



AUTEC POWER SYSTEMS

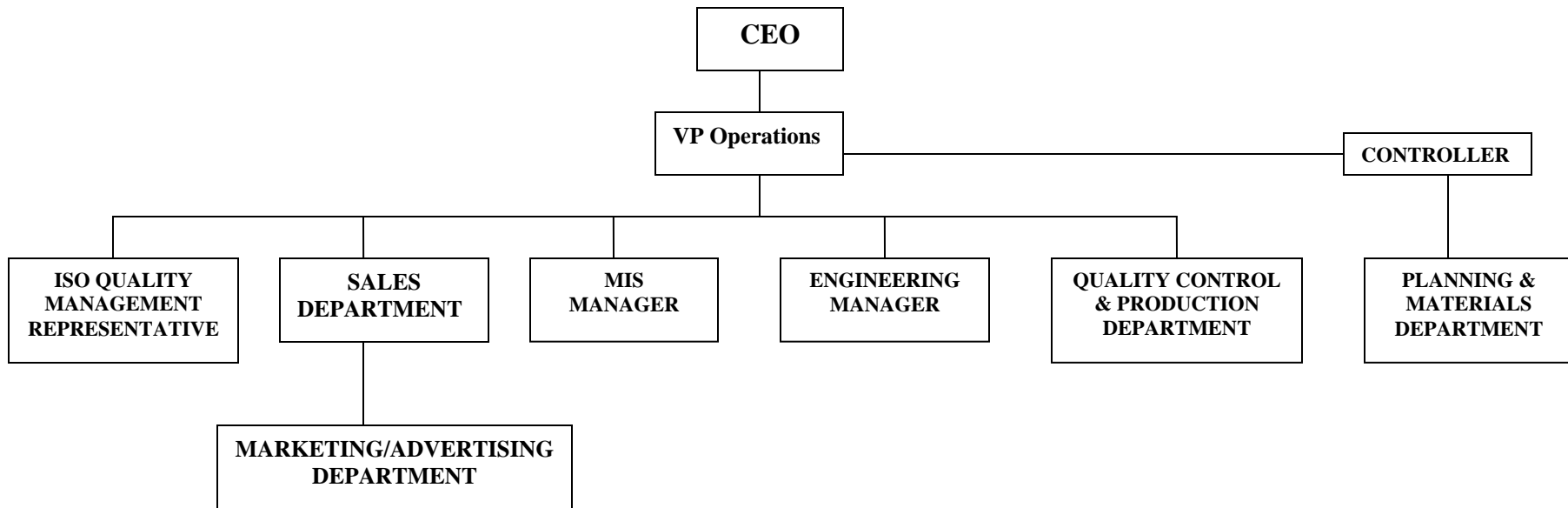
Quality Management System

ISO 9001:2000

ISO Management Rep.:	Signature: 	Date: 2/2/06
Chief Executive Officer:	Signature: 	Date: 2/2 '06

Autec Power Systems – Organization Chart

Rev 08/25/05



0. OUR MISSION, QUALITY POLICY, AND VALUES & BELIEFS

Our Mission and Quality Policy

We will meet or exceed our customer's expectations by continuously improving our processes, products and services.

Our Values and Beliefs

Maintain complete Integrity in all our actions

Work in partnership with our Customers to enhance their respect and loyalty

Maintain a participatory environment, rely on the innate excellence of our People, and provide a system in which they can excel

Help our People achieve their full potential through continuous education, training, and recognition of exemplary performance.

Make data-driven decisions that will maximize our opportunities for success

Recognize our responsibility as good citizens and good neighbors of the communities in which we operate.

Maintain beneficial supplier partnerships to assure that our needs and expectations for products and services are met.

Maintain a passion for Continuous Improvement and continuously improve our processes, products and services

1. SCOPE

1.1 General

This manual describes the Quality Management System (QMS) at, Autec Power Systems Inc., and defines requirements, assigns responsibility and provides guidance for its implementation. The AUTECH QMS has been developed in accordance with the fundamentals, requirements, and guidelines provided in ISO documents 9000:2000, 9001:2000, and 9004:2000.

1.2 Permissible exclusions

None.

2. CONTINUOUS IMPROVEMENT, ISO 9000, AND OUR MANAGEMENT SYSTEM

Our ISO 9000 based Quality Management System (QMS) has been developed in complete alignment with both our Continuous Improvement philosophy and our Management System. The QMS is that part of the overall management system which implements our Quality Policy, establishes procedures by which we meet or exceed customer expectations, and satisfies international system requirements for ISO registration.

3. OUR COMPANY & OUR PRODUCTS

Autec Power Systems, Inc. was established in 1989. As a wholesale distributor for switching power supplies. The company sells to a broad range of domestic and international customers including Fortune 500 companies. Autec Power Systems merged with Bridge Technologies, a Public Company, in December 1999.

