



High Performance Alloys, Inc.

Quality System Manual

ISO9001:2008

Revision History

Revision	Date	Review/Revision Description	Approvals
A	8/26/2008	Initial Release	President: <i>Russ Kerchner Jr.</i>
			QA Manager: <i>David L Monow</i>
B	3/20/2009	Revised to meet ISO 9001:2008	President: <i>Russ Kerchner Jr.</i>
			QA Manager: <i>David L Monow</i>
C	10/12/2009	Revised Section 9.1 (Organization Chart) to move Production Planner position from Purchasing/Sales/Marketing department to Plant Operations department.	President: <i>Russ Kerchner Jr.</i>
			QA Manager: <i>David L Monow</i>
D	2/23/2010	Revised to reflect organizational changes.	Top Management: <i>Frank W. Hill</i>
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Quality System Manual

Revision: D

Table of Contents

0	Company Profile.....	4
1	Scope	4
1.1	General.....	4
1.2	Application	4
2	Normative Reference	5
3	Terms and Definitions.....	5
4	Quality Management System.....	5
4.1	General Requirements.....	5
4.2	Documentation Requirements	6
5	Management Responsibility	7
5.1	Management Commitment	7
5.2	Customer Focus	7
5.3	Quality Policy.....	7
5.4	Planning.....	8
5.5	Responsibility, Authority, and Communication.....	9
5.6	Management Review	10
6	Resource Management	11
6.1	Provision of Resources.....	11
6.2	Human Resources	11
6.3	Infrastructure	11
6.4	Work Environment	12
7	Product Realization.....	12
7.1	Planning of Product Realization.....	12
7.2	Customer-Related Processes.....	12
7.3	Design and Development	13
7.4	Purchasing.....	13
7.5	Production and Service Provision.....	14
7.6	Control of Monitoring and Measuring Devices.....	15
8	Measurement, Analysis, and Improvement.....	15
8.1	General.....	15
8.2	Monitoring and Measurement.....	16
8.3	Control of Non-Conforming Product.....	16
8.4	Analysis of Data.....	16
8.5	Improvement.....	17
9	Appendices	18
9.1	Organization Chart.....	18
9.2	QMS Process Flowchart	19

0 Company Profile

Over the past 25 years, High Performance Alloys, Inc. has become a leader in the super alloys industry, supplying bar, sheet plate, pipe, tube fittings, flanges, fasteners, and formed angles to many fine OEM's in the aerospace, chemical processing, oil-gas, medical, and food processing industries. Our former President, Russ Kirchner, a Metallurgist and Corrosion Specialist (now retired), started this company in 1984 with the intent to sell small orders quickly and economically. No other companies offer the degree of fast, friendly service and depth of knowledge that we give to our customers. Along with distribution capabilities, High Performance Alloys, Inc. also offers other specialized alloy production services, including fabrication, machining, and testing.

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1 Scope

1.1 General

This quality manual provides specifics on the policies and procedures used by High Performance Alloys, Inc. to satisfy the requirements of the ISO9001:2008 Quality Management System. It provides comprehensive evidence to all customers, suppliers, and employees that High Performance Alloys, Inc. is committed to establishing and maintaining acceptable levels of measurable quality in its products, processes, and services in an effort to enhance customer satisfaction.

This manual outlines how High Performance Alloys, Inc. adopts a process approach to developing, implementing, and improving the effectiveness of the Quality Management System. Appendix Section 9.2 of this manual includes a flowchart, which identifies the processes used within High Performance Alloys, Inc.

1.2 Application

High Performance Alloys, Inc. has excluded the following from the applicable requirements of ISO9001:2008:

Section 7.5.2 Validation of Processes for Production and Service Provision

Servicing of product is not a subject of contracts with High Performance Alloys, Inc.'s customers. High Performance Alloys, Inc. products are usually incorporated by the customer into his product or processes. High Performance Alloys, Inc. generally delivers material FOB point of manufacture and does not service material in the customer's applications.



