MEGA
FLUID SYSTEMS

QUALITY MANAGEMENT SYSTEM MANUAL

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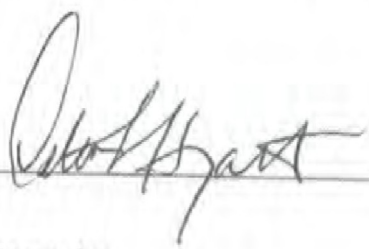
PREAMBLE

This manual addresses requirements of Mega Fluid System's Quality Management System. Management wholeheartedly endorses the principles of the ISO quality standard which serves as a basis for company's system. Mega Fluid System's Operations Manager is responsible for methods used to satisfy specification requirements and to produce products manufactured and/or assembled by the site.

The documentation system used by our facility is maintained in the PLM (Bluestar). It provides various databases for maintaining control and providing the latest documentation on demand. Personnel with passwords have access to the system; only a few have access allowing them to make changes.

We are extremely sensitive to the need for customer satisfaction, exceptional quality, and responsive service. Our commitment is to ensure customer loyalty through voice of the customer, teamwork, continual improvement, employee empowerment, and flexibility.

As a symbol of this commitment, I hereby affix my signature.



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President
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28 Sept '09
Date

1 Scope

1.1 General

This manual from Mega Fluid Systems outlines the policies and requirements for its Quality Management System, which is based on the principles outlined in the ISO 9001 quality standard.

Specifics regarding business unit processes and documentation are contained in the Sequence and Interaction of Key Quality Management System Processes in Attachment B.

1.2 Business scope

Mega Fluid Systems provides products and services for the design and manufacture of chemical delivery modules for the semiconductor industries.

2 Normative reference

Processes referenced in this manual are identified in the Sequence and Interaction of Key Quality Management System Processes, Attachment B.

3 Terms and definitions

- Top management – the President, Vice President of Engineering, and Operations Manager of Mega Fluid Systems, and immediate staff.
- Customer owned property – any type of product, assembly, sub-assembly, instrumentation, accessory, manuals, test equipment, tools, software, or shipping containers that belong to a customer.
- Product – the end result of meeting contract terms and conditions (e.g., assemblies, manufactured goods, documentation, services, etc.).
- Records – documentation of activities where records of those activities are required.
- PLM – (Product Lifecycle Management system) Data Storage Vault for all Engineering data except software code. (example: currently BlueStar but is subject to change)
- ERP – (Enterprise Resource Planning system) Business and Operations system for company. (example: currently AX but is subject to change)
- VSS – (Virtual Source Safe) Data security and storage vault for software code.

4 Quality Management System

4.1 General requirements

Mega Fluid Systems established, documented, implemented, and maintains a quality management system and continually improves its effectiveness. Processes needed for the quality management system have been determined and applied throughout the site. Sequences and interactions of these processes are further described in the Sequence and Interaction of Key Quality Management System Processes, Attachment B. Criteria and methods are in place, and resources have been allocated to ensure processes are controlled, and their operation is effective. Processes are monitored and analyzed to determine if they are achieving planned results. A program is in place to make continual improvements to processes.

Processes outsourced to vendors, including other Mega Fluid Systems facilities, have been determined, documented, and are controlled through the document control system.

4.2 Documentation requirements

Mega Fluid Systems has a documented quality policy and quality objectives, which are widely distributed at this site. A quality manual describes procedures that have been determined for effective planning, operation and control of processes. Records of the quality system are maintained by the business unit.

Product design is a corporate function and is controlled by corporate policies and procedures.

Documented procedures define controls needed to:

- approve documentation for adequacy prior to use
- review, update, and re-approve documents as necessary
- ensure that changes and current revision status of documents are identified
- ensure relevant versions of applicable documents are available at points-of-use
- ensure documents remain legible and readily available
- ensure documents of external origin determined by the organization to be necessary for the planning and operation of the quality management systems are identified and their distribution is controlled, and
- prevent unintended use of obsolete documents, and to apply suitable identification if they are retained for any purpose.

A documented procedure is established that defines the controls used for the identification, storage, protection, retrieval, retention, and disposition of records.

