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	Reviewed by: Barry D. Bennett, Sr. Quality Assurance Manager	Approved by: Bud Tyler Vice President/General Manager

1 SCOPE

General

The EF Precision Group (consisting of EF Precision Inc. and Precision Assembly Inc.) has developed and implemented the quality management system described in this manual to help our organization operate with increased effectiveness, consistency and with customer satisfaction. Our quality management system utilizes the process approach of ISO 9001:2000 and is guided by the principles contained in ISO 9004:2000 and in section #9, by FDA 97-4179.

Application

Our quality management system is certified to all applicable requirements contained in ISO 9001:2000, covers and encompasses all operations at our facility located at 2301 Computer Avenue, Willow Grove, Pennsylvania, USA 19090. The following table identifies ISO 9001:2000 requirements not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our quality management system.

ISO 9001:2000 Requirements **EXCLUSION TABLE**

Clause or sub-clause	Exclusion	Justification
7.3	Design and development	EF Precision Group is a contract manufacturer with no responsibility for or control of product design
7.5.1	Control of production and service provision	EF Precision Group has no control over the servicing aspect of product provided for its' customers and is not within the scope of its' line of business
7.5.2	Validation of processes for production and service provision	EF Precision Group has no control over the servicing aspect of process validation and is not within the scope of its' line of business

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2 NORMATIVE REFERENCE

The following external documents contain provisions which, though referenced in this manual, constitute provisions of our quality management system, to the extent specified:

ISO 9000:2000, Quality Management Systems – Fundamentals and vocabulary
ISO 9001:2000, Quality Management Systems – Requirements
ISO 9004:2000, Quality Management Systems – Guidelines for Performance Improvements
FDA 97-4179, Medical Device Quality Systems Manual: A Small Entity Compliance Guide

Appendix A, List of Referenced Quality Management System Documents, lists the Quality Assurance Procedures (QAP) referenced in this manual.

NOTE: The latest edition/revision of each referenced document applies. Documents are referenced throughout this manual only by document number.

3 TERMS AND DEFINITIONS

Our quality management system uses the same internationally recognized terms, vocabulary and definitions given in ISO 9000:2000.

Acronyms, terms, vocabulary and definitions unique to our organization, customers, industry and region used throughout our quality management system are as follows:

Acronyms:

CAO - Chief Accounting Officer/Controller
CEO - Chief Executive Officer
CHM - Chairman
DFC - Deployment Flowchart
HRM - Human Resource Manager
MM - Materials Manager
QAM - Quality Assurance Manager
QAP - Quality Assurance Procedure (a.k.a. Procedures)
SOP - Standard Operating Procedures (a.k.a. Work Instructions)
VP/GM - Vice President/General Manager
VP/M - Vice President/Manufacturing

Definitions:

EF Precision Inc. - operates as a manufacturer (machine jobbing shop) producing parts to customer drawings. Maintains separate billing for accounting purposes
Precision Assembly Inc. - operates as a manufacturer (assembly plant) purchasing products identified by customers, assembling those products and supplying them as a complete unit. Maintains separate billing for accounting purposes

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- Responsibility(ies) - as applied in this document, is used to indicate ownership of a requirement. Actions taken may be delegated by the person in the position identified. Each person in our organization may have responsibilities for multiple job functions
- Service - for the purpose of this document, is limited to “Customer Service” and not to be construed as a function of maintenance to an assembled product

4 QUALITY MANAGEMENT SYSTEM

General Requirements

Our quality management system is that part of our overall management system which implements our quality policy, establishes processes for providing products which meet or exceed customer requirements and satisfies ISO 9001:2000 and in section #9, by FDA 97-4179 guidelines.

The processes needed for our quality management system include those required by ISO 9001:2000 and in section #9, the guidelines of FDA 97-4179 as well as those required by our customers and a number of product realization processes unique to our business and operations. Responsibilities for and interaction of all of our processes are detailed in our QAP’s and SOP’s with visual status by the use of Forms as directed by the aforementioned procedures.

Documentation Requirements

4.2.1 General

Our quality management system includes documented statements of our quality policy and objectives, documented procedures required by ISO 9001:2000 and in section #9, guidelines recommended by FDA 97-4179 and other documentation needed to ensure effective operation and process control.

The quality management system documentation developed is appropriate to the size and type of our organization, the complexity and interaction of our processes and the competence of our personnel. Quality management system documents and data may be in hard copy or electronic media.

Quality management system documentation includes this quality manual, QAP’s, SOP’s, Forms and other internal and/or external documents and/or data needed to manage, perform or verify work affecting process or product quality.

We use QAP’s for identifying the “when” in a process, the SOP’s for the “how” in a process, the DFC’s provide a visual means to identify the process for cost efficiency and provide a vehicle to communicate sequence, interaction and responsibilities of all involved. We also develop and control other documentation and data generated as necessary to appropriately and effectively manage our business which is contained within the manual.

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4.2.2 Quality manual

This manual is the part of our quality management system that defines the scope of that system and documents the policy, procedures and processes we have implemented to achieve our quality objectives. Exhibit 4.2.4 utilizes a flowchart method of describing the interaction of processes. Each element identified, is headed by a process, i.e. Process 4 (Quality Management System – Document Control), Process 5 (Management Responsibility), Process 6 (Resource Management), Process 7 (Product Realization), Process 8 (Measurement, Analysis and Improvement), Process 9 (Buildings and Environment).

