17.0.01                            | Internal Quality Audits  | X       |             |            |           |            |       |                |            |
| P18.0.00                            | Employee Development and Training  |         |             |            |           |            |       | X              |            |
| P20.0.00                            | Statistical Techniques   | X       |             |            |           |            |       |                |            |

### **5.5.3 Internal Communication**

IMPCO's management with executive responsibility ensures that information regarding the Quality Management System is effectively communicated throughout the organization via the following:

- E-Mail
- Safety meeting conducted at a minimum once a year
- Posting boards
- Meeting

### **5.6 Management Review**

IMPCO's management with executive responsibility reviews the Quality Management System yearly to ensure its continuing suitability and effectiveness in satisfying the requirements of this Quality Manual and IMPCO's stated Quality Policy and objectives. Records of such reviews are maintained.

#### **Reference Documents:**

Company Organization Chart (See Human Resource for latest document)  
Company Quality policy (see page 6)  
Company Quality Manual  
Company procedure P01.3.01 Management & Resource Review  
Company procedure P17.0.01 Internal Quality Audits

## **6. Resource Management**

### **6.1 Provision of resources**

### **6.2 Human resources**

#### 6.2.1 General

#### 6.2.2 Competence, Awareness and Training

### **6.3 Infrastructure**

### **6.4 Work environment**

## **6.1 Provisions of Resources**

Management reviews and discusses company performance indicators and initiates changes /actions as appropriate. Priorities are established and resources allocated as necessary to achieve the company's objectives and to enhance customer satisfaction.

## **6.2 Human Resources**

### **6.2.1 General**

IMPCO's Human Resources Organization has established and maintains documented procedures for identifying training needs and coordinating the training of personnel performing activities affecting quality. Personnel performing specific assigned tasks are qualified on the basis of appropriate education, training and/or experience, as required. Formal training is provided to employees to ensure compliance to the published procedures and to encourage employee involvement in continual improvement.

### **6.2.2 Competence, Awareness and Training**

A job description specifying the education, knowledge, skills required and typical tasks is prepared/documented for each job position by the responsible manager and submitted to Human Resources for control and record keeping purposes.

When required, the employee receives on the job training under the supervision of the responsible manager or designee.

Employees are encouraged to continue their formal education through University study and/or recognized seminars.

Company organized/sponsored training/seminars are also provided as a means of improving the knowledge and skills of the workforce.

Performance appraisal is conducted for each employee by the responsible Manager.

### **6.3 Infrastructure**

IMPCO is organized with the following functions;

- Production
- Purchasing
- Quality
- Materials
- Shipping and Receiving
- Components design and testing
- Document Control
- Warranty
- Sales
- Human Resource
- Technical Service

### **6.4 Work Environment**

IMPCO is aware that the working environment factors affect personnel's motivation, satisfaction and performance as well as process conformity, with clear effects on the quality of products and companies services

To verify and make safety measures always efficient, IMPCO conducts a safety meeting at a minimum once a year to make sure all employees are satisfied with the safety of the working environment.

#### **Reference Documents:**

P18.0.00 Employee Development and Training

P09.0.07 Preventive Maintenance

## **7. Product Realization**

### **7.1 Planning of Product Realization**

#### **7.2 Customer Related Process**

- 7.2.1 Requirements related to the customer
- 7.2.2 Review of the product requirements
- 7.2.3 Customer communication

#### **7.3 Design and Development**

- 7.3.1 Design and development planning
- 7.3.2 Design and development input
- 7.3.3 Design and development output
- 7.3.4 Design and development review
- 7.3.5 Design and development verification
- 7.3.6 Design and development validation
- 7.3.7 Control of design and development modification

#### **7.4 Purchasing**

- 7.4.1 Purchasing process
- 7.4.2 Purchasing information
- 7.4.3 Verification of purchased product

#### **7.5 Product and Service Provision**

- 7.5.1 Control of production and service provision
- 7.5.2 Validation of processes for production and service provisions
- 7.5.3 Identification and traceability
- 7.5.4 Customer property
- 7.5.5 Preservation of product

#### **7.6 Control of monitoring and measuring devices**

## **7.1 Planning of Product Realization**

IMPCO has established processes defining the activities needed for product realization. In planning Product Realization the need for the following is determined as appropriate:

- Quality objectives and product requirements
- Processes, documents and resources to support product design, manufacture, Operation's and maintenance
- Verification, validation, monitoring, inspection, test and acceptance criteria
- Data and records of product realization and conformity
- The output of Product Realization planning is documented and communicated throughout the organization.

