LION
PRECISION

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Quality Manual

QM-9001

Revision 26

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Approved by: Don Martin, President

Revision	Date Issued	Description of Changes
001	01/98	Initial Release
002	03/98	Add 3.2; Change 4.2.3, 4.4.3, 4.6.4, 4.7, 4.8, 4.11.2, 4.14.3, 4.16, 4.19;
003	06/08/98	Updated 4.4.2, 4.4.4, 4.4.5, 4.9, 4.11.2, 4.13.1, 4.13.2, 4.17, 4.19;
004	07/31/98	Change Footer ("verify before use"); Add page numbers; Rewrite 4.1, 4.2, 4.4, 4.17, and 4.18; Change 4.6.4 (no urgent release); Change 4.19 (service not applicable);
005	10/03/98	Rewrite 4.3, 4.6, 4.10.2, 4.10.3, 4.16, 4.20; Correct assorted typos; Changed number to QM-9001 (was QM-MAN-9001);
006	11/09/98	Many changes after stakeholders meetings and meetings with ISO Consultant Russ Ziebell.
007	12/04/98	Changes made as a result of pre-assessment audit on 11/25/98.
008	01/02/99	Changes made as a result of review by Jerry Ensminger on 12/21/98.
009	01/20/99	Updated 4.14.
010	02/16/00	Edited job titles for reassignment of sections; Edited typos throughout;
011	02/21/00	Removed statement describing Equipment Approval processes are located in PROC 4.9 Process Control.
012	06/30/00	Changed frequency of each element's audit from semiannually to annually (per CA 149); Added SPC Projects to the list of things to review in the management review meeting (per CA 136)
013	2/6/01	Corrected typos; Updated responsibilities of ISO Coordinator and Engineering Documentation Coordinator (4.01 page 9); Updated Management Review Meeting agenda (4.01 page 11); clarified statement regarding Product ID Traceability (4.08 page 20).
014	3/30/01	Updated 4.2.3 (page 13) to new procedure for Project Planning.
015	9/10/01	Updated 4.1.1,4.13.1 and 4.15.5
016	9/13/01	Changed 3.2 Vision Statement, Add 3.3 Our Guiding Principles
017	2/27/02	Updated Quality Policy description as described in 2/26/02 Mgmt Review minutes Changed "Engineering Documentation Control" references to "Documentation Control"
018	5/21/02	Update Quality Manual for new job duties.
019	9/19/02	Updated 4.1.2.1, 4.3.4, 4.17, 4.18, 4.20.1
020	2/24/03	Updated to meet ISO 9001:2000 standard
021	6/30/03	Updated to show correlation between Vision Statement, Mission Statement, and Quality Policy. Also updated 6.3 – Infrastructure for clarification on ESD and building repairs.
022	9/8/05	Replaced Vision and Mission Statement with Purpose, Future, and Values (3.1-3.3). Removed duplications in Quality Objectives (5.4.1). Updated Key Responsibilities and Job Descriptions (5.5.1). Added CAF information (7.2.1, 7.5.3). Updated Nonconforming responsibilities (8.3)
023	5/09/08	Major review and alignment of quality manual with revisions applicable to lower level documentation structure and revised Vision/Mission/Values.
024	3/15/12	Changes to referenced terminology and addition of Supporting Documentation reference at end.
025	5/7/13	Changes to Lion's values, obsolescence of QM-APP2, add Japan Tech Center, and misc. small clarifications.
026	5/31/16	Purchased by MTA and moved to their Oakdale location. Updated location info. Removed Japan Technical Center.

2.1 Introduction

This manual describes the quality system in operation at Lion Precision in Oakdale, Minnesota.

Lion Precision has two facilities, one in Oakdale, MN and one in Colorado Springs, CO. The Oakdale, MN site is registered to the ISO 9001:2008 quality standard. All aspects of the Oakdale site's business concerned with the design, sale, production, and delivery of products are under the scope of ISO 9001. Lion Precision's Quality System is implemented in accordance with the ISO 9001 quality standard.

This Quality Manual includes Lion Precision's quality policy, a description of the operational systems to ensure product quality, and the policies that support the ISO 9001 quality system elements.