4.2.3 Control of documents

The QAM has overall responsibility for ensuring that all quality management system documents including forms used to create quality records are controlled. QAP 4.2.3 provides procedures necessary to:

- Approve documents for adequacy prior to issue
- Review, update as necessary and re-approve documents
- Identify the current revision status of documents
- Ensure that relevant versions of applications documents are available at points of use
- Ensure that documents remain legible, readily identifiable and retrievable
- Ensure that documents of external origin are identified and their distribution controlled
- Prevent the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose

4.2.4 Control of records

The QAM has overall responsibility for ensuring that all records required for the quality management system are controlled and maintained to provide evidence of conformance to requirements and effective operation of the quality management system. Records may be in the form of hard copy or electronic media. QAP 4.2.4 provide procedures necessary to control all records including documentation that describes:

- Results of processes performed including identification of the individual performing the activity
- Product/process evaluation for acceptance criteria
- Procedures, drawings or instructions used to perform an activity including revision or date of document
- Identification of material, parts or equipment used in the making of the product
- Personnel, material or equipment qualifications
- Pertinent technical records from suppliers

Exhibit 4.2.4 details the matrix for records.

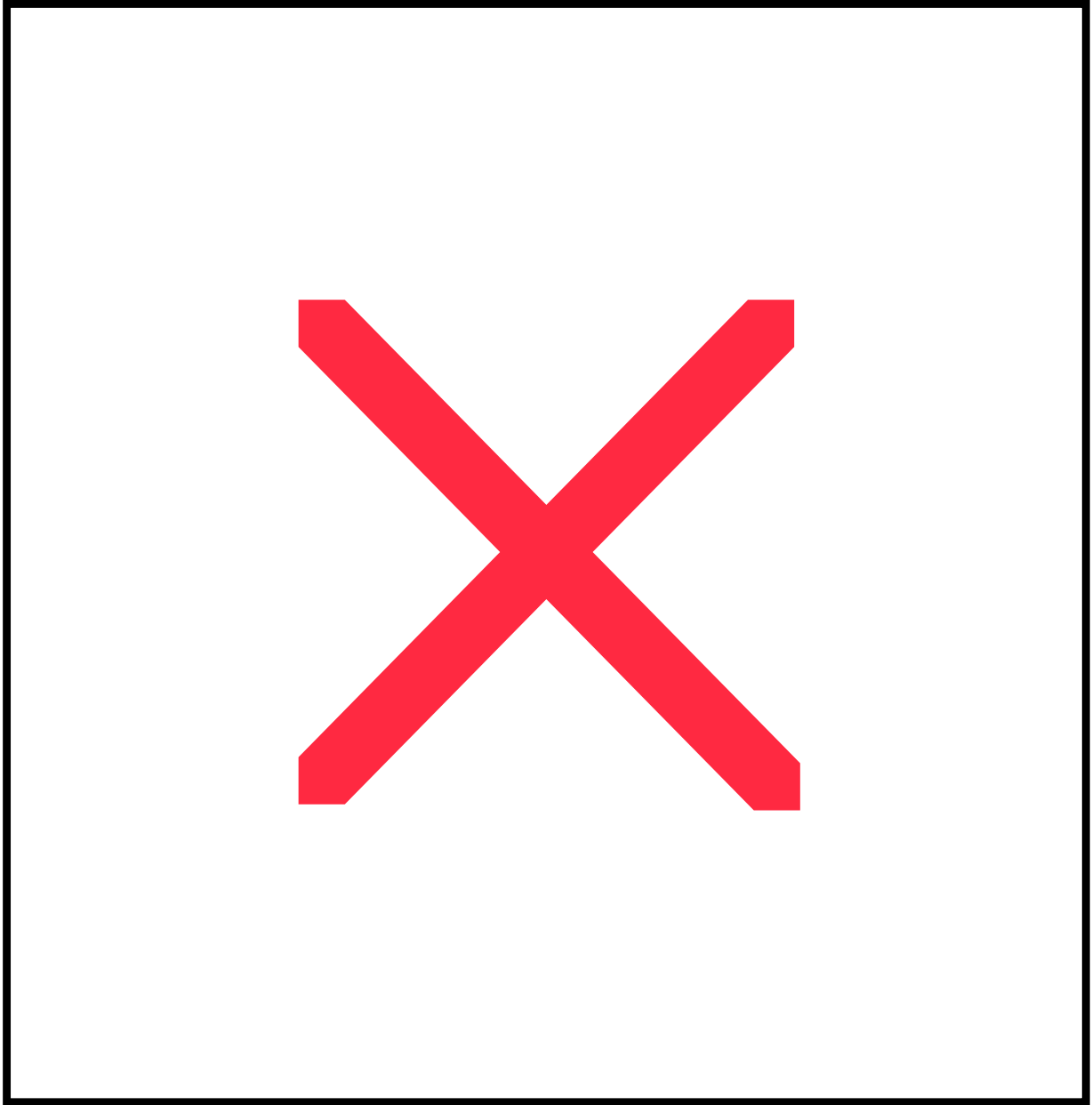


Exhibit 4.2.4

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5 MANAGEMENT RESPONSIBILITY

Management commitment

Top management provides evidence of its commitment to the development and improvement of the quality management system through both words and actions.

Our quality policy statement documents and communicates the importance of meeting or exceeding all applicable requirements (including customer, regulatory and legal requirements) by continually improving our processes, products and services.

EF Precision Group ensures that our policy is understood, implemented and maintained at all levels of the organization through our printed and verbal reinforcement of the quality policy statement and corporate level improvement objectives established and reviewed during management reviews conducted in accordance with QAP 5.1 and through operational objectives established and reviewed during employee performance reviews.

All managers demonstrate their commitment to the development and improvement of the quality management system through the provision of necessary resources and through their direct involvement in the internal audit process and continual improvement activities.

Customer focus

EF Precision Group's quality policy statement articulates our commitment to our customers. We will achieve customer satisfaction by continually improving processes, products and services to ensure they consistently meet or exceed customer requirements.