## **7.2 Customer Related Processes**

### **7.2.1 Determination of Requirements Related to the Product**

Impco sales group has established and maintains documented procedures for contract review and coordination of these activities.

Product requirements are determined for the following through a review of;

- Customer proposal/enquiry, technical specification, regulation and design practice as appropriate:
- Requirements specified by the customer, including the requirements for delivery and post-delivery activities
- Requirements not stated by the customer but necessary for specified or intended use, where known
- Statutory and regulatory requirements related to the product
- Additional requirements determined by IMPCO
- This activity is defined through the Request for Quote process.

### **7.2.2 Review of Requirements Related to the Product**

Requirements related to product are evaluated through the review of; Customer contract, technical specification, regulation and design practice as appropriate.

This activity is defined through the Contract Review process and is conducted prior to IMPCO's commitment to supply a product to the customer in order to ensure that:

- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- IMPCO's has the ability to meet the defined requirements
- Where the customer provides no documented statement of requirement, the customer requirements are confirmed by IMPCO's before acceptance. Once the Customer contract is accepted, it is formally acknowledged. Records of the contract review and actions arising from the review are maintained.
- All contract changes are evaluated, processed and communicated through the Contract Review process.

### **7.2.3 Customer Communication**

IMPCO has established effective means for Customer communication relative to:

- Product information
- Enquiries, contracts and changes
- Customer feedback and complaints

### **Reference Documents:**

P03.2.01 Contract Review

## **7.3 Design Development**

### **7.3.1 Design and Development Planning**

IMPCO has established procedures for the planning and control of design and development activities. As part of the planning process, the following is determined:

- Design and Development stages
- Review, verification and validation appropriate for each stage
- Responsibilities and authorities

When required, planning shall be in accordance with the agreed to Customer terms including; documentation, data, schedules and reviews as applicable. Planning addresses activities relative to Customer/Regulatory requirements and safety/functional objectives.

### **7.3.2 Design and Development Inputs**

Design and development inputs are determined to ensure product and product related requirements are identified. Inputs are reviewed for adequacy and records maintained which include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements as determined by IMPCO essential for design and development

### **7.3.3 Design and Development Output**

The output of design and development activities are provided in a form that enables verification against the design and development input, and are approved prior to release and reviewed by the cross functional team . Design and development outputs:

- Meet the input requirements for design and development  
Provide appropriate information for purchasing, production and service
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use
- Identify key characteristics when applicable

All pertinent data required to support the product manufacture, use or maintenance is defined including:

- Drawings, parts list and specifications
- Configuration baseline
- Relative information on product material, process and operation

#### **7.3.4 Design and Development Review**

Design/development reviews are performed at suitable stages in accordance with planned arrangements and are attended by the appropriate representatives (including IMPCO, Customer and/or Supplier participants) to:

- Evaluate the results of design and development to meet requirements
- Identify any problems and propose necessary actions
- Authorize progression to next stage
- Records of design/development reviews and actions are maintained.

#### **7.3.5 Design and Development Verification**

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.

Verification methods include: calculations, analysis, modeling, similarity comparison, tests and/or data review as appropriate. Records of the verification results and any necessary actions are maintained.

#### **7.3.6 Design and Development Validation**

Design Validation is a planned activity performed to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

#### **7.3.7 Control of Design and Development Changes**

Design changes are identified, documented, verified, validated and approved as appropriate prior to implementation. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and product already delivered.

The change control process includes provisions for Customer/Regulatory approval when required. Records of the changes and review are maintained.