4. QUALITY MANAGEMENT SYSTEM

4.1 General requirements

The Quality Management System (QMS) is that part of our overall business system which implements our Quality Policy, establishes procedures for providing products and services which meet or exceed customer expectations, and satisfies external quality system requirements. The QMS includes the policies, procedures, organizational structure, requirements and responsibilities for achieving our quality policy. The foundation for our QMS is found in our company's stated values and beliefs. Our values and beliefs provide guidelines that help to ensure the following objectives:

- Focus on our Customers
- Total Participation of our People
- Continuous Improvement

This Quality Manual and its associated procedures establish and document the means by which we implement, maintain and continually improve our QMS. It also identifies the criteria and methods required to ensure effective operation and control of the system, and identifies the measurement, monitoring, analysis, information, and actions necessary to achieve planned results and continuous improvement.

The processes needed for our QMS include those identified in the ISO 9001:2000 standard, as well as a number of critical production processes. These processes and their sequences and interactions are identified and described in *SOP- 4.1, Key Processes and Interactions*.

4.2 Documentation requirements

4.2.1 General

Our QMS documentation includes the quality manual, procedures required by the ISO 9001:2000 standard, and other procedures, work instructions, and documents which we employ to ensure effective operation and process control. The extent of our QMS documentation is dependent on the size and type of our organization, the complexity and interaction of our

processes, and the competence of our personnel.

4.2.2 Quality manual

QMS documentation includes this quality manual, the standard operating procedures (SOPs) referenced throughout this manual and identified in Appendix A, and other documents, data, forms, and records identified in this manual and associated procedures. Documents and data are in the form of both hard copy and electronic media. QMS documentation was developed based on the complexity of the work, the methods used, and the skills and training needed by employees involved in carrying out the activities.

SOPs are numbered using a system in which they receive the number of the quality manual paragraph they primarily address. For example, paragraph 4.2.3 of this manual addresses control of documents; therefore, the document control procedure is assigned document number SOP-4.2.3.

The processes needed for our QMS include those required by the ISO 9001:2000 standard as well as a number of other critical business and product realization processes unique to our operations. The sequence and interactions of these processes are described in *SOP- 4.1, Key Processes and Interactions*.

4.2.3 Control of documents

All QMS documents, including forms used to create quality records, are controlled. *SOP-4.2.3, Control of Documents*, provides the guidance and procedures necessary to:

- a) approve documents for adequacy prior to issue
- b) review, update as necessary and re-approve documents
- c) identify the current revision status of documents
- d) ensure that relevant versions of applicable documents are available at points of use
- e) ensure that documents remain legible, readily identifiable and retrievable
- f) ensure that documents of external origin are identified and their distribution controlled
- g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

4.2.4 Control of records

Records required for the QMS are controlled and maintained to provide evidence of conformance to requirements and of effective operation of the QMS. Quality records include all records maintained to demonstrate conformance to specified requirements and the effective operation of the quality system, including documentation that describes:

- a) results of processes performed, including identification of the individual performing the activity.
- b) product/process evaluation for acceptance criteria.
- c) procedures, drawings or instructions used to perform an activity, including revision and/or date of document.
- d) identification of material, parts, or equipment used in the making of the product.

- e) personnel, material or equipment qualifications.
- f) pertinent technical records from sub-contractors

Records may be in the form of hard copy or electronic media. *SOP-4.2.4, Control of Records*, provides the guidance and procedures necessary for the identification, storage, retrieval, protection, retention time and disposition of records.

5. MANAGEMENT RESPONSIBILITY

5.1 Management commitment

Top Management provides evidence of its commitment to the development and improvement of the quality management system through both words and actions. Refer to Section 0 for our Mission, Quality Policy, and Values and Beliefs. Together, these document and communicate the importance of meeting or exceeding customer expectations as well as regulatory and legal requirements, by continuously improving our processes, products, and services. We insure that our Mission, Quality Policy, and Values and Beliefs are understood, implemented, and maintained at all levels of the organization through documented training, regular communication, and verbal reinforcement.

Top Management also demonstrates its commitment to the development and improvement of the QMS by regularly establishing quality objectives. (*see section 5.4.1, Quality objectives*), conducting management reviews (*see section 5.6.1, General Management Review*), and ensuring the availability of necessary resources (*see section 6.1, Provision of Resources*).

5.2 Customer focus

Our Mission Statement and Quality Policy articulates our commitment to our Customers: *We will meet or exceed our customer's expectations by continuously improving our processes, products and services.* Customer expectations must be determined, understood, converted into

requirements, and have processes designed to exceed them in order to fulfill this Mission and Quality Policy on a daily basis.

We work hard to be an active partner with our customers, understanding their world and identifying solutions. Staying close to our customers is our primary method of determining and understanding their requirements and expectations, and we accomplish this objective through a multitude of channels. These include regular customer visits by our sales managers and representatives, trade shows, special customer visits by the leadership of our company to our largest customers to conduct joint planning sessions, phone and e-mail contact with multiple levels of our customers' organization through our customer service department, and customer audits of our facilities. These communications and interactions ultimately yield clear, explicit customer requirements and expectations in the form of a contractual agreement or customer specification. The QMS ensures that these requirements are fulfilled with the aim of exceeding our customers' expectations.

5.3 Quality policy

We will meet or exceed our customer's expectations by continuously improving our processes, products and services.