5 Management responsibility

5.1 Management commitment

Mega Fluid Systems management has an established Quality Policy for the corporation (see 5.3), which is distributed and communicated to the site and each employee. Quality objectives are established by the President.

Site management reviews are conducted for sales, operations, and quality at regular intervals. Top management reviews of pertinent data are also conducted on a regular basis. If reviews and Return on Investment studies of new product opportunities indicate the need for additional resources, management works through various Mega Fluid Systems organizations to coordinate and arrange for these resources.

5.2 Customer focus

From top management, through all levels of the business unit, Mega Fluid Systems strives to identify current and future customer needs, meet customer requirements, and exceed customer expectations.

Processes are established to ensure customer requirements are understood and met. Customer requirements are determined, converted to internal requirements, and communicated to the appropriate employees according to processes established for the site and a particular customer.

5.3 Quality policy

Mega Fluid Systems management embraces the following policy to direct high standards throughout the corporation:

*At **MEGA** **F**luid **S**ystems, we are committed to the highest standards of quality through our products, or customer satisfaction, and our continuous improvement which utilizes innovation and leadership.*

MEGA FLUID SYSTEMS

The policy is communicated to employees and is reviewed at appropriate intervals by business unit management to determine its continued application and adherence.

5.4 Planning

Quality objectives are established by management. These objectives may vary from customer to customer; however, they are measurable and consistent with the quality policy. Processes for achieving these objectives are spelled out.

The President is responsible for monitoring the quality management system to ensure that it meets quality objectives and customer expectations, and to ensure system integrity is not compromised when changes are planned and implemented.

5.5 Responsibility, authority and communication

A Management Representative is appointed by the Executive Staff. These individuals have the responsibility and authority to:

- ensure processes needed for the quality management system are established, implemented, and maintained
- report to the Operations Manager on performance of the quality management system and any need for improvement
- ensure awareness of customer requirements throughout the site, and
- act as a liaison with external parties such as customers, other facilities or auditors on matters relating to the quality management system.

The Operations Manager has defined responsibilities and authorities for effective quality management system operation and has communicated these throughout the organization. Examples of communicating quality management system effectiveness include department and management meetings, management reviews of the system, quality management system metrics, and Executive Staff meetings.

5.6 Management review

Top management reviews the overall quality management system annually to ensure its continuing suitability, adequacy, and effectiveness. This review assesses opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

The President reviews components of the quality management system monthly. At a minimum, these reviews include metrics for continued operation and improvement of site processes.

Metrics presented and minutes of the reviews are maintained as records.

Inputs to the monthly management review includes information on

- audit results
- customer feedback

- process performance and product conformity
- status of preventive and corrective actions
- follow-up actions from previous management reviews
- changes that could affect the quality management system, and
- recommendations for improvement.

Output from the monthly management review includes decisions and actions related to

- improvements to effectiveness of the quality management system and its processes
- improvements to products related to customer requirements, and
- resource needs.

Responsibilities for required actions are assigned to members of the review team. Decisions made during the meeting, assigned actions, and their due dates are recorded in meeting minutes.

6 Resource management

6.1 Provision of resources

The management has committed resources necessary to implement, maintain, and continually improve the quality management system.

6.2 Human resources

To ensure competence of personnel, job descriptions are published which identify qualifications required for each position that affects conformity to product requirements. These include requirements for education, skills, and experience. Job description requirements along with specific job training provide each position's required competence.

Qualifications are reviewed upon hire, when an employee changes positions, or when requirements for a position change. Records of employee qualifications are kept. If any difference is found between an employee's qualifications and requirements for a job, training or other action is taken to achieve the necessary competence for the job. Results of actions are evaluated for effectiveness. Employees are trained on the relevance and importance of their activities and how they contribute to achieving quality objectives.

Employee training and evaluation is documented according to the requirements listed in the Sequence and Interaction of Key Quality Management System Processes, Attachment B.

6.3 Infrastructure

The Management has determined the infrastructure required to provide product conformity. These requirements are communicated to Mega Fluid Systems corporate management which provides and

manages buildings, hardware and software associated with information technologies, capital equipment, and the communications system.

This site provides and maintains tools that are not capitalized including work stations. If changes or additions are necessary to the site, information technologies supplied services, the communication system, or capital equipment; processes are in place through Mega Fluid Systems corporate structure to request these changes and/or additions to the existing work environment.