High Performance Alloys, Inc. responds to customer's needs and requests dealing with technical and applications inquiries. Such responses could potentially include visits to the customer's facilities to evaluate the customer's applications of the High Performance Alloys, Inc. products. Such visits are not considered "servicing", as visits are not part of a contractual agreement between buyer and seller, nor is functionality of the product dependent upon regular maintenance.

Section 7.3 Design and Development:

High Performance Alloys, Inc. does not engage in design and development activities.

The exclusions above do not affect the ability or responsibility of High Performance Alloys, Inc. to provide product that meets customer and applicable regulatory requirements.

2 Normative Reference

This quality manual serves as a normative document for the entire quality system. For undated references, the latest edition of the normative document referred to applies.

3 Terms and Definitions

- HPA = High Performance Alloys, Inc.
- Supply chain = Supplier (Vendor) → Organization → Customer
- Top Management = President, Controller/Administrator, and IT Manager
- QMS = Quality Management System

4 Quality Management System

4.1 General Requirements

HPA has established a QMS that complies with ISO9001:2008 requirements and supports HPA's Quality Policy and objectives. HPA believes that quality is the responsibility of all individuals throughout HPA. The QMS shall:

- Identify all of the processes and their application within HPA
- Determine the flow and interaction of these processes
- Define the criteria and methods necessary to ensure effective operation and control of these processes
- Provide all resources necessary to support the operation and monitoring of these processes



- Monitor, measure, and analyze these processes
- Implement the actions required to achieve planned results and continual process improvement

HPA chooses to outsource some processes which affect product conformity, including some calibration and all material testing. HPA ensures control over these processes. Details regarding these controls are documented in the appropriate procedures within the QMS.

Appendix Section 9.2 of this manual includes a QMS flowchart, which describes the interaction of processes and associated procedures used within HPA.

4.2 Documentation Requirements

4.2.1 General

HPA has created all documentation required to ensure the effective planning, operation, and control of its processes. The QMS is structured in four levels:

LEVEL 1: The Quality Manual - the "roadmap" of the QMS.

LEVEL 2: Operating Procedures explain how the policies set forth in the Quality System Manual are to be implemented.

LEVEL 3: Work Instructions describe in detail how a particular task is performed.

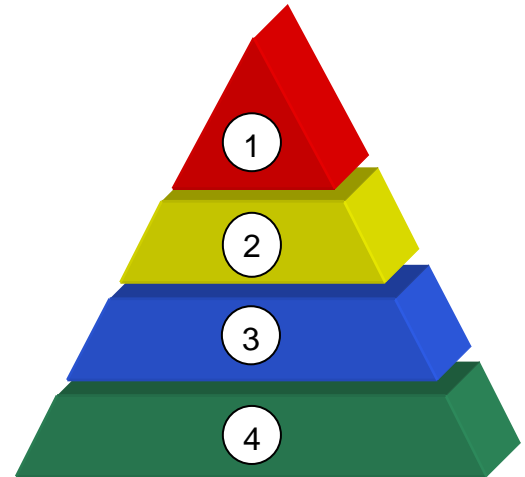
LEVEL 4: Forms and records are the basis for documenting the activity of the QMS. Industry specifications are also included in this level of documentation.

The Control of Documents (PR-42-01) and Control of Records (PR-42-02) procedures detail the approval, issue, and control of all QMS documentation.

4.2.2 Quality Manual

HPA has established and continually maintains this Quality System Manual as described in the Control of Documents procedure (PR-42-01). The purpose of this manual is to:

- Provide a general overview of the QMS
- Describe HPA's Quality Policy and Quality Objectives
- Reference all documented procedures included in the QMS
- Describe the sequence and interaction between the processes of the QMS and how they affect HPA at large



4.2.3 Control of Documents

HPA has established and continually maintains a system-level procedure entitled Control of Documents (PR-42-01), which establishes the methods for approving, reviewing, updating, and maintaining of all documents within the QMS.