A Mission statement typically expresses the purpose of an organization. The integration of our Mission and Quality Policy into a single statement symbolizes that our Quality Policy is integral to the purpose of our organization, and also guides the way we accomplish that purpose. Our Mission and Quality Policy indicates our commitment and focuses on what is important to us as an organization: *meeting or exceeding customer requirements*; and it prescribes the method by which we accomplish this: *by continuously improving our processes, products, and services*. Moreover, it acts as a compass in providing the direction and a framework for establishing and reviewing quality objectives.

We insure that our Mission Statement & Quality Policy is communicated and understood at all levels of the organization through documented training, regular communication, and verbal reinforcement.

Our Mission Statement and Quality Policy is controlled by its inclusion in this Quality Manual, and is reviewed annually at the Management Review meeting.

5.4 Planning

5.4.1 Quality objectives

At the management system level, our quality objectives are to achieve our Mission Statement and Quality Policy, and to maintain the integrity of and continuously improve a QMS that satisfies international requirements for ISO registration. At the operational level, product, project, and contract objectives are developed as appropriate to achieve customer satisfaction; see section 8.2.3 of this manual for more information. Management system level objectives are reviewed annually for achievement and continuing suitability during management reviews..

5.4.2 Quality management system planning

Our Quality Management System, as described in this Quality Manual and its associated procedures, is that part of the overall management system which implements our Quality Policy, establishes procedures by which we meet or exceed customer expectations, and satisfies international system requirements for ISO registration. As such, it also constitutes the AUTECH quality plan.

Our QMS identifies and plans for the resources needed to ensure that our quality objectives are met. This includes the identification and planning of QMS processes, the resources needed to ensure its successful implementation, and objectives for continuous improvement. Any changes to the system are conducted in a controlled manner so that the integrity of the QMS is continually maintained. Whenever a customer's specified requirements are such that they are beyond the control of our established QMS, a specific quality plan is developed for that process or product.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The Chief Executive Officer (CEO) sets direction and ensures the success of AUTECH. Other members of Top Management, while under the direction of the CEO, have primary responsibility for all operations under their control, including the QMS described herein. The following have the key responsibilities and authority for maintaining the integrity of our Quality Management System:

Top Management - Top Management is ultimately responsible for the quality of products and services provided by AUTECH since it controls the systems in which work is accomplished. Top Management is responsible for company-wide Strategic Planning and Quality Improvement Process Planning, the development of our Quality Policy, Vision, and Values & Beliefs, and provision of the necessary resources for accomplishing our group-level goals and objectives. Additionally, Top Management is responsible for conducting quality system reviews on an annual basis.

Management - Execution of the Strategic Plan, budgeting, and implementation of the quality management system and policies are the responsibility of Managers throughout the organization. This explicitly includes responsibility for implementation of our Quality Policy and ensuring adherence to our Values and Beliefs throughout the organization units for which they are responsible.

Employee Responsibility - All employees are responsible for the quality of their work and for their part in the overall processes used to provide products and services to our customers. Employees will identify and record any problems relating to the product, process, and quality system. Employees are also the key participants in process improvements and the identification of measures needed to ensure the continued success of our continuous improvement process. They will initiate, recommend, or provide solutions through the Corrective/Preventive Action Program. (*See SOP-8.5, Corrective and Preventive Action*)

For detailed information on current organizational structure and responsibilities, see Appendix B.

5.5.2 Management representative

The Quality Assurance Manager is appointed as the ISO Management Representative. Responsibilities of this position are to ensure that a quality system is established, implemented, and maintained in accordance with the ISO 9001:2000 standard, reporting to Top Management on performance of the QMS, promoting awareness of customer requirements throughout the organization, and ensuring that the performance of the system is reviewed as a basis for improvement.

5.5.3 Internal communication

We ensure communication regarding QMS processes and their effectiveness between all levels of our organization through documented training, the internal audit program, the

corrective/preventive action program, and regular formal and informal communications. Formal communication is facilitated through production team meetings, cross-functional improvement projects, employee bulletin board and company wide memorandums.

5.6 Management review

5.6.1 General

Top Management conducts a management review meeting annually to ensure the continuing suitability, adequacy, and effectiveness of the QMS. At this meeting, a number of Quality Management System components are reviewed to ensure that they remain current and applicable with business trends and market shifts. These include the Mission Statement and Quality Policy, Values and Beliefs, annual quality objectives, and the need for changes to the QMS.

5.6.2 Review input

The management review meeting includes a review of current performance and opportunities for improvement related to follow-up actions from earlier management reviews, customer feedback, the internal audit program, the corrective/preventive action program, the preventive maintenance program, process performance and product conformance data, and other changes that could affect the QMS.

5.6.3 Review output

At a minimum, outputs from management review meetings include actions required for improvement of the QMS and its processes, improvement of product related to customer requirements, and provision of resource needs. Results of management review meetings are recorded and maintained by the management representative. For additional information, *see PFC-5.6, Management Review Flow Chart.*

6. **RESOURCE MANAGEMENT**

6.1 Provision of resources

Appropriate resources, including trained employees, are identified and provided throughout the documented quality system. These include the resources needed to ensure implementation and improvement of the QMS, conduct audits, and address customer satisfaction.