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**Reference Documents:**

P04.2.01 Design and Development Planning  
P04.3.01 Organizational and Technical Interfaces  
P04.4.01 Design Input  
P04.5.01 Design Output  
P04.6.01 Design Review  
P04.7.01 Design Verification and Validation  
P04.9.01 Design Changes

## **7.4 Purchasing**

### **7.4.1 Purchase Process**

The IMPCO procurement system ensures that purchased products conform to specified requirements. Processes are established for the identification, evaluation, selection, monitoring and feedback of the IMPCO supply base. The level of control applied is dependent on the complexity and/or criticality of procured product or service.

Suppliers are evaluated and selected based on their ability to supply product in accordance with established requirements. Criteria for selection, evaluation, and re-evaluation have been established. Records of evaluations and any necessary actions arising from the evaluation are maintained.

IMPCO has defined the processes to control the supply base through the Supplier Quality Assurance Manual.

### **7.4.2 Purchase Information**

Product information is described on the Purchase Order and includes as appropriate:

- Drawing Number
- Drawing revision level
- Product description or part number; relative specifications, instructions and/or technical data and its corresponding issue
- Supplier quality requirements (Ref: Supplier Quality Manual)

IMPCO ensures the adequacy of specified purchase requirements prior to submittal to the supplier.

### **7.4.3 Verification of Purchased Product**

IMPCO has established procedures for inspection and related activities to ensure that purchased product meets specified requirements. Verification activities include as appropriate:

- Objective evidence of product conformity from the supplier
- Inspection/Audit at supplier facility
- Receiving inspection
- Supplier certification or verification delegation

Purchased product is not used or processed until it is verified as conforming unless it is released.



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**Reference Documents:**

P06.1.01 General Procurement  
P06.1.02 Procurement of Raw Materials  
P06.1.03 Procurement of MRO Supplies  
P06.1.04 Procurement of Capital Equipment  
P06.2.01 Evaluation of Suppliers  
P15.1.01 Receiving Production Materials  
P10.1.01 First Article Inspection  
P10.2.01 Receiving Inspection and Testing  
W06.1.01-06 Supplier Quality Assurance Manual

## **7.5 Production and Service Provision**

### **7.5.1 Control of Production and Service Provision**

Planning for production is performed with consideration to:

- Establishment of process controls and development of manufacturing instructions or routing instructions.
- Identification of in-process verification points where adequate verification cannot be performed at a later stage of realization
- Planned variable measurement of key characteristics
- Special processes

IMPCO has established procedures to ensure production is planned and carried out under controlled conditions. Controlled conditions include, as applicable:

- Description of product characteristics
- Availability of work instructions
- Use of suitable equipment
- Availability and use of monitoring and measuring devices
- Implementation of monitoring and measurement
- Implementation of release, delivery and post-delivery activities
- Accountability of product

### **Control of Service Operations**

Planning for service is performed with consideration to:

- Action/reports in regards to post delivery problems
- Control/update of technical documentation
- Approval, control and use of repair schemes

### **7.5.2 Validation of Processes for Production and Service Provision**

IMPCO has established procedures to validate any processes for production where the resulting output cannot be verified by subsequent monitoring or measurement. Validation includes as applicable:

- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of process and/or personnel including provisions for samples
- Use of specified methods and procedures, including control of significant operations and parameters, and changes thereto
- Requirements for data/records
- Re-validation

## **Exclusions**

- A. IMPCO products do not require special processes that cannot be validated during manufacturing or assembly.

### **7.5.3 Identification and Traceability**

IMPCO has established processes to ensure that product is identified throughout product realization including its status with respect to monitoring and measurement requirements. These processes also control the as-designed and identify the as-built configuration of product.

### **7.5.4 Customer Property**

IMPCO procedures define the controls relative to the handling of Customer property under its control and address:

- Handling and use
- Identification, verification, protection and maintenance
- Notification and reporting to customer involving damage or loss

### **7.5.5 Preservation of Product**

IMPCO has prescribed appropriate methods and means of preserving product conformity during internal processing through delivery. Where applicable in accordance with product specifications and/or applicable regulations, IMPCO procedures for identification, handling, storage, packaging, preservation, and delivery also cover the specific requirements.