4.2.4 Control of Records

HPA has established and continually maintains a system-level procedure entitled Control of Records (PR-42-02), which establishes the methods for identifying, collecting, indexing, accessing, filing, storing, maintaining, retaining, protecting, and disposing of quality records. The quality records provide evidence of conformance to requirements and of the effective operation of the QMS.

5 Management Responsibility

5.1 Management Commitment

HPA's Top Management is committed to:

- Providing effective communication throughout HPA regarding the importance of meeting customer requirements, as well as regulatory and legal requirements
- Establishing a quality policy and quality objectives
- Participating in Management Reviews
- Providing adequate resources for maintaining an effective QMS

5.2 Customer Focus

Top Management is committed to enhancing customer satisfaction. This commitment is accomplished by determining and understanding customer requirements and ensuring that HPA meets these requirements.

5.3 Quality Policy

Top Management has established a quality policy as a framework for establishing quality objectives.

HPAlloy's Quality Policy

High Performance Alloys, Inc. is committed to:



- Providing high performance super alloy materials, products, and services that meet or exceed customer requirements
- Communicating to employees the responsibility they share in maintaining an effective QMS
- Evaluating performance metrics such as customer satisfaction, product conformance, corrective/preventive actions, and vendor surveys to assess the continuing suitability and to continually improve the effectiveness of the QMS

5.4 Planning

5.4.1 Quality Objectives

Top Management has established measurable quality objectives for HPA. These objectives, derived from the quality policy stated in Section 5.3 above, are listed as follows:

- 100% HPA employee satisfaction by:
 - fostering an environment of teamwork through open internal communications and employee performance appraisals
 - providing adequate training and resources
- 100% customer satisfaction
- 100% on time delivery of product
- Effective communication with customers throughout sales, production, and delivery processes
- Prompt and effective detection, control, response, and prevention of non-conformities throughout HPA
- Meeting or exceeding the requirements of ISO 9001:2008

Top Management reviews these quality objectives during Management Review meetings in order to assess opportunities for improvement.

5.4.2 QMS Planning

In general, the quality plans are consistent with the normal methods of operation covered by existing procedures. These plans ensure that quality objectives set forth in the quality policy and those identified during Management Review meetings are met. Where customer-specified

requirements identify activities that are outside of the standard methods and practices, a separate quality plan will be prepared and issued.

As part of the regular maintenance of the QMS, proposed modifications to processes and procedures are reviewed during Management Review meetings to ensure that the requirements of the QMS have been addressed prior to the implementation of any modifications. This review ensures that no new process is implemented without first considering the actions that must be taken to ensure that HPA remains in compliance with the QMS as it is documented. Items evaluated and planned actions are documented in the Management Review meeting minutes.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

The lines of responsibility and reporting for all employees are documented on HPA organization chart, which appears in Appendix Section 9.1 of this document. In order to ensure that employees understand their authorities and responsibilities associated with the QMS, authorities and responsibilities are further documented in job descriptions.

- All authorities and responsibilities reside with Top Management and are delegated to functions and/or individual employees within their control as appropriate.
- All employees who manage, perform and/or verify work are responsible for the quality of products produced by HPA.
- All such employees are authorized to identify and record problems relating to products, processes, and the QMS as a whole. All employees have the responsibility to comply with documented procedures and the direction of management.
- All employees have the responsibility to assure that processes which they are performing are in a state of control and that the tasks are completed in a responsible manner.
- All employees are also responsible for identifying nonconforming product, marking such product as being nonconforming, notifying management, and controlling further processing until the problem has been corrected. To prevent non-conformities, they may also initiate, recommend, or provide solutions through designated channels, such as the Corrective and Preventive Action system.