6.2 Human resources

6.2.1 General

We believe that our Employees are our most valuable asset. In line with our Values and Beliefs, we do our best to help them achieve their full potential through continuous education and training.

6.2.2 Competence, awareness and training. People assigned responsibilities defined in the QMS are competent based on education, training, skills, and experience.

6.2.2.a *Need Determination.* We determine employee training, awareness, and competency needs through a variety of methods. Emerging competency needs are identified during the strategic planning process. Position descriptions are maintained for each position held at AUTECH to document the specific competencies needed to ensure the quality of AUTECH 's products and services. All employees are evaluated and qualified on the basis of documented or demonstrated competencies. Qualification records for all employees are maintained.

6.2.2.b *Provision.* We develop and provide training that balances organizational competency needs with the development and career needs of our employees. In addition, Quality Improvement Process Training and ISO 9000 Awareness Training are provided to all employees. When an SOP is updated and implemented, those employees responsible for that specific process are trained prior to deployment of the new or changed process or procedure. Individual Personal Development Plans are generated with each employee on an annual basis. We use these Personal Development Plans to determine both inside and outside training needs for the fiscal year. We maintain records for all training received.

6.2.2.c *Effectiveness.* We evaluate the effectiveness of the training through immediate feedback (outside seminar evaluation and successful certification of employees at a given level) and longer term evaluation through the employee performance review process. Ultimately, comprehensive measures such as productivity, on-time delivery, and customer satisfaction are the most critical measures of training effectiveness.

6.2.2.d *Employee Contributions.* We ensure that our employees are aware of the relevance and importance of their activities and how they contribute to the achievement of our quality objectives. This is accomplished through ISO 9000 Awareness Training, QMS procedure/process training, qualification reviews, and employee participation in the strategic planning process.

6.3 Infrastructure

We identify, provide and maintain the facilities needed to achieve product conformance, including workspace and associated facilities, equipment, hardware and software, and supporting services.

6.4 Work environment

We have identified and manage the human & physical factors needed to achieve product conformance and exceed customer expectations. Our people are the key to our success, and the human and physical factors under which they work are of paramount importance. A suitable working environment is maintained to ensure product quality.

Regarding human factors, one of our objectives is to be an “employer of choice” in the 21st century. In addition to providing generous benefits, we accomplish this by providing flexibility,

interesting work, a balance between work and family life, opportunities to give back to the community, and perhaps most importantly, the total involvement of our employees in an empowered environment of continuous improvement. We engender total participation by structuring a team environment, utilizing participative leadership styles, and involving employees in continuous improvement teams.

Regarding physical factors, we employ a wide range of activities to monitor and improve workplace safety, health, and ergonomics. These include adherence to good manufacturing practices, safety team meetings, and training.

7. PRODUCT REALIZATION

7.1 Planning of product realization

Our QMS plans for, identifies and documents our realization processes, and thereby insures consistency with other requirements of the QMS. The QMS development, planning, and implementation process included the identification of product and customer quality objectives; the need to establish processes and documentation, and provide resources and facilities specific to the product; verification and validation activities, and the criteria for acceptability; and records necessary to provide confidence of conformity of processes and product. These elements are addressed in this manual and its associated procedures. Whenever required by the customer and/or when customer specified requirements are beyond the control of our established QMS, a specific quality plan is developed for that process or product.

Our approach to process management involves determining what the customer wants, developing a process capable of meeting these requirements, ensuring that the inputs to the process are appropriate, measuring process performance, and evaluating and improving the process to ensure it continues to perform as designed. The following sections describe our methods for achieving these objectives.

7.2 Customer-related processes

Achieving our Mission “to meet or exceed customer expectations” requires that we determine and understand our customers’ requirements, consistently meet those requirements, and maintain close contact and ample communication with our customers. These efforts are described below

7.2.1 Determination of requirements related to the product

We determine requirements through two primary mechanisms: either sales managers negotiate annual contracts; or customer service employees receive and negotiate customer orders. Ultimately, requirements for most major customers are identified in contracts that are documented and reviewed annually. For some customers, where no annual contract exists, an order constitutes a contract, and we insure that the customer’s requirements are clearly identified.

Applicable customer requirements include product requirements specified by the customer,

including the requirements for availability, delivery and support; product requirements not specified by the customer but necessary for intended or specified use; and obligations related to product, including regulatory and legal requirements.

7.2.2 Review of requirements related to the product

7.2.2.a Purpose of Review. We review customers' product requirements to ensure that they are clearly stated, understood, and recorded. This includes ensuring that product requirements are defined; that where the customer provides no documented statement of requirement, the customer requirements are confirmed before acceptance; that contract or order requirements differing from those previously expressed are resolved; and that we have the ability to meet defined requirements. We ensure that these criteria are met prior to making a delivery commitment.

7.2.2.b Type of Review - Contract. The type of review is dependent upon how customer requirements are identified. As previously described, contracts are negotiated and reviewed annually. Each contract is reviewed by the appropriate sales manager prior to the contract's date of expiration. Upon receipt of an order against a contract, customer service reviews the order against the customer's contract, insuring consistency between the order and contractually established requirements. If customer service receives an order from a customer in which any of their requirements, i.e. product, price, quantity or packaging differs from their contract, they contact the customer to discuss and correct any discrepancies. Customer service deals directly with the customer to resolve any discrepancies.