Lion Precision works with its suppliers, internal resources, and customers to provide sensor and measurement systems that are unique in terms of application and performance. Customers often use Lion Precision products to solve measurement problems that cannot be resolved with alternative commercial products. The cost and performance of our sensor technology creates high expectations in the minds of our customers. It is essential that we provide the highest quality products in order to earn and maintain the confidence of our customers.

The president of Lion Precision approves this quality manual. Quality system documents are controlled as described in the document control procedure. This includes instructions to have controlled copies uniquely identified and have locations identified on a maintained document.

This manual and all supporting documents support the ISO 9001 International Quality Standards, ANSI/ASQC 9001:2008 with no exclusions.

3.2 What We Do

Provide optimized sensing solutions by partnering with our customers to ensure our mutual success.

3.2 What We Are Becoming

An organization responding to customer challenges with increasing speed and effectiveness.

3.3 What We Value

Responding to Customer Requirements
Always Improving
Demonstrating Responsibility and Integrity
Having Pride in Work
Having Fun

3.4 Quality Policy

The Quality Policy at Lion is:

Customer Satisfaction results from
a Motivated Workforce,
Innovative Products
and Operational Excellence.

The Quality Policy is maintained as Section 5.3 of this document. The Quality Policy is reviewed as described in Section 5.6 Management Review and during Internal Audits. This policy articulates our **Quality Objectives** of Customer Satisfaction, Innovative Products, Motivated Workforce, Operational Excellence, and Continued Growth.

4.1 General Requirements

Lion Precision has established, documented, implemented, and currently maintains and continually improves its quality management system in accordance with the requirements of ISO 9001:2008. The quality management system is evaluated via internal audits, documentation reviews, management reviews, and through daily use.

The quality element identification generally follows the following numbering structure:

100 series – Quality
200 series – Admin, Training, HR
300 series – Engineering
400 series – Purchasing
500 series – Manufacturing
600 series – Inventory Control, Shipping, Receiving
700 series – Sales, Marketing
800 series – Technical Support, Calibration

The processes that make up the quality system are described and outlined in QM-APP4 – Lion Precision Process Map. QM-APP4 identifies the sequence and interaction of these processes.

Lion Precision exercises control over the aspects of outsourcing through applicable operational processes.

4.2 Documentation Requirements

4.2.1 General

This quality manual identifies and describes Lion Precision's quality policy (see section 5.3) and quality objectives (see section 5.4.1). Documented procedures are prepared and are consistent with the ISO 9001 standard and the Lion Precision Quality Policy. These procedures are implemented throughout the organization and are available in both hard copy and electronic formats.

Lion Precision's quality system is documented in four levels:

Level 1: Quality Manual
Level 2: Procedures and Plans
Level 3: Instructions and Methods (Work Instructions)
Level 4: Quality Records

The level of documentation to support the quality system is based on skills, methods, and training required by the personnel responsible for the performed work. It is the responsibility of Documentation Control to provide revision control and organization of the master and controlled copies of all Level 1, 2, and 3 quality system documents. Controlled records (Level 4 documents) are maintained and controlled as described in Controlled Records Procedure.

4.2.2 Quality Manual

All aspects of the Oakdale, Minnesota location of Lion Precision concerned with the design, manufacture and sales, of sensors and control systems for industrial markets are under the scope of ISO 9001:2000.

The following documents describe how the Lion Precision quality system is integrated into company operations:
QM-APP1 – Organizational Chart
QM-APP4 - Process Map for Lion Precision

4.2.3 Control of documents

Lion Precision has established and maintained documented procedures to control all documents supporting the quality system including external documents (see Document Control).

Document owners, identified within the header or footer of documentation and/or Master List of Controlled Documents, review, maintain, and approve procedures, work instructions, and other quality documentation. It is the owner's responsibility to create and submit a document in its final form to Documentation Control.

Documents are reviewed and approved for adequacy by authorized personnel before issue. A master list of documents is on Lion's information system identifying the current revision status and is readily available to ensure correct documents are used (see Master List of Controlled Documents).

Documents are available where needed, as determined by management or area supervisors, to ensure quality system operations. Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use. Any obsolete documents that are preserved are identified and archived.

Changes to documents are reviewed and approved by the same authority group as the originals, unless otherwise designated by management. Background information is available to those who review and approve changes. The authorizing person/group determines when and where the nature of the change will be recorded.

4.2.4 Control of records

Procedures are documented and maintained for identification, storage, accessing, maintenance, and disposition of records.