5.5.2 Management Representative

Top Management has appointed HPA's Quality Assurance Manager as the Management Representative as required by the ISO9001:2008 standard. Irrespective of other duties, the Management Representative has the responsibility for:

- Establishing, implementing, and maintaining of the QMS as well as ensuring that it continues to be compliant with the requirements of ISO 9001:2008.
- Evaluating of the effectiveness of the QMS, reporting on it to Top Management and other attendees at scheduled Management Review meetings, making suggestions to improve the system.
- Approving, coordinating, and controlling of the Corrective and Preventive Action system and the Internal Audit system, including the verification of implemented Corrective and Preventive Actions to ensure that they are effective.
- Serving as the primary liaison to external parties on matters concerning the QMS.
- Ensuring that all employees are aware of the importance of meeting customer requirements and how those requirements relate to their work activities.

In the absence of the Management Representative, the Controller/Administrator shall assume these responsibilities.

5.5.3 Internal Communication

Although informal communication is an effective method of transmitting information relating to products and processes, formal mechanisms are in place to document and facilitate such communication. The effectiveness of internal communications and any further formalization of such communications are considered during Management Review meetings.

The effectiveness of the QMS processes are communicated to the various levels and functions through use of QMS documentation, training, Internal Audits and subsequent reporting, Document and Data Control, Corrective and Preventive Action systems, and Management Review meetings. Further communication regarding such production processes and their effectiveness is achieved via employee meetings, memos, bulleting boards, etc.

5.6 Management Review

5.6.1 General

Management Review meetings are held to assess and evaluate the QMS to ensure its continued effectiveness and suitability in satisfying the requirements of ISO 9001:2008 and HPA's stated quality policy and objectives. Reviews are carried out according to the Management Review procedure (PR-56-01).

5.6.2 Review Input

During Management Review meetings, Top Management reviews current performance and improvement opportunities arising from a variety of sources. These sources are delineated in the Management Review procedure (PR-56-01).

5.6.3 Review Output

Outputs from Management Review meetings include action items regarding the improvement of the QMS, improvement of the product in relation to customer requirements, and the identification of any needed resources to ensure the continuing satisfaction of HPA's customers.

6 Resource Management

6.1 Provision of Resources

Processes affecting the quality of our products and the success of the business have been identified and are described in this manual. Top Management ensures that resource requirements are identified and that adequate resources and trained employees are provided. Any employee may also identify resource needs by which such resource needs are also fulfilled.

Resources needed to implement and improve QMS processes, including enhancing customer satisfaction by meeting their requirements, are identified during Management Review meetings as described in Section 5.6 above.

6.2 Human Resources

6.2.1 General

All HPA personnel who affect the conformity to product requirements are qualified to perform specific tasks on the basis of the appropriate education, training, skill, and experience as evidenced by qualifications and training records. Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the QMS.

6.2.2 Competence, Training and Awareness

Training needs are determined and fulfilled according to the Competence, Training and Awareness procedure (PR-62-01). All employees, from inquiry to delivery, receive appropriate training to ensure that they are aware of their duties, responsibilities, and level of authority as defined on job descriptions and to ensure that the working practices specified in QMS documentation are implemented and followed.

6.3 Infrastructure

Top Management ensures that our facilities are maintained appropriately to achieve conformity of the product, including workspaces, equipment, software, and any supporting services, including transport, communication, and information technology (IT) systems. Such considerations are discussed during Management Review meetings.

6.3 Work Environment

Top Management determines and manages the work environment needed to achieve conformity to product requirements. The work environment consists of physical, environmental, and other factors, including health and safety conditions, work methods, handling methods, noise, temperature, humidity, lighting, and weather. Such factors are discussed during Management Review meetings.

7 Product Realization

7.1 Planning of Product Realization

In general, HPA's realization process planning is consistent with our normal methods of operation covered by existing procedures. In planning the processes for realization of products falling outside our normal methods, the following is considered:

- Quality objectives for products, projects or contracts, as applicable
- The need to establish processes and documentation and to provide any necessary resources specific to the product
- The required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance
- Any records necessary to provide confidence of conformity of the processes and resulting product

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Customer requirements are determined by the Purchasing/Sales Department during the inquiry, quotation, and order acceptance stages of customer contact. As described in the Quotations procedure (PR-72-01), the Purchasing/Sales Department determines:

- Customer requirements, including availability, delivery and post-delivery activities
- Requirements not stated by the customer but necessary for specified or intended use, where known
- Statutory and regulatory requirements applicable to the product
- Any additional requirements that HPA considers necessary

7.2.2 Review of Requirements Related to the Product

Prior to submission of a quotation or acceptance of an order, the Purchasing/Sales Department reviews the customer's requirements for the product to ensure that they have been clearly defined and documented. Such a review, as defined in the Quotations procedure (PR-72-01), also ensures that HPA has the ability to meet those requirements. If a received order or contract differs from the associated quotation, the differences are resolved before accepting and processing the order.