In order to meet or exceed customer requirements on a daily basis, unspecified requirements and other customer expectations must be determined, understood and converted into requirements, so that, processes and systems can be established and maintained to meet or exceed those requirements.

EF Precision Group works hard to be an active team member with our customers through regular customer visits by our sales personnel and trade shows involving senior managers from our company and those of our key customers, customer audits at our facility and through our web site: www.efgroup.com. These communications and interactions ultimately yield clear, explicit customer requirements and expectations in the form of a contractual agreement or customer specification. The VP/GM has overall responsibility for ensuring these requirements are met or exceeded with the overall aim of achieving high levels of customer satisfaction.

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5.3 Quality Policy

IT IS OUR COMMITMENT THAT QUALITY IS BUILT INTO ALL PRODUCTS AND SERVICES, AND THE RESPONSIBILITY OF ALL ASPECTS OF OUR ORGANIZATION. THIS PHILOSOPHY OF RESPONSIBILITY ALLOWS US TO MAINTAIN OUR UNFAILING REPUTATION FOR QUALITY AND CUSTOMER SATISFACTION.

Our quality policy statement indicates our commitment and focuses on what is important to us as an organization: achieving customer satisfaction; and it prescribes the method by which we accomplish this: by continually improving processes, products and services to ensure they consistently meet or exceed requirements. Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing key corporate level performance measures and related improvement objectives.

EF Precision Group ensures that the quality policy is communicated and understood at all levels of the organization through documented training, regular communication and reinforcement during performance reviews.

Our quality policy statement is controlled by inclusion in this manual and is reviewed during management review meetings for continued suitability.

5.4 Planning

5.4.1 Quality objectives

Our overall quality goal is to achieve our quality policy, maintain the integrity and continual improvement of our quality management system that satisfies the requirements of ISO 9001:2000. At the corporate level, responsible managers will monitor and measure performance in the areas outlined below, and where needed, establishes measurable improvement objectives.

- Customer satisfaction: VP/GM
- Supplier performance: MM
- Overall quality management system: VP/GM
- Overall financial operational efficiency: CAO/CONTROLLER
- Competency and training effectiveness: QAM
- Overall effectiveness of EF Precision Groups' production operations: VP/M
- Overall product quality: QAM

Corporate level improvement objectives will be documented, implemented and reviewed for achievement and continued suitability during management reviews conducted by Top management.

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At the operational level, all officers, managers and supervisors will monitor and measure performance of processes within their respective areas of responsibility and where appropriate, establish measurable improvement objectives. Operational level improvement objectives will be documented, implemented and reviewed for achievement and continued suitability during performance reviews.

5.4.2 Quality management system planning

The quality management system planning process involves the establishment and communication of our quality policy and objectives through issuance of this manual and its associated procedures and the provision of resources needed for its effective implementation. Accordingly, this manual constitutes our overall quality management system implementation plan. Our management review process and internal audit process ensure the integrity of our quality management system is maintained when significant changes are planned and implemented.

The QAM develops a quality plan for specific products, projects or contracts whenever customer requirements exceed the capability or intent of the product/service realization and support processes described in our quality management system.

5.5 Responsibility, authority and communication

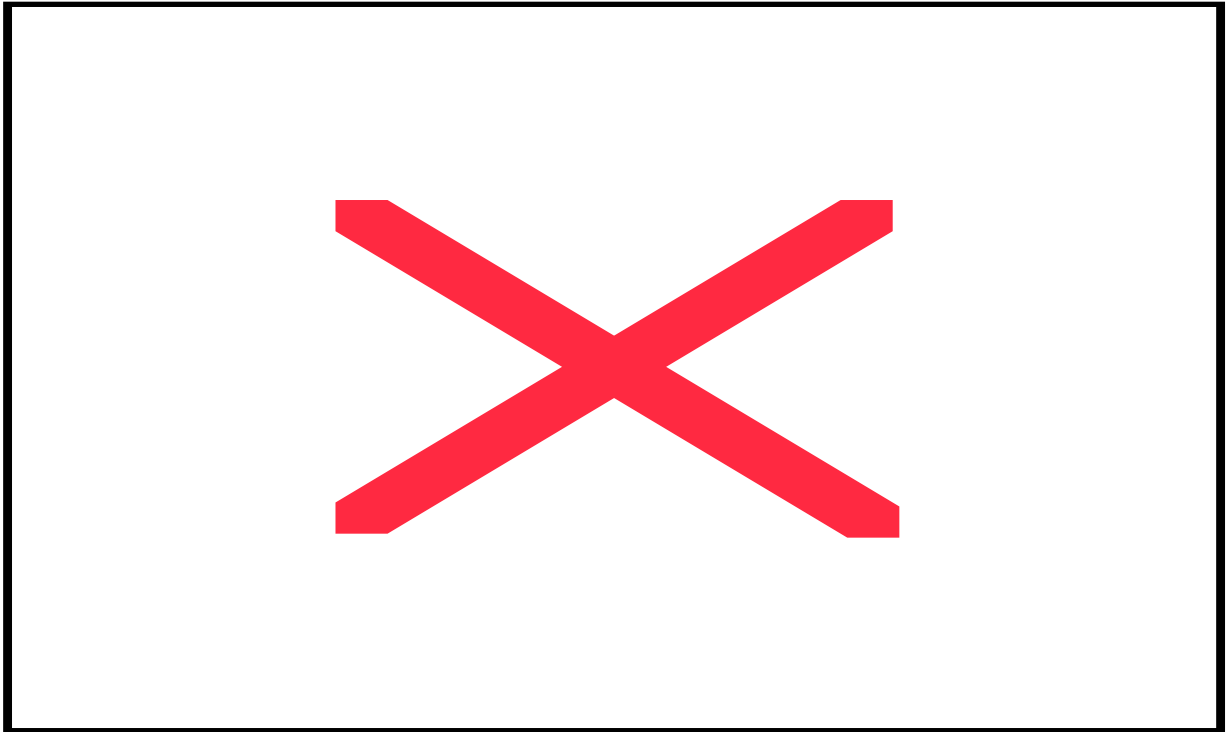
5.5.1 Responsibility and authority

The CHM and CEO set direction and ensures the success of the EF Precision Group. Other members of Top management include the VP/GM; VP/M; CAO/CONTROLLER; and HRM. The interrelationship of Top management and other key personnel are depicted in our organizational chart, hereafter identified as Exhibit 5.5.1.