Information Technology provides periodic data backup services, including off-site storage, to provide business continuity in the event of disrupted operations.

6.4 Work environment

Corporate facility management determines and manages the work environment needed to achieve conformity of product including cleanliness to avoid particle contamination, adequate light, heat, humidity control, noise, vibration, safety rules, and ergonomics.

7 Product realization

7.1 Planning of product realization

Quality planning is done before new products or processes are implemented. As appropriate, the following are determined by the planning process and implemented:

- quality objectives and requirements for the product
- processes, documents, and resources specific to the product
- required verification, validation, monitoring, measurement, inspection and test activities specific to the product and criteria for product acceptance, and
- records to provide evidence that realization processes and resulting product meet requirements.

Quality planning outputs comply with forms specified by processes for the site, department, or group affected by the plans.

7.2 Customer-related processes

Customer requirements are determined before acceptance on an order. As appropriate, determination includes:

- requirements specified by the customer
- requirements for delivery, and for 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, and
- any additional requirements considered necessary by the Management.

Affected departments shall review requirements related to the product. This review is conducted prior to commitment to supply a product to the customer (e.g., acceptance of contracts or orders or acceptance of changes to contracts or orders) and shall ensure that:

- product requirements are defined
- contract or order requirements differing from those previously expressed are resolved
- the Management is able to meet defined requirements, and
- records of the results and actions arising from the review are maintained.

Where the customer provides no documented statement of requirements, customer requirements are confirmed before acceptance.

Where product requirements are changed, the site ensures relevant documents are amended and appropriate personnel are made aware of the changes.

The site has determined and implemented effective arrangements for communicating with customers in relation to

- product information
- inquiries, contracts or order handling, including amendments, and
- customer feedback, including customer complaints.

7.3 Design and development

The organization has processes established for planning and controlling the design and development of product as applicable. A process is in place and documented (see Sequence and Interaction of Key Quality Management System Processes, Attachment B) that describes how the organization:

- progresses through the design and development stages
- determines and performs the required reviews
- performs verification and validation that are appropriate to each design and development stage, and
- determines and assigns responsibilities and authorities for design and development.

When different departments are involved in design and development, the process provides direction to ensure effective communication and clear assignment of responsibility. Planning output is updated, as appropriate, as the design and development progresses.

Design and development inputs are determined and records maintained. Inputs are determined by customer requirements.

Design and development outputs are documented in a format suitable for verification against the inputs. Design and development outputs:

- meet the input requirements
- provide appropriate information for purchasing, production and for service provision
- contain or reference product acceptance criteria, and
- specify the characteristics of the product that are essential for its safe and proper use.

The design and development process specifies the stages at which systematic reviews of design and development are performed. The results of these reviews are documented as specified by the design process. Design reviews:

- evaluate the ability of the results of design and development of the product to determine if they fulfill customer requirements
- identify any problems and propose necessary actions, and
- include representatives of departments and groups concerned with the design and development stage(s) being reviewed.

Records of the results of the reviews and any necessary actions are maintained.

Verification is performed per the design process (see site matrix for documentation references) to ensure that the design and development outputs meet the design and development inputs requirements. Records of the results of the verification and any necessary actions are maintained.

Design and development validation is performed per the design process to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use or application. Validation is completed prior to delivery or implementation of the product whenever practicable. Records of the results of validation and any necessary actions are maintained.

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes the effect of the changes on constituent parts and delivered product. Records of the results of the review of changes and any necessary actions are maintained.

7.4 Purchasing

Purchasing processes are established that ensure purchased products conform to specific purchase requirements.

Suppliers are evaluated and selected based on their ability to supply products in accordance with the requirements outlined in purchasing process documentation. Criteria for supplier selection, evaluation

and re-evaluation are established. Records of supplier evaluations and any necessary actions are maintained.

Purchasing information describes products to be purchased, including, where appropriate:

- requirements for approval of products, procedures, processes and equipment
- requirements for qualification of personnel, and
- quality management system requirements.

The purchasing associate(s) ensures adequacy of specified purchase requirements before orders are placed with suppliers.