When customers submit change orders regarding the product or their order, the changes are received and reviewed against the original order. Any changes that require amendments to process or product documentation will result in revising the affected documents and notifying all affected employees according to the appropriate procedures.

7.2.3 Customer Communication

Any other communications by customers will be routed to the Purchasing/Sales Department, which will respond appropriately according to the Quotations procedure (PR-72-01), the Purchasing and Sales procedure (PR-74-01) and/or the Corrective and Preventive Action procedures (PR-85-01 and PR-85-02 respectively). Where appropriate, the Purchasing/Sales Department may authorize other employees to serve as liaison to the customer for technical questions or other specific reasons. The Purchasing/Sales Department will also solicit customer feedback through appropriate means.

[7.3 Design and Development](#)

This section is excluded per section 1.2 of this Quality System Manual.

[7.4 Purchasing](#)

7.4.1 Purchasing Process

HPA's purchasing processes, including supplier evaluation and selection, are controlled according to the Purchasing and Sales procedure (PR-74-01), which ensures that purchased product and services conform to the applicable requirements. The type and extent of control exerted over such vendors and their product or service depends on the impact of the product or service on the realization process and/or the quality of the final product. The Purchasing and Sales procedure (PR-74-01) also describes the process that HPA employs for the creation, confirmation, and amendment of sales orders.

7.4.2 Purchasing Information

Designated employees are authorized to identify resource or purchasing requirements. As appropriate, a purchase order is initiated to procure the needed items. The purchase order details all necessary information and pertinent specifications including, where applicable, the requirements for qualification of personnel, or any QMS requirements. All purchasing documents



involving product are reviewed by the Purchasing/Sales Department for accuracy and completeness prior to release.

7.4.3 Verification of Purchased Product

Purchased products are verified upon receipt according to the Control of Production procedure (PR-75-01). When requested, all purchased products are to be supplied with appropriate product certification per the Material Testing and Certification procedure (PR-74-02). If HPA or its customers should decide to verify products at our vendor's premises prior to delivery, the arrangements, verification, and release of such products will be determined and documented by the Purchasing/Sales Department.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

The Control of Production procedure (PR-75-01) describes methods by which HPA plans and carries out production and service operations.

7.5.2 Validation of Processes for Production and Service Provision

This section is excluded per section 1.2 of this Quality Manual.

7.5.3 Identification and Traceability

The Control of Production procedure (PR-75-01) defines, where appropriate, the means by which HPA:

- Identifies the product by suitable means throughout the realization process
- Identifies the product status with respect to monitoring and measurement requirements throughout the realization process
- Controls the unique identification of the product (where traceability is a requirement) and maintains records

7.5.4 Customer Property

Occasionally customers supply materials that HPA will use to manufacture into a finished product per pre-determined requirements in accordance with Section 7.2.1 of this manual. Such items shall be handled with care within HPA per the Control of Production procedure (PR-75-01).

7.5.5 Preservation of Product

All materials and products under HPA control are stored and handled in such a way as to preserve conformity of the product, including any constituent parts. Such protection is also extended to product being delivered, which is packaged appropriately to preserve conformity during delivery according to the Packaging and Shipping procedure (PR-75-02).

7.6 Control of Monitoring and Measuring Devices

The Equipment Calibration and Maintenance procedure (PR-76-01) describes HPA's methods for calibrating (internal and external), maintenance, and disposition of equipment used to manufacture product or measure product conformity to specified requirements. The procedure identifies work instructions as well as the calibration frequency and location (internal or external) for each piece of equipment.