Overall quality management system responsibility and authority is as follows:

Top management – Members of Top management are ultimately responsible for the quality of EF Precision Groups’ products and related services since they control the systems and processes by which work is accomplished. Top management is responsible for strategic planning, development and communication of the quality policy, quality management system planning, including the establishment and implementation of corporate level objectives and the provision of resources needed to implement and improve the quality management system. Top management also conducts and documents quality management system management reviews no less than every 6 months.

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Operational level management – Members of operational level management such as department managers, supervisors and team leaders are responsible for the execution of the strategic plan and implementation of the processes and systems described in this manual. Operational level management is responsible for planning and controlling quality management system processes within their area(s) of responsibility including the establishment and implementation of operational level objectives and the provision of resources needed to implement and improve these processes. Operational level management also conducts employee performance reviews.

Subordinate employees – All subordinate employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform. Subordinate employees also identify and report any known or potential problems and recommend related solutions through the internal audit and/or corrective/preventive action processes.

Detailed responsibilities and authorities for quality management system implementation and improvement are contained in QAPs' and SOPs' referenced throughout this manual and other quality management system documents including flow charts, job descriptions, etc.

5.5.2 Management representative

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The ISO management representative appointed by EF Precision Group is the QAM with delegated responsibilities for ensuring that a quality system is established, implemented and maintained in accordance with ISO 9001:2000 requirements, for reporting to Top Management on performance of the quality management system, for promoting awareness of customer requirements throughout the organization and for ensuring that the performance of the quality management system is reviewed for effectiveness, continuing suitability and the need for improvement.

5.5.3 Internal communication

EF Precision Group communicates information regarding quality management system processes and their effectiveness through documented training, internal audits, corrective/preventive action processes and regular informal communications. All operational level management personnel are responsible for establishing internal communications as needed to convey to their subordinate employees the relevance and importance of their activities. Typically this information is conveyed through departmental team meetings, specific improvement projects and/or individual discussion.

5.6 Management review

5.6.1 General

Top management conducts a management review annually to ensure the continuing suitability, adequacy and effectiveness of the quality management system. The primary inputs reviewed include data that measures the conformance and performance of the quality management system. Conformance is primarily assured through internal audits and demonstrated through a review of internal audit results and the ability to correct/prevent problems. Performance is primarily assured through the implementation of corporate/operational level objectives and demonstrated through a review of our ability to achieve desired results. The output of Top management review meetings are actions taken to make necessary changes to the quality management system including the quality policy, corporate level improvement objectives and the provision of resources to implement these actions. The procedure is identified in QAP 5.6.1

5.6.2 Review input

The Top management review meeting includes a review of current performance, corrective/preventive action(s) status and opportunities for improvement related to follow-up actions from earlier Top management reviews and changes that could affect the quality management system. Also reviewed for status and continuing suitability are the corporate level quality objectives related to customer satisfaction, supplier performance, overall quality management system effectiveness, operational efficiency, competency/training effectiveness, overall product quality and overall manufacturing performance.

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5.6.3 Review output

At a minimum, outputs from Top management review meetings include new/revised corporate level improvement objectives and any related actions required for improvement of the quality management system and its processes, improvement of product related to customer requirements and provisions of resource needs. Results of Top management review meetings are documented and maintained by the VP/GM.

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 quality management system and our products/services, conduct audits and implement other actions aimed at enhancing customer satisfaction.

6.2 Human resources

6.2.1 General

EF Precision Group believes that our employees are our most valuable asset and does its' best to help them achieve their full potential through continual education and training.

6.2.2 Competence, awareness and training

The competency of people assigned responsibilities defined in the quality management system is determined on the basis of education, training, skills and experience. The HRM has the responsibility for administering EF Precision Groups' Human Resource Programs.

EF Precision Group determines competency needs including employee training and awareness through a variety of methods. Top management identifies emerging needs during strategic planning meetings. These needs are identified as job functions that need to be filled through external recruitment, internal reassignment/promotion or subcontracting actions.

The VP/GM, with input from Top management or operational level management, may elect or delegate the responsibility to evaluate and qualify applicants for specific job openings on the basis of documented or demonstrated competencies.

Where possible, EF Precision Group will help existing employees qualify for new/changed jobs through provisions of appropriate education and training including on-the-job training. The HRM, with input from Top management or operational level management (as required), establishes and maintains job descriptions for each position at EF Precision Group to document the specific competencies needed to ensure the quality of EF Precision Groups' products.

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Top management and operational level management re-evaluate subordinate employee competencies and evaluate subordinate employee performance against established objectives through our annual performance review process. Subordinate employee competency and training records are maintained by the HRM.

Training needs identified as a result of the evaluations (addressed above) are passed on to the HRM for appropriate planning and timely provision. EF Precision Group develops and provides training that balances organizational needs with the development and career needs of our employees. When a quality management system process is established or significantly changes employees involved in the specific process, training prior to implementation is conducted and training records updated.