An inspection program is established and implemented that ensures purchased products meet specified purchase requirements. If verification is performed at the supplier's location, intended verification arrangements and methods of product release are stated in purchasing information.

7.5 Production and service provision

Production and service provisions are planned and carried out under controlled conditions and include, as applicable:

- information that describes product characteristics
- work instructions, as necessary
- suitable equipment
- availability and use of monitoring and measuring equipment
- monitoring and measurement, and
- product release, delivery, and post-delivery activities.

Processes for production and service provisions are validated where resulting output cannot be verified by subsequent monitoring or measurement, and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation includes:

- defined criteria for process review and approval
- approval of equipment and qualification of personnel
- use of specific methods and procedures
- requirements for records, and
- re-validation.

A process for product identification throughout product realization is established. The process includes identification of product status with respect to monitoring and measurement requirements throughout the product realization process. Where traceability is required, unique product identification is controlled and records maintained.

A process is in place for preservation of product, including identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

A documented process is established for customers that request our design services to be utilized in the joint development of a new product. During joint development, the customer exercises complete control of their IP, the design process, and design verification and validation.

7.6 Control of monitoring and measuring devices

Monitoring and measurement equipment needed to provide evidence of product conformity requirements are implemented. Processes ensure monitoring and measurement are carried out in a manner consistent with requirements.

To ensure valid results, measuring equipment is:

- calibrated and/or verified, or both, at specific intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification is recorded.
- adjusted or re-adjusted as necessary
- have identification in order to determine its calibration status
- safeguarded from adjustments that would invalidate measurement result, and
- protected from damage and deterioration during handling, maintenance and storage.

When equipment is found out of conformance, a process for assessing and recording the validity of previous measuring results is in place. Appropriate action is taken on the equipment and any product affected by out-of-tolerance measurement devices. Records of calibration and verification results are maintained.

When used in monitoring and measurement of specified requirements, capability of computer software used in the process is confirmed prior to initial use and reconfirmed as necessary.

8 Measurement, analysis and improvement

8.1 General

Monitoring, measurement, analysis, and improvement processes are planned and implemented to

- demonstrate conformity to requirements
- ensure conformity of the quality management system, and

- continually improve effectiveness of the quality management system.

These processes are identified and include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

The site monitors information to ensure customer requirements are met. Methods for obtaining and using this information are identified.

Internal audits are conducted at planned intervals to determine whether the quality management system:

- conforms to the planned arrangements and to the quality management system requirements, and
- is effectively implemented and maintained.

An audit program has been designed and implemented. It identifies an audit schedule based on the importance of the areas to be audited, as well as results of previous audits. Audit criteria, scope, frequency, and methods are defined.

Records of the audit and their results are maintained.

The manager of the area being audited is responsible to ensure actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include verification of actions and reporting of verification results.

Suitable methods are applied for monitoring and measuring the quality management system processes. These methods demonstrate the ability of processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate.

Product characteristics are monitored and measured to verify product requirements are fulfilled. This is carried out at appropriate stages of product realization in accordance with established processes. Evidence of conformity with acceptance criteria is maintained.

Records indicate person(s) authorizing release of products for the delivery to the customer. Product release does not occur until planned arrangements are satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of nonconforming product

Products that do not conform to requirements are identified and controlled to prevent unintended use or delivery. Controls, related responsibilities, and authorities for dealing with nonconforming product are defined in process documentation. Records are maintained that describe the nature of nonconformities and subsequent actions, including concessions obtained.

8.4 Analysis of data

Appropriate data are collected and analyzed to demonstrate suitability and effectiveness of the quality management system and to evaluate where continual improvement can be made. A process for determining, collecting and analyzing this data is in place (see site matrix for document references).

Data analysis shall provide information relating to:

- customer satisfaction
- conformance to product requirements
- characteristics and trends of processes and products including opportunities for preventive action, and
- suppliers.

8.5 Improvement

A continual improvement program is established to continually improve effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

Corrective action is taken to eliminate causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of nonconformities.

A documented procedure defines requirements for

- reviewing nonconformities, including customer complaints
- determining causes of nonconformities
- evaluating the need for action to ensure that nonconformities do not recur
- determining and implementing action needed,
- recording results of action taken, and
- reviewing corrective action taken.