Controlled records define the conformance to specified requirements and effectiveness of the quality system. Controlled records received from suppliers will be included in this element. Quality records are legible and stored in secure locations to prevent loss or damage. Records are maintained as documented. If contractually stipulated, customers have access to quality records.

Controlled records may be in the form of electronic or hard copy.

5.1 Management commitment

Lion Precision Management is responsible for communicating the importance of meeting customer and regulatory requirements throughout the company. This is done via meetings, internal communication (emails, memos, etc), training and orientation, and the customer order review process.

Management is also responsible for establishing and reviewing quality objectives as specified in section 5.4.1 of this manual.

Management reviews are attended by Lion Precision management where the quality policy, quality objectives, availability of resources, and other topics integral to the Lion Precision quality system are reviewed (see section 5.6 of this manual).

It is the philosophy of Lion Precision that quality is an attitude adopted individually by each person. The purpose of policies and procedures is to enable and encourage each individual to make "quality decisions." It is the responsibility of the President to encourage and support each individual in his or her quest to make "quality decisions."

5.2 Customer focus

Contract Review is used to ensure the customer's needs are fully understood and met before order fulfillment. This includes:

- Documenting and reviewing requirements with customers
- Creating and reviewing of customer quotations
- Reviewing of customer orders by the sales department before releasing to production
- Agreement regarding contract terms and product requirements between the customer and Lion Precision before product is shipped
- Communicating to all employees involved in the product delivery to ensure customer requirements are understood.
- Identifying and improving customer satisfaction.

5.3 Quality Policy

The Quality Policy at Lion is:

Customer Satisfaction results from
a Motivated Workforce,
Innovative Products
and Operational Excellence.

The above Quality Policy is communicated to all management participating in the Management Review Meetings and to all employees as a part of workforce training. The Quality Policy is also displayed in various work areas of Lion Precision employees.

5.4 Planning

5.4.1 Quality Objectives

The quality policy is supported by the following quality objectives:

- Customer Satisfaction
- Product Innovation
- Workforce Motivation
- Operational Excellence
- Continued Growth

Quality Objective Key Business Metrics are developed in support of the quality policy and associated objectives. The Key Business Metrics are reviewed on a monthly basis by key leadership.

Lion Precision Values are also aligned with our Quality Objectives:

What We Value	What we do because we value this…
Customer Satisfaction	Ensure processes are designed with the customer in mind (Amaze our customers) Supply the highest quality products and services possible to meet expectations and requirements Understand the customers' concerns and critical problems, and collaborate to solve them Model integrity and honesty
Innovative Products	Anticipate and respond to marketplace changes Maintain awareness of technological advancements Develop new products that meet or anticipate our customer's needs Pursue advances in sensing technology that improve our customer's results
Motivated Workforce	Foster an environment that respects and supports the talents and needs of others Accept and expect personal responsibility Promote effective and open communication Partner in the company's financial success
Operational Excellence	Perform continuous improvement Be proactive in problem prevention Maintain a safe working environment Focus on adding value for the customer
Continued Growth	Align all activities with Values, Purpose, and Envisioned Future Cultivate strong customer relationships Understand and use resources effectively Focus on desired results

5.4.2 Quality management system planning

There are three types of quality planning at Lion Precision: Product Planning, Project Planning, and setting Quality Goals. All three types of planning are implemented to meet the requirements in clause 4.1 as well as the quality objectives established by Lion Precision management.

Product Planning is in response to an identified market need. The design process controls the development process for new products. The procedure is used to identify customer requirements and to ensure internal capability to meet those requirements. Product Planning also includes the end-of-life considerations for products no longer offered as standard products.

Project Planning is a formal process where opportunities for improvement or problems are identified, and a plan is developed accordingly. Many times these plans address preventive measures involving quality, process, or service improvement. Projects are initiated as the result of input from any and all employees and may come from, but are not limited to, areas such as Performance Goals, Department Targets, and plans as a result of Strategic Planning. Projects are assigned to individuals or groups by management. These individuals or groups are responsible for development and execution of the project plan.

Management ensures the integrity of Lion Precision's quality management system is maintained when changes to the system are planned and implemented.

The methods of implementing change at Lion Precision:
1. Organization plans, objectives, and goals derived from the company business plan
2. Preventive/Corrective Actions
3. Engineering Change Orders (ECO's)

Based on the business plan, department supervisors work with management and their departments to develop project plans. Project plans contain measurable objectives, and/or specific targets. All employees are involved in this process.