Training provided is evaluated through immediate feedback from the subordinate employee and the management person who identified the training requirement. Training is considered effective if human error can be eliminated as a root cause of problems/nonconformities and is documented on the training record. The QAM with input from other responsible members of management, monitors and measures the overall effectiveness of training and other actions taken to meet competency needs and provides related recommendations to Top management for review and action.

EF Precision Group ensures that its' 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 quality management system training, qualification reviews and participation in the internal audit and continual improvement process. The procedure is identified in QAP 6.2.2.

6.3 Infrastructure

The VP/GM has overall responsibility for day-to-day business operations which include identifying, providing and maintaining the resources needed to achieve product conformance. The VP/M has overall responsibility for workspace and associated facilities, equipment, hardware, software and supporting services, facilities and equipment maintenance. The procedure is identified in QAP 6.3.

6.4 Work environment

EF Precision Group provides employee benefits, job and schedule flexibility, interesting work and involvement in continual improvement.

The company engenders total participation by involving employees in internal audit and continual improvement activities. The HRM has overall responsibility for identifying, implementing and maintaining effective employee benefit programs.

EF Precision Group monitors and improves workplace safety, health and ergonomics including adherence to good manufacturing practices and training. A suitable working environment is maintained to ensure product quality.

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The VP/M has overall responsibility for identifying, implementing and maintaining safety and environmental management systems, processes and controls needed to ensure product conformance and meet customer, statutory or regulatory requirements.

7 PRODUCT REALIZATION

7.1 Planning of product realization

EF Precision Groups' quality management system identifies and plans for our product realization processes to ensure consistency with all applicable requirements, including customer requirements, statutory/legal requirements, as well as EF Precision Groups' product performance objectives.

The outputs of product realization planning include the specific methods, facilities, equipment, people and materials/support services needed to achieve all desired results for a particular product, purchase order or contract. Product planning also includes the identification of verification/validation activities, the criteria for acceptability and the records necessary to provide confidence of product conformance.

The elements of product realization planning that apply to all products are addressed in this manual and its associated procedures and other lower level documents.

When customer specified requirements are beyond the control or capability of our established quality management system, the VP/M has overall responsibility for developing and implementing a specific plan for that process or product.

Our approach to process management involves determining what the customers wants, developing processes and systems capable of meeting those requirements, ensuring that process inputs are appropriate, monitoring and measuring process activities and outputs to ensure desired results are achieved, improving the process as needed to reduce variation, eliminate waste and enhance customer satisfaction. The procedure is identified in QAP 7.1.

7.2 Customer related processes

7.2.1 Determination of requirements related to the product

Achieving our quality policy requires that we determine, understand and consistently meet or exceed our customers' requirements and expectations and that we establish effective communication systems with our customers with regard to product information, inquiries, purchase order/contract or order handling and related changes and customer feedback including customer complaints. The VP/GM has overall responsibility for developing and implementing effective customer related processes.

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Sales personnel generate quotes/bids and negotiate final contracts/orders, receive customer orders for items including those previously bid or negotiated. Requirements for all customers are identified in received contracts/orders. Typical applicable customer requirements include product requirements, delivery, packaging and certifications.

7.2.2 Review of requirements related to the product

The VP/GM reviews customer requirements identified during the determination process 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 requirements the customer requirements are confirmed before acceptance; that contract or purchase order requirements differing from those previously expressed are resolved; and that we have the ability to meet defined requirements.

EF Precision Group ensures that these criteria are met prior to making a delivery commitment. Where product requirements are changed, we ensure relevant documents are amended and relevant personnel are made aware of the changed requirements. The procedure is identified in QAP 7.2.2.

7.2.3 Customer communication

EF Precision Groups' manufacturing capability is available through a number of different sources. The VP/GM provides facility information directly to customers including verbal and printed information. The company web site, www.efgroup.com which contains extensive capability information including past and present customers also allows the customers to contact us. Inquiries are handled by sales personnel.

EF Precision Group pays particular attention to customer feedback including customer complaints and customer satisfaction. The company maintains a toll-free telephone number and a wide sales network to encourage and address customer feedback including complaints. Customer satisfaction is evaluated on an on-going basis by sales personnel. The procedure is identified in QAP 7.2.3.

7.3 Design and development

This element is not applicable by exclusion

7.4 Purchasing

7.4.1 Purchasing process

EF Precision Group works toward teaming relationships with its suppliers to ensure that purchased products and services meet applicable requirements.

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The type and extent of control over the purchasing process 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 or products; the results of supplier evaluations and past performance and applicable regulations.

The MM defines and documents 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 products or services in accordance with our requirements. The results of evaluations and follow-up actions are recorded. EF Precision Group also maintains a list of approved suppliers. The procedure is identified in QAP 7.4.1.

7.4.2 Purchasing information

Purchasing documents contain the appropriate data to clearly and fully describe requirements for purchased materials and services including, where applicable, requirements for approval or qualification of product, procedures, processes/systems, equipment and/or personnel.

The MM ensures that all purchasing documents are reviewed for completeness and adequacy prior to issuance. The procedure is identified in QAP 7.4.2.

7.4.3 Verification of purchased product

The QAM ensures that incoming product is approved prior to release. In some cases, criteria for approval of incoming product will be specified in a product quality plan and may include data submitted by the supplier, including statistical data, certificates of conformance, etc. The QAM plans and implements appropriate statistical techniques to verify purchased product. All requirements for approval of purchased product and/or supplier procedures, processes, equipment, personnel and/or quality systems will be specified in applicable purchasing documents.

Neither EF Precision Group nor its' customers currently perform verification activities at our suppliers facilities however, should the desire to perform such verification be a future requirement, the QAM will document the intended verification arrangements and method of product release.