Preventive action is taken to eliminate causes of potential nonconformities before they occur. Preventive actions are appropriate to the effects of potential problems.

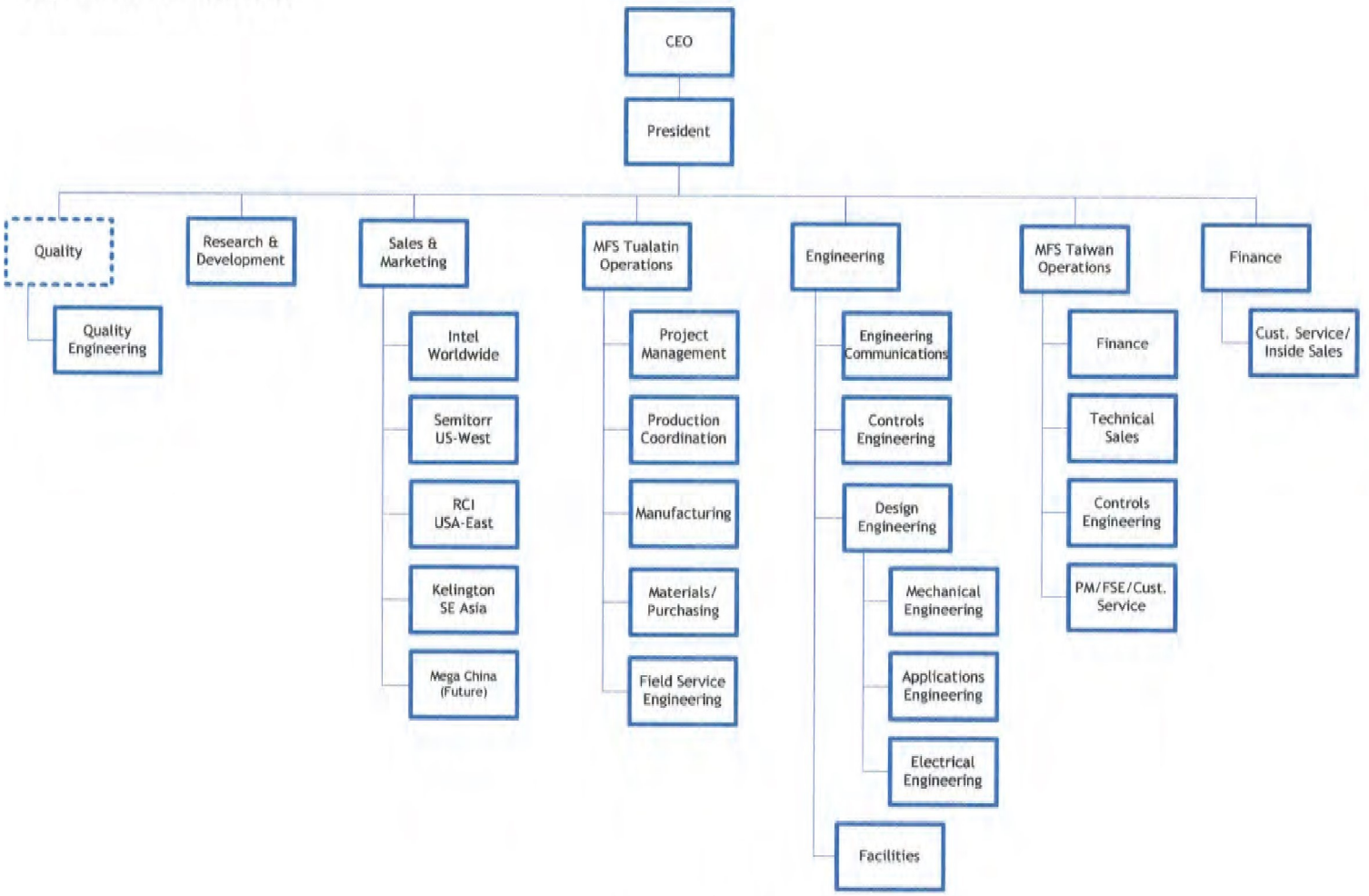
A documented procedure defines requirements for:

- determining potential nonconformities and their causes
- evaluating the need for action to prevent occurrence of nonconformities
- determining and implementing action needed
- recording results of action taken, and
- reviewing preventive action taken.