7.2.2.c Type of Review - Order. Upon receipt of an order for which no prior contract exists, customer service determines and reviews the customer's requirements. Most products are from a standardized product and packaging list. For any special request, customer service discusses with the appropriate department, individual or team the possibility of meeting that request. Customer service determines on an ongoing basis whether orders can be met.

7.2.2.d Record of Results. The results of the review process and follow-up action are ultimately recorded in either a contract, and/or an order which is entered into the SBT accounting computer program. Entry of the order constitutes evidence of contract review.

7.2.2.e Changes to Product Requirements. Where product requirements are changed, all changes are communicated by the sales manager in writing or via E-mail to customer service who then updates the customer file and stores a hard copy of the change.

7.2.3 Customer communication

Sales managers and customer service representatives are primarily responsible for communications with our customers. Among others issues, these communications may be related to product info, inquiries, contracts, contract amendments, and order handling.

We pay particular attention to customer feedback, including customer satisfaction and complaints. We have a toll-free number, Quality training, and wide sales network to encourage and address customer feedback, particularly customer complaints. Any employee receiving

negative feedback from a customer is responsible for resolving the issue, or referring to an appropriate individual for resolution. Additionally, that employee will also complete and initiate a corrective/preventive action request to preclude recurrence of the issue.

7.3 Design and/or development

7.3.1 Design and/or development planning

Design and/or development originates in the Engineering department. Using project management planning tools (available software etc.), each design team leader establishes a plan that includes:

- design and development in structured and manageable stages.
- predetermined reviews of design and development.
- scheduled verification activities.
- the identified validation.

Control of the design and/or development process occurs when the team leader utilizes the planning tools to:

- assign responsibilities.
- establish authorities.
- update and track progress.

7.3.2 Design and/or development inputs

SOP-7.3, Design and Development is used to define design and/or development input requirements including:

- the functional and performance requirements as derived from customer input
- legal and regulatory requirements which apply
- useful information or experience from previous similar design and development efforts
- other necessary requirements

Before finalizing documentation of required inputs, incomplete, ambiguous or conflicting requirements are resolved..

7.3.3 Design and/or development outputs

Utilizing *SOP-7.3, Design and Development*, assures that design and/or development output will:

- comply with the design and/or development input requirements.
- include information needed for production and service.
- include or reference acceptance criteria.
- indicate design characteristics critical to the safe and proper operation of the product.
- be approved before issuance.

7.3.4 Design and/or development review

During the evolution of each product design or process development, planned reviews must occur in accordance with *SOP-7.3, Design and Development..* The reviews are intended to assure that requirements are being fulfilled. When they are not, those involved in the review must propose a remedy for each identified problem. All functions concerned with the stage being reviewed are represented at the review. Design or development review results are recorded. For additional information, see *SOP-4.2.4, Control of Records.*

7.3.5 Design and/or development verification

SOP-7.3, Design and Development provides direction for determining that output meets design and/or development inputs through design and/or development verification. Records of verifications are created and retained in accordance with *SOP-4.2.4, Control of Records.*

7.3.6 Design and/or development validation

Product or service resulting from design and/or development efforts is validated to assure that it performs to expectations or that it is suitable for application. Validation Guidance for conducting design and/or development validation is found in *SOP-7.3, Design and Development.* Records of validations are created and retained in accordance with *SOP-4.2.4, Control of Records.*

7.3.7 Control of design and/or development changes

SOP-7.3, Design and Development provides for the identification, documentation and control of all design and development changes. Control includes the assessment of the impact of changes upon component parts and completed products including those that have already been delivered. Control also includes the determination of treatment required for each change. That treatment may include verification and/or validation. Changes deemed ready for implementation are approved in accordance with applicable procedures. Change review records are kept as indicated in *SOP-4.2.4, Control of Records.*

7.4 Purchasing

We ensure that purchased products and services that impact the final quality of our products, conform to our requirements. We accomplish this objective by clearly identifying our requirements, working in partnership with our suppliers, and utilizing appropriate verification activities.

7.4.1 Purchasing process

This manual and associated procedures establish the methods by which we control our purchasing process to ensure product conforms to requirements. The type and extent of control is dependent upon the effect on subsequent realization processes and their output, as well as consideration of other characteristics including: the type of product; the potential impact of the product on our processes, products, or services; the results of supplier evaluations and past performance; and applicable regulations.

We have defined and documented the supplier approval process, including criteria for selection, the extent of control to be exercised, and periodic evaluation. Suppliers are evaluated and selected based on their ability to supply product in accordance with our requirements. The results of evaluations and follow/up actions are recorded. Additionally, we maintain a record of approved suppliers.

7.4.2 Purchasing information

Purchasing documents contain the appropriate data to clearly and fully describe materials which are being purchased. When appropriate, this includes requirements for approval or qualification of product, procedures, processes, equipment, and personnel; and QMS requirements.