Formal input and feedback instruments for the Quality System are explained in the Corrective/Preventive Action procedure. All employees are trained in the use of these procedures and are authorized to use it. This provides the mechanisms for routing to the correct department, verification of solutions, and any additional controls needed. Corrective and preventive actions are tracked from initiation to closure.

The way to make changes to product, or processes, is through ECO’s. The procedure is described in the Documentation Control procedure. All employees are encouraged to find areas of improvement and submit requests when appropriate.

5.5.1 Responsibility and Authority

Lion Precision is organized along traditional lines. There are departments for Sales and Marketing, Engineering, Accounting, Material Control/Operations Planning, Quality, and Operations. In order for the company to meet its objectives, it is imperative that all departments maintain a team-oriented attitude, where the "team" is the entire company.

QM-APP 1 – Lion Precision Organization Chart is available to show responsibilities and relationships.

Key responsibilities, authorities, and interfaces regarding the quality system have been assigned to the Management Representative, ISO Coordinator, Documentation Control, and Operations Manager.

Individuals and lines of authority are defined on the organizational chart and within corresponding job descriptions.

All individuals have the freedom and authority to suggest changes to a product, process, or the quality system including:

- Initiating action which prevents the occurrence of nonconformances
- Identifying and recording product, process, and quality system problems
- Initiating, recommending, or providing solutions through designated channels
- Verifying the implementation of solutions
- Controlling further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected

Job descriptions are maintained by Human Resources. The organizational chart, QM-APP1 - Lion Precision Organization Chart is maintained by the ISO Coordinator and details the company structure. Both documents are available for review by all employees.

In addition to job descriptions, specific responsibilities are also identified within procedures.

5.5.2 Management Representative

At Lion Precision, the Management Representative is the company President. The President has overall authority for implementation of the Quality System. These responsibilities include but are not limited to the following:

- Development of quality plans and strategies to implement and manage quality improvement.
- Lead the quality integration effort in all aspects of the organization to ensure systemic deployment.
- Ensure compliance to ISO 9001 through scheduled audits, management reviews, and preventive/corrective actions.
- Ensure adequate resources, training, and tools are available.
- Ensure processes necessary for an effective quality management system are established, implemented, and maintained.
- Communicate awareness of customer requirements throughout Lion Precision.

5.5.3 Internal Communication

Lines of communication are cross-functional and open at Lion Precision. Communication between and within departments occurs via email, open discussion, departmental meetings, company meetings, etc.

The effectiveness of the quality system is communicated during management review meetings, company meetings, availability of management review meeting minutes, posting of applicable monthly business metrics, and internal audit results.

5.6 Management Review

5.6.1 General

The ISO Coordinator schedules management review meetings at a minimum of once per year. The ISO Coordinator and the Management Representative may decide to schedule meetings more frequently.

The ISO Coordinator determines the attendance at these meetings based on the material to be reviewed and assigns action items and follow-up meetings as determined during the meeting. Records of the Management Review are completed and maintained by the ISO Coordinator.

5.6.2 Review Input

Agenda items for the management review shall include, but are not limited to:

- Follow-up on Action Items from last Management Review
- Audit Results since last Management Review
- Customer Feedback/Satisfaction
- Corrective and Preventive Actions
- Performance to Quality Objectives
- Review of Quality Policy
- Changes that can affect the Quality Management System
- Opportunities for Improvement

5.6.3 Review output

Management Review input items are discussed and used to assess the overall effectiveness of the quality system. Where inadequate progress toward objectives or goals is found, project plans or corrective actions are initiated to assure the situation remains visible for management.

The Management Review minutes include decisions and actions related to improvement of the effectiveness of the QMS and its processes, improvement of product related to customer requirements, and resource needs.

6 Resource Management

6.1 Provision of resources

Documented procedures have been established to ensure employees are provided with the proper training, equipment, and skills to do their job with the goals of customer satisfaction and quality system effectiveness in mind.

Personnel requirements to accomplish management, work, and verification activities are determined from product sales forecasts and from organizational goals and objectives developed from the annual business plan and budget.

6.2 Human Resources

6.2.1 General

Employees of Lion Precision are competent on the basis of one or more or a combination of education, training, skills, and experience.