7.5 Production and service provision

7.5.1 Control of production and service provision

EF Precision Group utilizes a process focused approach to control operations related to production. Our initial focus is to ensure the quality of process inputs – that is, employees, material facilities equipment and methods. Employees must be equipped to perform the process properly through appropriate education, training and certification. Material must meet specified requirements and be properly identified, stored and issued.

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Equipment and facilities must be adequate, accurate, available and properly utilized. Work instructions and other important data must be current and correct. Methods must be appropriate and capable of accomplishing the desired results. The appropriateness of all these fundamental process inputs must be assured, processes must be measured, monitored and controlled to assure effectiveness and evaluated for continual improvement.

The VP/GM reviews operational data as well as progress towards achievement of corporate level product performance objectives and provides related recommendations for review by Top management. The VP/M has overall responsibility for managing our production processes and ensures that production jobs are planned, scheduled and carried out in accordance with procedures (QAP's and SOP's).

Information inputs to the process include both product characteristics and appropriate work instruction containing specific work methods and/or other pertinent information. The VP/M through operational level management personnel ensures that all appropriate information including final product specifications, raw material characteristics and the required product parameters, is provided to production personnel throughout the production process. Such information is provided through job schedules/plans, production meetings, work instructions posted in areas where they are needed and/or through job specific information included in individual job packs.

The necessity for detailed work instructions is minimal as the knowledge, skill level, training and ability of our employees is consistently being updated and reviewed. The job traveler contains information from the drawing, customer requirements, special notes, etc. which accompanies the job as it proceeds through the production process.

The VP/M ensures the suitability and availability of all equipment and facilities used for production.

The QAM ensures that monitoring and measuring devices capable of meeting the measuring requirements are available for use during production.

Operational level production supervisors ensure that production personnel monitor the quality of their own work and understand the procedures for reporting related problems and/or suspected nonconforming conditions. The QAM is responsible for planning and implementing in-process inspections needed to ensure process control and product quality.

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/order. The QAM ensures that records of product approval are maintained and clearly indicate the authorizing employee. EF Precision Group currently does not perform post-delivery activities. The procedure is identified in QAP 7.5.1

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7.5.2 Validation of processes for production and service provision

EF Precision Group defines processes in which the results cannot be verified by subsequent monitoring or measurement as “Special Processes”. This includes any processes where deficiencies may become apparent only after the product is in use. EF Precision Group product processes do not currently include any “Special Processes”.

7.5.3 Identification and traceability

The identification and status of product is established and maintained throughout all product processes.

Traceability records are established and maintained as required. The QAM has overall responsibility for establishing and maintaining product identification throughout all stages of production and delivery.

EF Precision Group establishes and maintains product monitoring and measurement status through the use of both physical identification tags/labels and electronic records. Additionally, physical location in designated hold or production process areas is an indicator of product status. The VP/M, through operational level management personnel, ensures that all incoming, in-process and final product is suitably identified and the current status is appropriately tracked and displayed in accordance with QAP 7.5.3.

Where customer required, the QAM establishes and maintains appropriate traceability records in accordance with the customers’ requirements. Where products are made in lots or batches, we identify and record a unique lot or batch number and related information on the job traveler.

7.5.4 Customer property

EF Precision Group identifies, verifies, protects and maintains customer property provided for use or incorporated into the product applying the same process controls as we do to purchased product and other material inputs to the process. Whenever required by the customer or when customer specified requirements for property management are beyond the control or capability of our established quality management system, the QAM has overall responsibility for documenting and communicating such requirements in the product quality plan. The QAM ensures that lost, damaged or unsuitable customer property is recorded on a corrective/preventive action request and immediately reported to the customer. Customer intellectual property when identified, will be utilized and controlled as directed by the customer.

7.5.5 Preservation of product

The VP/M through operational level management personnel has overall responsibility for establishing and implementing a product handling system that ensures product conformity is preserved during internal processing and delivery to the intended destination.

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This system includes the handling, storage, packaging, delivery and protection of final product as well as in-process constituents of the final product. Products are handled and stored in a manner that prevents damage or deterioration pending delivery. Each processing department ensures controls are implemented to prevent mixing conforming and nonconforming materials. Packing ensures specified or original manufacturing packaging is utilized; all components and products are suitably packed to prevent deterioration or damage during storage and delivery. The procedure is identified in QAP 7.5.5.

7.6 Control of monitoring and measuring devices

The QAM is responsible for establishing and maintaining an effective system for identifying, selecting and controlling the use of monitoring and measuring devices used to provide evidence of product conformance to established requirements.

All product drawing dimensions will be checked with the accuracy required to assure conformity to those requirements. We identify and select monitoring and measurement devices and verify their capability of meeting such requirement prior to use.

Monitoring and measuring devices are used and controlled in a manner that ensures continuing suitability. This includes ensuring that the environmental conditions are suitable for the calibration, inspections, measurements and tests being carried out. We also define the processes employed for the on-going calibration, control and maintenance of monitoring and measuring devices including their identification, location, frequency/method of checks, uses/acceptance criteria and the action to be taken when results are unsatisfactory.

All monitoring and measuring devices that are used for product acceptance (as identified in ISO 10012) are identified and calibrated at prescribed intervals against certified equipment having a known valid relationship to N.I.S.T. It does not apply to other items of measuring equipment.

When monitoring and measuring devices are found to be out of calibration (or when calibration status is not known), they are adjusted or re-adjusted as necessary and the validity of previous measuring results are documented; actions taken are documented, including appropriate corrective/preventive actions to remedy the situation and preclude its recurrence.

Appropriate calibration records are maintained to document results of calibration activities and suitable indicators are used to show current calibration status.