We conduct an appropriate review to ensure the adequacy of specified requirements contained in the purchasing documents prior to the placement of an order.

7.4.3 Verification of purchased product

Incoming product is not released for production prior to verification.

Neither we nor our customers currently perform verification activities at our suppliers' premises. Should we or our customers choose to do so in the future, we will specify the intended verification arrangements and method of product release in our purchasing documents.

7.5 Production and service provision

7.5.1 Control of production and service provision

We utilize a process-focused approach to operations control. The primary focus of this approach is assuring the quality of process inputs - that is, employees, information, material, facilities and equipment - and monitoring the process. Employees must be equipped to perform the process properly through appropriate education, training, and certification. Work instructions and other important data must be current and correct. Material must meet specified requirements and be properly identified, stored, and issued. Equipment and facilities must be adequate, accurate, available and properly utilized. The appropriateness of these fundamental process inputs must be assured, and processes must be measured, controlled and evaluated for continuous improvement.

Section 6.2 of this manual addresses our strategy for insuring the adequacy of our employees, Section 7.4 addresses material inputs, and Section 6.3 addresses facilities.

7.5.1.a Information. Information inputs to the process include both product characteristics and appropriate work instructions. In addition to final product specifications, raw material characteristics and the required product parameters at critical process steps are available to process operators as required.

7.5.1.b Work Instructions. The necessity for and required detail of work instructions is dependent upon the knowledge, skills, and abilities of our employees and the complexity of the work process. All production-related processes are performed by trained, qualified, certified

operators (*See Section 6.2*) which minimizes the requirements for detailed work instructions. However, critical production steps are identified and provided in Work Instructions or Process Notes.

7.5.1.c *Equipment.* All equipment used for production and service operations is suitable, and is maintained in accordance with manufacturers specifications or instructions.

7.5.1.d *Measuring and monitoring devices.* We have identified and ensure the availability of measuring and monitoring devices capable of meeting our measurement requirements.

7.5.1.e *Monitoring activities.* We have identified and implemented the appropriate measurement and monitoring activities necessary to ensure process control. These are discussed more fully in *Sections 8.2.3, Monitoring and measurement of processes, and 8.2.4, monitoring and measurement of product.*

7.5.1.f *Release, delivery, and post-delivery processes.* Release of product is dependent on its compliance with all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order. Records of product approval are maintained and clearly indicate the authorizing employee. We do not currently perform post-delivery activities.

7.5.2. Validation of processes for production and service provision

We define processes in which the results cannot be verified by subsequent measurement or monitoring as “Special Processes.” This includes any processes where deficiencies may become apparent only after the product is in use or the service has been delivered.

When applicable, requirements for special process validation, including qualification of the process; qualification of equipment and personnel; use of defined methodologies and procedures; requirements for records; and re-validation; are carried out per quality plans developed internally by engineering and production personnel.

7.5.3 Identification and traceability

Identification and traceability is critical in our industry. We identify and record the unique identification of the product to ensure effective traceability. Where product is made in lots or batches, we identify a unique lot or batch number.

We identify measurement and monitoring status using a manual paper system. Additionally, physical location is an indicator of product status. All incoming, in-process, and final product is suitably identified and the current status is appropriately tracked and displayed.

7.5.4 Customer property

We exercise care with any customer property while it is under our control use. We identify, verify, protect and maintain customer property provided for use or incorporation into the product, applying the same process controls as we do to other material inputs to the process. Should any customer property be lost, damaged or otherwise found to be unsuitable, the

occurrence is recorded on a corrective/preventive action request and reported to the customer.

7.5.5 Preservation of product

Our product preservation system is designed to insure that our products meet or exceed customer expectations. The system addresses the handling, storage, packaging, preservation, and delivery of final product as well as in-process constituents of the final product.

7.5.5.a Handling. All products are handled in a manner that prevents damage, contamination, misuse or deterioration at all stages of production.

7.5.5.b Storage. Products are stored on-site. Defined storage areas are designated for products to prevent damage or deterioration of the product pending its use or delivery. Procedures for receipt and dispatch of material are defined and documented. All final products have a shelf life, and are inspected at specified time intervals to assess their condition.

7.5.5.c Packaging. Products approved for delivery are packaged in a manner to protect the product during storage and delivery. Appropriate packing materials are used, including pallets, banding, and shrink-wrap.

7.5.5.d Preservation. The environmental conditions (temperature, humidity, etc.) necessary for proper preservation are defined and documented. Other measures to assure preservation of products, such as pest control, are also carried out according to specified time intervals.

7.5.5.e Delivery. Our products are shipped in many different manners, ranging from the customer picking up the product to professional delivery companies. Products are loaded in a manner to prevent damage and unauthorized tampering during delivery. Tamper evident seals and other devices are used where required and in accordance with customer requirements. These procedures, combined with the procedures for determining product status and identifying non-conforming product, provide adequate assurance that the condition of the product when it is received by our customers is such that it meets their requirements.

7.6 Control of monitoring and measuring devices

The Production manager (or designee) are responsible for the calibration program which establishes and maintains documented procedures to control, calibrate and maintain measuring and monitoring devices. Each employee is responsible for using a capable measuring instrument that has been calibrated when conducting documented process inspections.