Specific requirements for each employee are defined in the appropriate document (i.e. job description, job opening ad, etc.)

6.2.2 Competence, Awareness, and Training

The Training Procedure describes the methods for identifying skills, experience, training, and education needs and methods for tracking training and education activities for all employees.

Employee competency requirements are documented in Lion Precision's job descriptions. Job descriptions are updated, stored, and maintained for all employees. Training is required to ensure competency in the areas listed in the job descriptions. Human Resources is responsible for the maintenance of job descriptions and training records. Job descriptions are stored electronically. Training records for all employees are maintained on training spreadsheets.

Employee skills, education, training, and experience are matched to the job to be performed. At a minimum, training needs are reviewed on an annual basis by the supervisor. This review process occurs during the employee annual review.

Job descriptions are updated by the employee and supervisor as needed and submitted to Human Resources. If it is determined that an employee needs additional skills to perform a task, the supervisor and others as appropriate will assist the employee in obtaining the proper training or development. Training records are updated upon completion of training activities.

6.3 Infrastructure

Lion Precision provides state of the art equipment, in an excellent facility, to ensure an environment where trained employees are motivated to produce quality products. Preventive maintenance is performed where necessary on production equipment. Electro-static discharge protection is incorporated throughout the production environment via ESD floors, wrist/ankle straps, etc.

Building equipment such as air conditioners and furnaces are maintained by the Manager of Operations. The Manager of Operations is also responsible for coordinating building repairs (electricity, structural, etc.).

6.4 Work environment

Each employee has the responsibility to ensure the work environment is suitable to maintain and improve the quality system. Every employee is encouraged to suggest changes and improvements to the quality system, product lines, or any other area affecting their job.

Safety is important to Lion Precision, and where required, OSHA standards are followed.

Environmental factors, such as humidity, temperature, noise, etc., are controlled based on needs through each department or building area. No documented standards or requirements are recorded.

7 Product Realization

7.1 Planning of product realization

The major processes of Lion Precision are identified in QM-APP4 – Process Map. The Process Map identifies the sequence of processes required to build product, though not all processes may be required for each product development and are documented as needed. The quality plan followed consists of the procedures identified in this quality manual and the associated work instructions.

The quality plan consisting of Lion Precision's procedures and work instructions ensure requirements of customers and of the ISO 9001:2008 standard are met.

All employees may suggest recommendations for obtaining new equipment to ensure product quality.

Lion Precision's quality system is a 'living' system and is updated as needed. Management reviews and audits ensure ongoing suitability and effectiveness of the quality system. Each employee also has a responsibility to ensure the quality system is implemented effectively through the audit process, corrective and preventive actions, control of nonconforming product, and management reviews.

Documentation Control ensures documentation is compatible with all processes and functions within Lion Precision. Work instructions and test procedures identify standards of product acceptability. These standards may include, but are not limited to drawings, schematics, test procedures, bills of materials, and assembly instructions. Documentation of product realization is specified within Documentation Control.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

The customer order process follows the Contract Review process.

Requirements are reviewed prior to acceptance of the order. Customer requirements may be in the form of request for quote, purchase order, or verbal order.

For customer driven designs (i.e. a design for a particular customer), input requirements are captured during the initial contract review process. The design process begins upon customer, sales, and engineering review and acceptance of the product requirements. Any time it is determined requirements cannot be met, or there are incomplete, ambiguous, or conflicting requirements, sales will be notified. It will be sales' responsibility to resolve all conflicts and other issues with the customer.

Requirements not specifically stated by the customer but Lion Precision is aware of (i.e. ESD procedures, etc) is included in Lion Precision's process, including statutory and regulatory requirements considered during the design stage of the product.

Verbal customer orders follow the same procedures as orders placed via mail, fax, email, etc.

7.2.2 Review of Requirements Related to the Product

At Lion Precision, Contract Review refers to quotations provided to customers by Lion Precision personnel, and to purchase orders or contracts for goods and services from customers.

Contract Review is performed to ensure the customer's needs are fully understood and met before order fulfillment. This includes:
Documenting and reviewing requirements with customers
Creating and reviewing of customer quotations
Reviewing of customer orders by the sales department before releasing to manufacturing
Agreement regarding contract terms and product requirements between the customer and Lion Precision before product is shipped
Communicating to all employees involved in product fulfillment to ensure customer requirements are understood.