Those pieces of monitoring and measuring devices that lend themselves to sealing are safeguarded from adjustment that would otherwise invalidate the calibration.

All monitoring and measuring devices are handled, maintained and stored in a manner that ensures accuracy and fitness for use. The procedure is identified in QAP 7.6.

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8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

EF Precision Group has defined, planned and implemented the monitoring, measurement, analysis and improvement processes needed to assure product and quality management system conformity and achieve continual improvement. These activities include assessment of customer satisfaction, completion of internal audits, monitoring and measurement of processes and the monitoring and measurement of product. The procedure is identified in QAP 8.1.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Customers are the reason we exist and drive our quality policy. Data collected by sales personnel during routine communications provide our primary basis for assessing customer satisfaction. The VP/GM has overall responsibility for identifying and reviewing customer requirements and for monitoring and measuring customer satisfaction.

Customer complaints are immediately forwarded to the VP/GM for action. Customer complaints are documented and monitored through resolution by our corrective/preventive action process.

Sales personnel will use all means (verbal/written) to ascertain the customer's overall perception of how well we are meeting their requirements and to document any recommendations for improvement. Customer feedback is reviewed by sales personnel to initiate any corrective/preventive actions needed.

The VP/GM periodically reviews customer feedback, as well as progress towards achievement of corporate level customer satisfaction improvement objectives, and provides related recommendations for review by Top management. The procedure is identified in QAP 8.2.1.

8.2.2 Internal audit

Internal audit results are critical inputs to aid in assessing the effectiveness of our quality management system and in identifying opportunities for improvement. Their purpose is to; determine whether the quality management system conforms to control requirements (ISO/FDA/customer); determine whether the process has been effectively implemented and maintained; and to identify opportunities for improvement.

The quality management system process, function or quality system element under review is effective if it is achieving the desired results or established objectives. In addition, employee ideas for improving process effectiveness or efficiency are actively sought during internal audits. Internal audit results are also used to determine the scope, nature and frequency of future internal audits of processes, functions or quality system elements where ineffectiveness or inefficiency is most likely to be found. Accordingly, the internal audit process is a key method for communicating with and involving employees in continual improvement.

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Top management or operational level management may request that an audit be conducted to gather “value added” data serving as input to aid in monitoring, measurement and improvement of quality management system processes and systems.

The QAM has overall responsibility for managing the internal audit 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. Each of our quality management system processes is reviewed at least once annually.

Management responsible for the area audited implement timely corrective action to eliminate detected nonconformances and their causes and initiate other appropriate action in response to employee identified opportunities for improvement. Follow-ups are conducted to verify timely and effective implementation of the proposed action.

The QAM maintains all internal audit records, including training records and results of internal audit related follow-ups, periodically reviews internal audit results, as well as, progress towards achievement of corporate level objectives aimed at improving overall quality management system effectiveness and provides related recommendations for review by Top management. The procedure is identified in QAP 8.2.2.

8.2.3 Monitoring and measurement of processes

EF Precision Group applies suitable methods for monitoring and measuring of all quality management system processes. Quality management system processes are documented, measured, controlled and evaluated to ensure they are effective and to identify opportunities for improvement. The manager with overall responsibility for the process, develops key measures used to quantify process effectiveness and/or efficiency.

A process is effective if desired results are achieved. Effectiveness can be measured in terms of product quality, process accuracy, delivery/schedule performance, cost/budget performance, employee/function performance against established objectives and/or customer satisfaction.

A process is efficient when resource utilization is optimal. Efficiency can be measured in terms of total resource utilization, productivity indicators and/or waste/rework costs or hours.

Since effectiveness is of primary importance to our customers and efficiency is of primary importance to management, achieving and improving effectiveness and efficiency of all our processes is critical to our success.

The QAM is responsible for planning and implementing formal in-process inspection activities, including those using statistical techniques to ensure process control at the product, project or contract level.

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8.2.4 Monitoring and measurement of product

The QAM has overall responsibility for planning and implementing effective product monitoring and measurement systems including receiving, in-process and final inspection and test activities and the use of appropriate statistical techniques needed to ensure process control at the product, project or contract level.

Receiving inspection is performed to ensure quality of purchased products. Process monitoring is performed by production personnel throughout all product realization processes. In-process inspections are performed by production and quality personnel in accordance with the quality plan. All finished product is verified by final inspection/tests specified on the customers' drawing/purchase order requirements.

Products are not released for further processing or delivery until there is objective evidence that all requirements have been met.

Test and inspection records are maintained for a minimum of seven years. These records include final inspection authority and identify and confirm that all critical parameters are in accordance with established requirements and specifications.

Product is not released or delivered until all planned inspections and tests have been completed and records have been maintained providing evidence of conformity with acceptance criteria and identifying the person authorizing release. Nonconforming product is identified and controlled to prevent its inadvertent use. The procedure is identified in QAP 8.2.4.

8.3 Control of nonconforming product

EF Precision Group ensures that nonconforming purchased product, in-process materials and finished product is identified and controlled to prevent inadvertent use. The QAM has overall responsibility for implementing an effective process for identifying, documenting, segregating, evaluating and disposing of nonconforming product.

Identification of nonconforming product originates from inspection, internal testing or customer complaint. Employees clearly mark or otherwise identify nonconforming product. The MM will notify the customer of customer supplied nonconforming product.

The QAM has the responsibility to enter the nonconformance into the corrective action system identifying the nonconforming product (and lot number if applicable), describe the nonconformance and location where the nonconforming product is being held pending further review or disposition. Nonconforming product is segregated from approved lots pending evaluation and disposition.

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The QAM has the responsibility to perform the initial evaluation of nonconforming product in accordance with approved test and inspection procedures. If needed, other technical personnel may become involved in the evaluation and recommendation for disposition.