We have defined the process employed for the control of measuring and monitoring devices including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory.

We determine the measurements to be made and the accuracy required to assure conformity of our product to specified requirements. We identify and select equipment that is capable of the accuracy and precision necessary.

Measuring and monitoring devices are used in a manner that ensures that measurement capability is

consistent with the measurement requirements. This includes ensuring that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out. We control all measuring and monitoring devices that can have an effect on product quality. Software used for measuring and monitoring of specified requirements shall be validated prior to use.

7.6.a Periodic Calibration.

We have identified all measuring and monitoring devices that can affect product quality and calibrate and adjust them at prescribed intervals against certified equipment having a known valid relationship to internationally or nationally known standards. Where no such standards exist, the basis used for calibration is documented.

7.6.b Safeguard from Adjustment

We ensure that measuring and monitoring devices are safeguarded from adjustment that would invalidate the calibration.

7.6.c Protection from Damage

We ensure that handling, maintenance and storage of measuring and monitoring devices is such that accuracy and fitness for use is maintained.

7.6.d Calibration Records

We maintain appropriate records for all measuring and monitoring devices. We identify measuring and monitoring devices with suitable indicators or approved identification records to show the calibration status. A record of calibration results is maintained.

7.6.e Validity Re-assessment

We re-assess and document the validity of previous inspection and test results when measuring and monitoring devices are found to be out of calibration. In addition, a corrective/preventive action request is submitted to initiate an investigation to preclude recurrence.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

We have defined, planned, and implemented the monitoring, measurement, analysis and improvement processes needed to assure product and QMS conformity and achieve continuous quality management system improvement. These activities include assessment of customer satisfaction; QMS performance audits; process control, including statistical techniques where appropriate; and assessment of product characteristics.

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

Customers are the reason we exist, and drive our quality policy “to meet or exceed customer expectations.” We collect, monitor, and evaluate information on customer satisfaction in order to determine how well we are performing against this critical objective.

Our objective is to be particularly responsive to customer dissatisfaction or complaints. Anyone receiving a complaint from a customer has the responsibility for documenting the complaint on AUTECH *Form 8.5-1, Corrective/Preventive Action Request*. In addition, the person receiving the complaint will try to solve the problem immediately. If that individual cannot resolve the problem, then the call will be transferred to an appropriate employee for resolution.

8.2.2 Internal audit

Internal audits are critical to the success of our Quality Management System. They help to determine the effectiveness of the system, as well as to identify opportunities for improvement. If the system is effective (i.e. achieving the desired results, performance and/or improvement objectives) internal audits can aid in identifying additional opportunities for improvement. If the system is not effective, internal audits will help determine the scope, nature and source of the problem as well as possible corrective actions needed to achieve effectiveness. The results of these audits form an integral part of the continual improvement process.

Internal audits are conducted in accordance with a published schedule that identifies the audit scope and frequency. The schedule is developed on the basis of status and importance of the activity to be audited and previous audit results. At a minimum, each our key processes (see *SOP- 4.1, Key Processes and Interactions*) are evaluated on an annual basis. The purpose of these internal audits is to: determine whether the QMS conforms to the requirements of the ISO 9001:2000 standard; to determine whether the process has been effectively implemented and maintained; and to identify opportunities for improvement. The management representative maintains records of audits, including corrective action requests.

Audits are coordinated by the Management Representative, and carried out by trained personnel who do not have direct responsibility for the activity being audited. Auditors record audit results and submit findings to appropriate personnel with responsibility for the process audited.

Management responsible for the process audited is responsible for taking timely corrective action to eliminate detected nonconformances and their causes, and documenting these actions on the corrective action request.

Follow-ups are conducted to verify timely and effective implementation of the proposed action; and verification results are recorded on the corrective/preventive action form.

Our internal audit program is implemented by *SOP - 8.2.2, Internal Audit Program*, and includes the responsibilities and requirements for conducting audits, ensuring their independence, recording results and reporting to management.

8.2.3 Monitoring and measurement of processes

We apply suitable methods for measurement and monitoring of those processes necessary to meet our customers' requirements. As previously discussed, we utilize a process-focused approach to operations control. The primary focus of this approach is assuring the quality of process inputs - that is, employees, information, material, facilities and equipment - and monitoring the process. Processes are measured, controlled and evaluated both to ensure that they continue to satisfy their intended purpose and provide the required output and to identify opportunities for continuous improvement.

Measures are organized into a number of categories, and include process accuracy as measured by chemical and sensory analyses, on time delivery, continuous and annual employee performance evaluations, and improvements as evidenced by schedule reductions.

8.2.4 Monitoring and measurement of product

We sample, measure, and monitor the characteristics of our product through all phases of production. Measurement and monitoring serves to guide the production process as well as to verify that all product requirements are met.

Receiving inspection is conducted to ensure quality of purchased product. In-process testing is conducted throughout the process. All finished product is tested to ensure it conforms to specifications.

8.2.4.a *Evidence of conformity.* Test and inspection records are maintained for a minimum of three years. These records include final inspection authority and identify and confirm that all critical parameters are in accordance with published specifications. Additionally, product samples are stored for a minimum of 3 years.