Quotations for customers and incoming customer orders are reviewed to ensure customer requirements are fully identified and Lion Precision is capable of meeting the requirements. The following items are reviewed as necessary: technical requirements, delivery dates, export documentation requirements, special packaging requirements, shipping method, shipping payment terms, and invoice payment terms.

Any requirements that are different from the quotation or order are resolved before a product is shipped.

Changes to an order are reviewed with the customer to ensure agreed upon requirements have been established before shipment of product. This also includes processes and procedures for communicating changes to all employees involved in the development and delivery of products. This applies to all activities from sales to engineering, manufacturing, test, handling, and shipping.

Lion Precision stores and maintains records of customer quotations in the information system and records of contract review in the customer sales order file. Part numbers of products used to fulfill customer orders are recorded in the customer sales order file. Revision levels will be recorded on the sales order upon customer's request. Records are maintained according to the Control of Records procedure.

7.2.3 Customer Communication

Customer communication is very important to the success of Lion Precision. We maintain open communication with our customers through our website, email, newsletters, etc.

Customers are encouraged to call, email, fax, or write us with any questions or comments they have with our products.

Customer complaints are handled through the corrective action system as described in the Corrective/Preventive Action procedure. Customer comments and concerns are discussed in sales meetings as well as management reviews.

7.3 Design and Development

7.3.1 Design and Development Planning

The Design Control process ensures that customer and product requirements are fully understood and communicated to the Engineering Department.

Lion Precision creates plans for product design and development. The plans include tasks and who will be responsible for the tasks. The person responsible for the task will be qualified for the task or they will be trained. Product plans are updated as the design evolves. Planning procedures include, but are not limited to, the following:

- Identify and record design inputs
- Product design outputs
- Plan periodic design reviews
- Evaluate designs for design verification and validation
- Evaluate for product safety and other regulatory requirements

The Design Control procedure and its associated work instructions and forms describe the following:

- Identification of groups involved in the design-input process and their responsibility and authority
- Interfaces between groups
- Cross-functional meetings to review progress, functionality, and coordination

7.3.2 Design and Development Inputs

There are two distinct methods for capturing design requirements. The first is when a design is being developed for a particular customer and the second is when a general product is being developed.

For customer driven designs (i.e. a design for a particular customer), input requirements are captured during the contract review process by obtaining the product definition requirements. These requirements are confirmed with the Engineering Department and are entered into a sales contract. The design process begins upon customer, sales, and engineering review and acceptance of the product requirements. Any time it is determined requirements cannot be met, or there are incomplete, ambiguous, or conflicting requirements, sales will be notified. It will be sales' responsibility to resolve all conflicts and other issues with the customer.

For non-customer driven designs, input requirements are negotiated between sales and engineering, agreed upon, and recorded. Incomplete, ambiguous, or conflicting requirements will be resolved between sales and engineering as events occur during the design process.

Applicable regulatory requirements are considered in the Design Input stage.

7.3.3 Design and Development Outputs

The design process produces documentation that describes the end product. The documentation is created and reviewed by engineering (changes are maintained by Documentation Control). The final design documents must:

- Demonstrate that design-input requirements have been met
- Ensure Design Output documents adequately describe the product so that parts can be purchased and it can be produced
- Include or refer to acceptance criteria as necessary (test/inspection procedures)
- Create product specifications and operating manuals which includes instructions on proper handling and operating directions of product
- Include characteristics to ensure safe and proper use.

A review of the design output documents occurs before product release.

7.3.4 Design and Development Review

Design reviews are conducted by the Engineering Department and any other parties determined by Engineering. Design reviews are documented and maintained as records. Changes resulting from reviews are conducted according to section 7.3.7 Design and Development Changes.

7.3.5 Design and Development Verification

Design verification activities are performed to ensure the design output requirements meet the design input requirements. Engineering shall determine the proper verification methods for all products to use during the review. Design verification measurements are documented and maintained as records.

7.3.6 Design and Development Validation

The customer through prototype or beta type units or other appropriate method performs design validation. Design validation is performed during the design process and before final release of the product. Engineering is to decide if additional testing for product validation is required.

7.3.7 Control of Design and Development Changes

The Engineering Department approves changes to designs. Changes to designs may be made directly on the schematics or drawings if the product is being produced for a one-time use. If the product will have on-going sales, an Engineering Change Order is generated and a new document is created. ECO's ensure all technical data is adequately captured and distributed to the appropriate areas.