The results of the evaluation and resultant disposition determinations will be documented. Dispositions resulting from the evaluation may include:

- Use as is
- Rework
- Scrap
- RTV

Reworked nonconforming product is re-verified after correction to demonstrate conformity to original requirements.

In the event that nonconforming product is detected after delivery, the QAM will notify the customer and initiate action appropriate to the effects, or potential effects, of the nonconformity.

Records of the nonconformities and any actions taken including concessions obtained will be maintained as documented evidence of such nonconformity. The procedure is identified in QAP 8.3.

8.4 Analysis of data

Top management and operational level management collect and analyze data using appropriate statistical techniques to determine the suitability and effectiveness of elements of the quality management system applicable to their area(s) of responsibility and to identify opportunities for improvement. Data is analyzed to assess achievement of the corporate level quality objectives related to, customer satisfaction, supplier performance, overall quality management system effectiveness, overall operational efficiency and competency and training effectiveness.

Results of data analysis together with related recommendations are presented to Top management for review and action during management reviews.

8.5 Improvement

8.5.1 Continual improvement

The continual improvement process at EF Precision Group begins with the establishment of our quality policy and objectives for improvement based on key measures established by Top management. Customer satisfaction, internal audit, process and product performance data is then collected, analyzed and monitored to assess progress against objectives and identify opportunities for improvement.

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Corrective actions are initiated when desired results are not achieved and preventive actions are initiated to prevent the occurrence of problems or to implement other improvement actions.

Actions are prioritized and implemented on the basis of data: the impact of failures/problems is used to prioritize needed corrective actions and risks are evaluated to identify and prioritize needed preventive actions.

The effectiveness of corrective and preventive actions taken as well as the overall progress towards achieving corporate level improvement objectives is assessed through our management review process. At EF Precision Group, our “baseline” performance begins with meeting customer and control (ISO 9001:2000 requirements and in section #9, FDA 97-4179 guidelines) expectations.

All inputs to the management review process are used to establish new/changed improvement objectives and to initiate additional improvement actions.

The QAM has overall responsibility for establishing and implementing an effective corrective and preventive action system.

8.5.2 Corrective action

Evidence of nonconforming product, customer dissatisfaction and ineffective processes is used to drive our corrective action system because they indicate that a current problem exists requiring immediate correction and possible additional action aimed at eliminating or reducing the likelihood of its recurrence. Investigating and eliminating the root cause of these failures is a critical part of our continual improvement process. We apply controls and follow-up to ensure that effective corrective action is taken appropriate to the impact of the problem encountered.

In addition, the QAM summarizes and analyzes corrective action data to identify trends needed to assess overall effectiveness of the corrective action system and to develop related recommendations for improvement.

The corrective action system is considered effective if specific problems are resolved or corrected and data indicates that the same or similar problems have not recurred. Results of this analysis and related recommendations are presented to Top management for review and action during management reviews. The procedure is identified in QAP 8.5.2.

8.5.3 Preventive action

Data from internal audits, customer feedback and employee suggestions is collected and analyzed to identify the actions needed to eliminate the causes of potential problems and thereby prevent their occurrence. Investigating and eliminating the root cause of potential failures is a critical part of our continual improvement process. We apply controls and follow-up to ensure that effective preventive action is taken appropriate to the risk and impact of potential problems and losses.

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In addition, the QAM summarizes and analyzes preventive action data to identify trends needed to assess overall effectiveness of the preventive action system and to development related recommendations for improvement. The preventive action system is considered effective if potential losses have been avoided. Results of this analysis and related recommendations are presented to Top management for review and action during management reviews. The procedure is identified in QAP 8.5.3.

9 BUILDINGS AND ENVIRONMENT

9.1 General

EF Precision Groups' facilities are controlled for maintenance and environmental conditions so that finished product will meet customer requirements. Adequate space is available for manufacturing, receiving, storage, packaging/labeling, etc. Environmental controls such as heating and air conditioning are maintained to ensure consistent and stable conditions during the manufacturing process.

9.2 Maintenance and sanitation

The VP/M is responsible for overall facility control and conditions. Maintenance on the facility is monitored daily. The sanitation facilities are monitored on a continual basis for correct drainage and cleanliness conditions. The procedure is identified in QAP 9.2.

9.3 Insect and rodent control

The VP/M is responsible for overall facility pest control. The facility is monitored for insects and rodents with applicable measures taken to prevent infestation of any type. The procedure is identified in QAP 9.3.

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Appendix A

List of Referenced Quality Management System Documents

Document No.	Title
QAP 4.2.3	Document Control
QAP 4.2.4	Quality Records
QAP 5.1	Management Responsibilities and Authority
QAP 5.6.1	Management Review - General
QAP 6.2.2	Competence, Awareness and Training
QAP 6.3	Infrastructure
QAP 7.1	Planning of Product Realization
QAP 7.2.2	Review of Requirements Related to the Product
QAP 7.2.3	Customer Communication
QAP 7.4.1	Purchasing Process
QAP 7.4.2	Purchasing Information
QAP 7.5.1	Control of Production and Service Provision
QAP 7.5.3	Identification and traceability
QAP 7.5.5	Preservation of Product
QAP 7.6	Control of Monitoring and Measuring Devices
QAP 8.1	Measurements, Analysis and Improvement - General
QAP 8.2.1	Customer Satisfaction
QAP 8.2.2	Internal Audits
QAP 8.2.4	Monitoring and Measuring of Product
QAP 8.3	Control of Nonconforming Product
QAP 8.5.2	Corrective Action
QAP 8.5.3	Preventive Action
QAP 9.2	Maintenance and Sanitation
QAP 9.3	Insect and Rodent Control