9 Summary of Changes

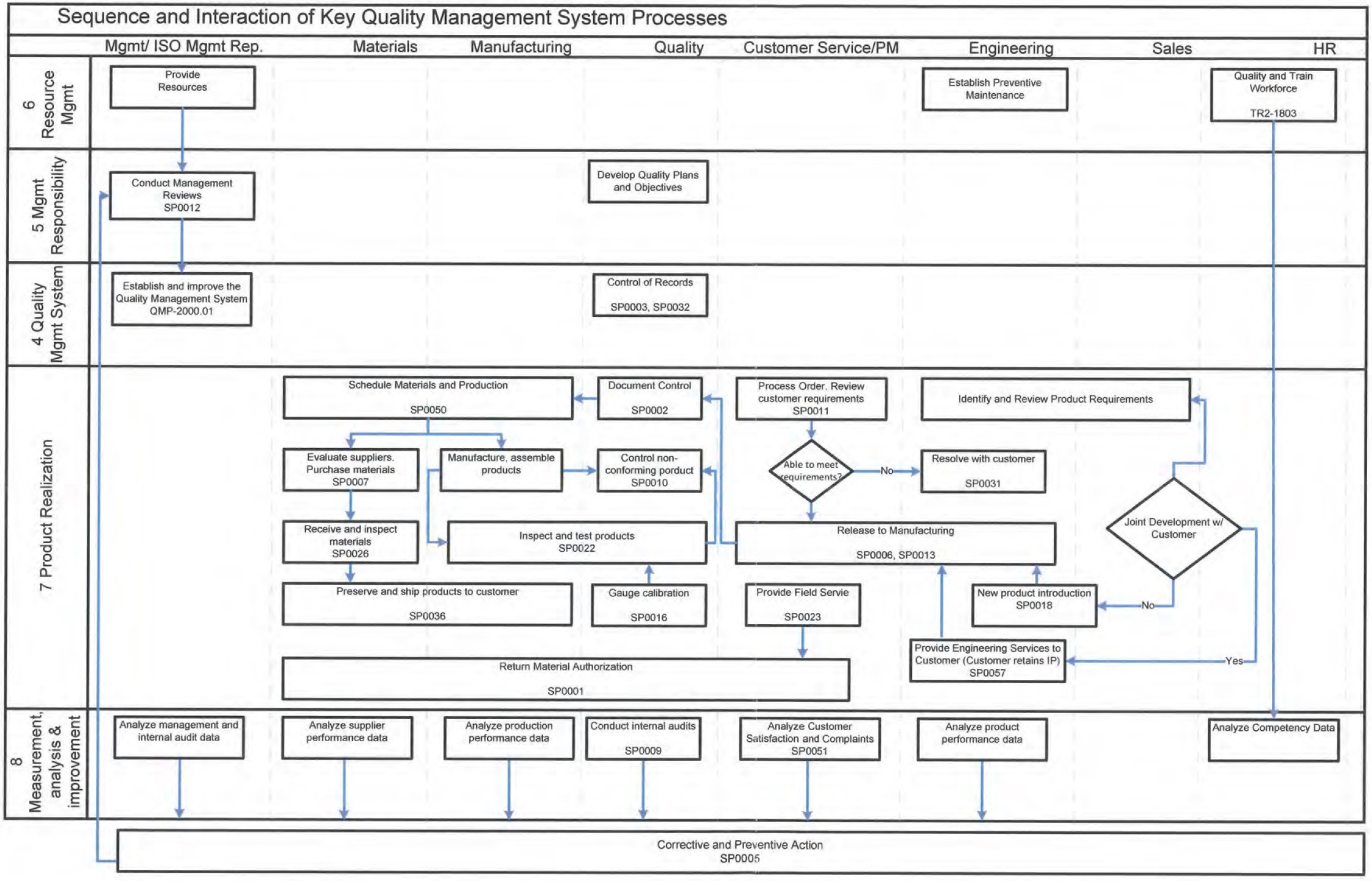
Revision	Description of Change
001	New Procedure

Key Process Matrix



Attachment A

Key Process Matrix



Attachment B

Sequence and Interaction of Key Quality Management System Processes

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