7.4 Purchasing

7.4.1 Purchasing process

The Purchasing process ensures purchased products meet agreed upon specifications and requirements. Lion Precision uses the terms 'supplier' and 'vendor' interchangeably.

Lion Precision evaluates and selects suppliers on their ability to meet specifications and requirements. Supplier performance is monitored and recorded to ensure quality. The degree of control exercised over suppliers is determined by the critical quality factors involved in the purchased product. This determination is based on the purchased product significance in meeting customer requirements.

7.4.2 Purchasing Information

Procedures are developed and maintained to ensure all pertinent product information is communicated to a supplier. Engineering is responsible for establishing and maintaining specifications to properly identify product. Purchasing is responsible to provide the supplier with drawings and specifications to ensure conformance to requirements as appropriate. Purchasing has the responsibility for reviewing and approving purchasing documents.

7.4.3 Verification of Purchased Product

When verification of purchased product is performed at the supplier's site, the purchasing documentation will identify the verification methods and the requirements for product release. When stated by contract the customer or a representative may verify product release at Lion Precision or at the supplier's facility. Verification by the customer shall not absolve Lion Precision of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer. The customer maintains the right to product rejection upon final delivery if the product does not perform to contracted specifications and requirements. Additionally, verification of product at a supplier's facility cannot be used by Lion Precision as evidence of an effective control of quality by the supplier – Lion Precision is still responsible for the quality control of the product.

Incoming products are not used until inspected or verified to conformance to specified requirements as documented in the appropriate procedures or documentation. The extent of inspection and test of product is determined by the quality control exercised by the supplier as demonstrated through delivery of conforming and nonconforming product.

Incoming product used in the production process is verified and recorded within the information system. Nonconforming incoming product is identified and segregated to ensure it is not used in production according to documented processes.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

Lion Precision has documented and maintained procedures to ensure product quality throughout the production process.

Manufacturing does production planning with input from sales forecasting, customer orders, engineering requirements, and other material planning activities.

Processes are identified and test procedures are developed by Engineering to ensure product quality. These processes are monitored by manufacturing and improved upon when appropriate.

Lion Precision provides state of the art equipment, in an excellent facility, to ensure an environment where trained employees are motivated to produce quality products. Documented procedures and quality plans support process training.

Lion Precision is able to verify process performance through inspection and testing of product. Highly skilled employees that are specialists in their occupations perform in-process monitoring to support process control.

Processes are documented and maintained for handling, storage, packaging, preservation, and delivery of product.

Lion Precision ensures proper preservation of product after final inspection and test. When a contract specifies, Lion Precision ensures product preservation during delivery to the customer. Lion Precision shipping personnel are trained to package product for shipment without damage.

Lion Precision performs service on equipment it sells on an order-by-order basis. Service and contract review is performed through the repair processes within engineering, sales, and operations as assigned.

7.5.2 Validation of Processes for Production and Service Provision

Processes at Lion Precision can be verified by inspection and testing of product. Processes that cannot be verified by inspection and testing of product are carried out by qualified personnel and requires continuous monitoring of the process to ensure specified requirements are met. These processes may include but are not limited to ESD control, soldering and potting.

Equipment used in such procedures will be defined in work instructions, when necessary. Qualification of personnel is recorded in training records.

Nonconformance's' follow the nonconforming process.

7.5.3 Identification and Traceability

Lion Precision identifies materials and products with part numbers, revision levels (when applicable), serial numbers (when applicable), etc. to prevent the inadvertent use of an incorrect part in a finished product. Documented procedures are established to identify products from receipt at Lion Precision through manufacturing to delivery and acceptance by the customer. When traceability is required, unique coding is used and recorded to track products.

Records are established and maintained to verify all documented inspection and test procedures have been completed and whether the product had passed or failed. Records must include the acceptance criteria for product release. Nonconforming product is handled in accordance with the nonconforming process.

Inspection and test records identify the inspection person responsible for the release of product.

The Inspection and Test Status process describes how Lion Precision identifies the inspection and test status of product throughout the production process. Additionally, practices are documented and maintained to ensure only conforming product is used in the production process.