8 Measurement, Analysis, and Improvement

8.1 General

Planning for monitoring, measurement, analysis and improvement activities occurs at two levels:

Product Level: Ensuring and demonstrating conformity to product requirements.

The Plant Manager and Quality Assurance Manager are responsible for determining the appropriate production processes, measuring and monitoring activities used during production, and inspection in daily operations. Such activities are reviewed during Management Review meetings, where customer satisfaction is analyzed to determine where improvements at the product level can be made.

System Level: Ensuring and demonstrating conformity of the QMS to the requirements of ISO 9001 and to HPA's own established procedures and policies as well as the achievement of objectives.

Such planning at the system level includes scheduling Internal Audits and measuring customer satisfaction. It also addresses the continual improvement and effectiveness of the QMS and opportunities for preventive action. Top Management evaluates the effectiveness of measuring and monitoring activities during Management Review meetings, where further application of such activities is also considered, including the use of statistical techniques. Any such activities identified are implemented and recorded per the Management Review procedure (PR-56-01). This level of planning is focused upon the measuring processes, determining system conformity, and achieving improvement to the QMS.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction and customer perception are considered during Management Review meetings as described in Section 5.6 of this manual. Customer satisfaction and perception data is a vital tool in driving improvement of the QMS. The Monitoring and Measurement procedure (PR-82-02) describes the methods for collection, monitoring, and analysis of customer satisfaction and perception data.

8.2.2 Internal Audit

HPA conducts periodic Internal Audits in accordance with the Internal Audit procedure (PR-82-01). Internal Audits allow HPA to determine whether or not the QMS conforms to the planned arrangements of product realization, the requirements of ISO 9001:2008, and the QMS requirements that HPA has established. This procedure also defines how HPA conducts internal audits to determine whether the QMS is effectively implemented, documented, and maintained.

8.2.3 Monitoring and Measurement of Processes

The Monitoring and Measurement procedure (PR-82-02) describes the methods HPA has implemented to ensure that HPA's processes achieve planned results. When the results of the events are not achieved, the Corrective Action procedure (PR-85-01) shall be utilized as appropriate to ensure conformity of the product.

8.2.4 Monitoring and Measurement of Product

The Monitoring and Measurement procedure (PR-82-02) describes the methods HPA employs for monitoring and measuring the characteristics of the product throughout the product realization process to verify that the product requirements have been met.

8.3 Control of Non-Conforming Product

HPA makes every effort to prevent product that does not conform to specified requirements from reaching the customer. The Control of Nonconformity procedure (PR-83-01) describes the methods HPA utilizes to identify and control nonconforming product.

8.4 Analysis of Data

HPA regularly analyzes data that demonstrates the suitability and effectiveness of the QMS. Such data can reveal ways HPA can use to make continual improvements within the QMS. In addition, HPA employs a c=0 approach to collect sampled data during product inspections as described in the Statistical Sampling for Inspection procedure (PR-84-01). All data is analyzed at Management Review meetings per the Management Review procedure (PR-56-01).

8.5 Improvement

8.5.1 Continual Improvement

HPA shall continually improve the effectiveness of the QMS through use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and Management Review. Continual improvement activities will be reviewed during Management Review meetings and will be documented in accordance with the Corrective Action procedure (PR-85-01) and the Preventive Action procedure (PR-85-02).