8.2.4.b *Product release and delivery.* Product is not normally released from the production area until the required inspection and tests have verified that it meets specification and the appropriate documents have been completed. If un-inspected product is released for any reasons, it is done so under conditions of positive recall. Non-conforming product is held until an authorized employee obtains necessary approval. *See Section 8.3, Control of Nonconforming Product.*

8.3 Control of nonconforming product

We ensure that product which does not conform to requirements is identified and controlled to prevent unintended use or delivery. For more information, *see SOP - 8.3, Control of Nonconforming Product.*

Our process control methods provide for the identification, documentation, evaluation, segregation, and disposition of nonconforming raw materials and finished product to prevent inadvertent use.

Identification. Identification of nonconforming product originates from inspection, internal testing, or customer complaint. Employees clearly mark non-conforming product; if required by contract, the sales team will notify the customer.

Documentation. Authorized employees will document nonconforming product and identify lot number, description of nonconformance, and location of material. This information will be input into the corrective action system.

Evaluation. Authorized employees will evaluate incoming, in-process, and final product in accordance with approved test and inspection procedures.

Segregation. Non-conforming product is segregated pending final disposition.

Disposition. Lab technicians or other authorized employees will inspect non-conforming product and decide to:

- rework the raw material or finished product to meet specified requirements
- regrade for an alternative application or product
- seek customer concession for delivery as is
- request a Waiver for raw materials from an authorized employee
- reject to sub-contractor
- dispose

Any product disposal will be in accordance with environmental controls.

8.3.a. *Correction and re-verification.* Nonconforming product is corrected and re-verified after correction to demonstrate conformity. Raw materials identified as not meeting specifications must be either rejected or segregated for special instructions. Finished product not meeting specifications must be reworked or scrapped.

8.3.b *Product recall.* In the event nonconforming finished product leaves our facility, we notify the customer and institute trace and recall procedures.

8.3.c *Nonconformance reporting.* Reporting of rectification of nonconforming product is not typically required. However, such rectification is reported for concession if required by the customer.

8.4 Analysis of data

We collect and analyze appropriate data to determine the suitability and effectiveness of our QMS and to identify opportunities for continuous improvement. This includes data generated by measuring and monitoring activities, customer feedback, our supplier partnership process, the corrective/preventive action system, and our audit process. We analyze the data to provide information on customer satisfaction including conformance to customer requirements, process and product characteristics and trends, and supplier performance.

8.5 Improvement

8.5.1 Continual improvement

At AUTECH, continual improvement is a planned activity. We plan and manage the processes necessary for the continual improvement of the QMS through the establishment of objectives, the planning of the process, the provision of resources and information needed to carry out the process, the monitoring of related measures needed to assess process effectiveness and efficiency, and the identification/implementation of actions needed to achieve desired results. We accomplish this through the use of our quality policy, strategic and operational objectives, audit results, analysis of process and product performance data, corrective and preventive action, and the management review process.

8.5.2 Corrective action

Non-conforming product, processes, and services drive corrective action. As part of our QMS and continuous improvement process, we investigate and document non-conformances to determine the corrective action needed to preclude their recurrence. Based on the results of this investigation, we implement corrective action to eliminate the root cause of the nonconformities in order to prevent their recurrence. We apply controls and follow-up to ensure that corrective action is taken and is effective. Corrective actions are appropriate to the impact of the problems encountered.

Standard Operating Procedure SOP - 8.5, Corrective and Preventive Action, defines and documents requirements for identifying non-conformities (including customer complaints); determining the causes of nonconformity; evaluating the need for actions to ensure that non-conformities do not recur; determining and implementing the corrective action needed; recording results of action taken; and reviewing of corrective action taken.

Results of the Corrective/Preventive Action program are summarized and trended to identify opportunities for improvement. This information is reviewed during the management review meeting. For additional information, see *SOP-8.5, Corrective and Preventive Action*, and *SOP-5.6, Management Review*.

8.5.3 Preventive action

Preventive action is driven by internal audits, customer feedback, employee suggestions, and the management review meeting. We identify the preventive actions needed to eliminate the causes of potential nonconformities to prevent their occurrence. Preventive actions taken are appropriate to the impact of the potential problems.

SOP - 8.5, Corrective and Preventive Action, defines and documents requirements for identifying potential nonconformities and their causes; determining and ensuring the implementation of preventive actions needed; recording the results of action taken; and reviewing for effectiveness the preventive actions taken.

APPENDIX A

Master List of all Quality Management System Documents and their Revisions

<u>Title</u>	<u>Procedure</u>	<u>Rev</u>
Quality Management System	QM-1	8/25/05
Key Processes and Interactions	SOP - 4.1	5/4/05
Control of Documents	SOP - 4.2.3	4/28/05
Control of Records	SOP - 4.2.4	10/22/04
Design and Development	SOP - 7.3	10/22/04
Internal Audit Program	SOP - 8.2.2	10/22/04
Control of Nonconforming Product	SOP - 8.3	10/22/04
Corrective and Preventive Action	SOP - 8.5	10/22/04