#### **Reference Documents:**

P07.1.01 Control of Customer Supplied Product  
P08.0.01 Product Identification and Traceability  
P09.0.00 Production  
P09.0.01 Manufacturing Process Instructions  
P09.0.02 Manufacturing Process Control  
P09.0.03 Tooling Control - Suppliers  
P09.0.05 Tooling Control - Machining  
P09.0.06 MRP  
P09.0.07 Preventive Maintenance  
P15.1.01 Receiving Production Materials  
P15.2.01 Handling/Storage/Packaging/Preservation  
P15.3.01 Delivery

## **7.6 Control of Monitoring and Measuring Devices**

IMPCO procedures ensure; the requirement for, and the devices needed, to monitor and measure product and process are determined. Equipment used to provide evidence of product conformity is controlled and includes items such as:

- Inspection and test devices,
- Automated test equipment,
- Customer supplied equipment.

Guidelines for the selection of appropriate equipment and required environmental conditions for calibration, inspection and test are defined.

IMPCO has defined a calibration process and maintains a register of these monitoring and measuring devices which specify; equipment type, identification, location, interval, method and acceptance criteria.

Where required to ensure valid results, measuring equipment is:

Calibrated at specified intervals or prior to use, against standards traceable to national or international measurement standards; where no such standards exist, the basis for calibration/verification;

- Is recorded
- Adjusted/readjusted as necessary
- Identified as to its calibration status
- Safeguarded from adjustments which would invalidate measurement
- Protected from damage and deterioration
- Recalled for calibration by a defined method

When equipment is found not to conform to requirements; previous measurements are assessed, and appropriate action taken on the equipment and affected product. This activity is performed initially and reconfirmed as necessary. Records of calibration results and verification are maintained.

### **Reference Documents:**

P11.1.01 Control of Inspection, Measurement and Test Equipment

## **8. Measurement, Analysis, and Improvement**

### **8.1 General**

### **8.2 Monitoring and Measurement**

8.2.1 Customer Satisfaction

8.2.2 Internal Audit

8.2.3 Monitoring and Measurement of Processes

8.2.4 Monitoring and Measurement of Product

### **8.3 Control of Nonconforming Product**

### **8.4 Analysis of Data**

### **8.5 Improvement**

8.5.1 Continual Improvement

8.5.2 Corrective Actions

8.5.3 Preventive Actions

## **8.0 Measurement, Analysis, and Improvement**

### **8.1 General**

IMPCO has established methods for the planning and implementation of the monitoring, measurement, analysis and improvement processes needed to:

- Demonstrate product conformity
- Ensure conformity of the Quality Management System
- Continually improve the effectiveness of the Quality Management System

These processes include determination of applicable methods, including statistical techniques, and the extent of their use. Depending on the nature of product and specified requirements, statistical techniques may be used to support the following as applicable:

- Design verification (Reliability, Maintainability, Safety)
- Process capability/control
- Acceptance sampling

## **8.2 Monitoring and Measurement**

### **8.2.1 Customer Satisfaction**

IMPCO has a profound interest in the perception of its Customers relative to meeting its requirements. IMPCO has developed the means to obtain this information and in conjunction with specific feedback from its Customers generates measures of Customer satisfaction.

The methods for obtaining, analyzing and using Customer satisfaction data are defined.

### **8.2.2 Internal Audit**

Internal audits are an integral part of the IMPCO's Quality Program. Audits are planned and conducted to determine whether the Quality Management System :

- Conforms to planned arrangements, established Quality System requirements and applicable standards
- Is effectively implemented and maintained
- The Audit program is documented and defines responsibilities and requirements for; planning and conducting audits, reporting results and maintaining records.

- Audits take into consideration; the status and importance of the product, process and/or system to be audited, as well as results of previous audits. The audit criteria, scope (including contract and regulatory requirements), frequency and method are defined. The selection of auditors and conduct ensure objectivity and impartiality of the audit process. Auditors do not audit their own work or audit areas where they have key responsibility. Audit planning includes the preparation/review of applicable standards, procedures and/or checklists as appropriate.