8.5.2 Corrective Action

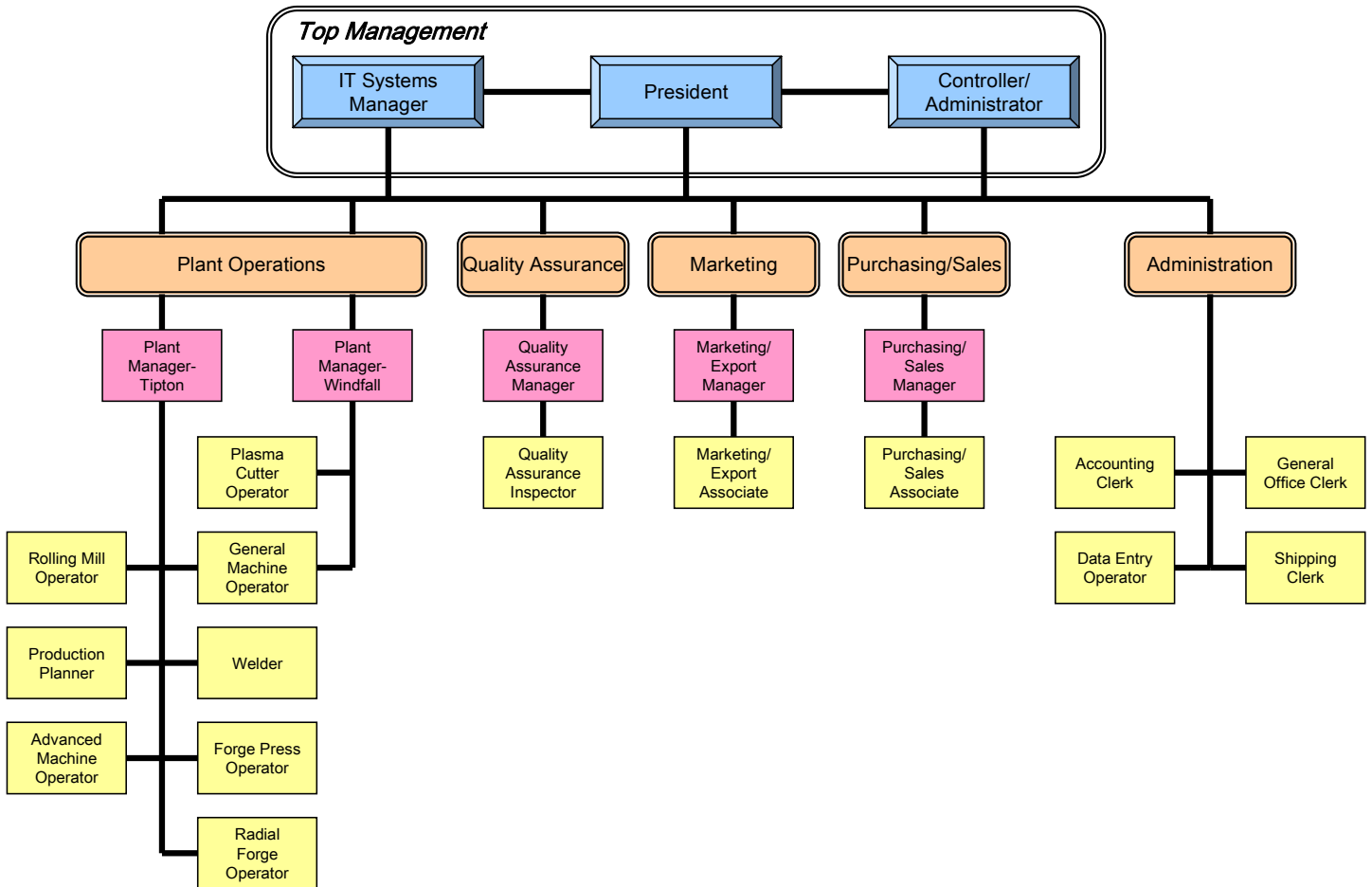
Corrective Actions are undertaken to eliminate the causes of non-conformities in order to prevent their recurrence. Actions taken are appropriate to the impact of the problems encountered. Corrective Actions are initiated according to the Corrective Action procedure (PR-85-01).

8.5.3 Preventive Action

Request for Preventive Actions typically arise in the same manner as those for Corrective Actions, although Preventive Actions are undertaken to eliminate the causes of potential non-conformities. Such requests will be processed as delineated in the Preventive Action procedure (PR-85-02).

9 Appendices

9.1 Organization Chart



9.2 QMS Process Flowchart