Where findings requiring actions are discovered, corrective actions are issued and assigned to the responsible manager. Follow up activities verify the actions taken and their effectiveness.

### **8.2.3 Monitoring and Measurement of Processes**

IMPCO has developed methods for monitoring and measurement of Quality System processes. The methods demonstrate the ability of the process to achieve planned results. When planned results are not achieved, correction and preventive actions are taken, as appropriate, to ensure product conformity.

### **8.2.4 Monitoring and Measurement of Product**

Inspection and test operations are planned throughout product realization. IMPCO has established processes to define the type and level of monitoring and measurement of product characteristics to ensure product conformity. Where key characteristics are identified, they are monitored and controlled.

When acceptance sampling is specified, its use is statistically valid and appropriate. Product is not released for further processing, stocking or delivery until all planned arrangements have been completed and product is verified as conforming to stated requirements. Evidence of product conformity and records of product release authority are maintained.

### **Reference Documents:**

P01.3.01 Management Review  
P09.0.01 Manufacturing Process Instructions  
P10.2.01 Receiving Inspection and Testing  
P10.4.01 Final Inspection and Testing  
P12.0.00 Inspection and Test Status  
P15.1.01 Receiving Production Materials  
P17.0.01 Internal Quality Audits

### **8.3 Control of Nonconforming Product**

IMPCO has established, documented and implemented a process for the identification, segregation, disposition and control of nonconforming product to prevent its unintended use or delivery. Upon detection, nonconforming product is recorded and action taken to:

- Eliminate the nonconformity
- Authorize its use
- Preclude its original or intended use or application
- Nonconforming product which is repaired or reworked is re-verified for conformance to stated requirements. Product dispositioned scrap is returned to the supplier or scrapped in-house.
- When nonconforming product may affect the reliability or safety of previously delivered product, IMPCO will take action appropriate to the effects or potential effects including contacting the Customer with all pertinent information in a timely fashion. Records of nonconforming product and subsequent actions are maintained.

### **8.4 Analysis of Data**

IMPCO determines, collects and analyzes appropriate data to demonstrate the effectiveness of the Quality Management System and to evaluate where improvement can be made. This information includes data which is generated from monitoring and measurement of processes and other relevant sources.

The analysis of data provides information relative to:

- Customer satisfaction
- Product conformity
- Product/process characteristics, trends and improvement opportunities
- Supplier performance

## **8.5 Improvement**

### **8.5.1 Continual Improvement**

IMPCO is committed to continually improving the effectiveness of the Quality Management System through the establishment, review and use of the following:

- Quality policy
- Quality objectives
- Audit results
- Analysis of data
- Corrective actions
- Preventive actions
- Management review
- Customer feedback

### **8.5.2 Corrective Action**

IMPCO's Quality Assurance Organization has established and maintains documented procedures for implementing corrective action. Any corrective action taken to eliminate the causes of actual or potential nonconformities is appropriate to the magnitude of problem and commensurate to the associated risks.

When required, changes to the procedures resulting from corrective actions are documented.

IMPCO's procedures for corrective action include the following:

- Effective handling of customer complaints
- Reports of product nonconformities
- Investigation of the cause of nonconformities relating to product, process and Quality System
- Determination of the corrective action needed to eliminate the cause of nonconformities, and application of controls to ensure that corrective action is taken and that it is effective.

### **Preventive Action**

IMPCO's procedures for preventive action include the use of appropriate sources of information such as;

- processes and work operations which affect product quality,
- Concessions
- Audit results
- Quality records
- Service reports
- Customer complaints

To detect, analyze and eliminate potential causes of nonconformities, determination of the steps needed to deal with any problems requiring preventive action, initiation of preventive action and application of controls to ensure that it is effective and ensuring that relevant information on actions taken is submitted for management review.

### **Reference Documents:**

P01.3.01 Management Review  
P14.1.01 Corrective and Preventive Action  
P14.1.02 Returned Materials  
P17.0.01 Internal Quality Audits