Identification of inspection and test status includes, but is not limited to, the Work Order Traveler, serial number documentation, tags, labels, routing labels, or location.

7.5.4 Customer property

The Control of Customer Supplied Product process ensures customer supplied product is properly verified, handled, stored, and maintained. Customer supplied product includes tools, gauging, packaging, and product for installation into a product or a product sent in for repair or calibration.

Inadvertent damage to, or loss of, customer-supplied product is immediately recorded and communicated to the customer for resolution.

Verification of customer-supplied product does not absolve the customer from supplying acceptable products. Customer supplied product unsuitable for use is recorded and communicated to the customer for resolution.

7.5.5 Preservation of product

Handling processes are detailed to ensure the proper handling of product throughout the production and delivery process.

Designated areas are used to store product before use or delivery. These areas ensure the product will not be damaged and will not deteriorate. Processes are established for authorizing transportation to and from designated storage areas. Inspection intervals are established to ensure products are reviewed for possible deterioration.

Packaging and labeling processes are controlled to ensure conformance to the specified requirements of the product being shipped.

Lion Precision ensures products are properly stored, segregated, and preserved when under the organization's control. All products with a restricted shelf life are clearly labeled and personnel are trained to scrap material when it is beyond shelf life. The condition of product stored is assessed for damage during cycle counting.

Lion Precision ensures proper preservation of product after final inspection and test. When a contract specifies, Lion Precision ensures product preservation during delivery to the customer. Lion Precision shipping personnel are trained to package product for shipment without damage.

7.6 Control of Monitoring and Measuring Devices

Control of Inspection, Measuring, and Test Equipment documentation ensures measuring and test equipment is controlled, calibrated, and capable of consistently measuring product conformance to specified requirements. Measuring and test equipment includes any software used to measure product conformance to specified requirements.

When using calibrated measurement, inspection, or test equipment the measurement uncertainty of the equipment is known and the equipment is capable of accurately measuring capability to the specified requirements.

Test software and hardware for ensuring product capability are verified before placement into production and rechecked at periodic intervals to ensure control. Records are established to verify control.

When specifically requested, technical data pertaining to measurement, inspection, or test equipment is available to customers or the customer's representative to ensure compliance to functional specifications.

Lion Precision has determined the measurements necessary to ensure the product performs to specified requirements. The accuracy and precision of measurement, inspection, or test equipment are consistent with the required measurement capability.

Equipment requiring calibration is identified and calibrated before release and prescribed intervals for recalibration are established. The scheduled calibration of equipment is normally done so that it is traceable to a recognized standard. If a recognized standard does not exist, Lion Precision will establish a calibration standard. All calibration processes and procedures are documented and maintained.

All identified measurement, inspection, and test equipment has its calibration status visibly indicated. Records of equipment calibration status are stored and maintained.

Corrective action procedures have been established for equipment that does not meet specified requirements. When inspection, measuring, or test equipment is found to be out of calibration, previous inspections and test results are assessed and documented to determine their validity.

Environmental conditions are controlled where necessary to ensure proper conditions for calibration, measurements, and inspections.

Proper handling, preservation, and storage of equipment is maintained to ensure calibration is safeguarded.

Adjustments to measurement, inspection, and test equipment are safeguarded to ensure calibration stability.

8 Measurement, Analysis, and Improvement

8.1 General

Monitoring, Measurement, Analysis, and Improvement activities are implemented at Lion Precision to demonstrate product conformity, quality system effectiveness and conformity, and continually improve the quality system and its products.

Measurement criteria is identified in response to quality objectives and management business decisions. Department supervisors are responsible for measurement and improvement activities within their department. Results from such activities are discussed in management reviews.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction is determined through a number of channels, primarily through the periodic customer survey and direct communication with customers. Feedback on Lion Precision's performance, customer perception, product performance, and market needs is collected.

Information gathered is compiled and discussed in sales meetings and the management review meeting.

8.2.2 Internal Audit

Procedures are documented and maintained for planning and implementing internal audits. Audits are conducted a minimum of once per year on each clause and scheduled based on the status and importance of activity to be audited. If criticality of the work being performed deems necessary, audit intervals will be increased. The ISO Coordinator, and/or Management Representative have authority to adjust audit intervals.

Audits ensure the quality system including processes, procedures, and work instructions, are effective and that quality objectives are being addressed. The audit process includes evaluation of objective evidence to determine the effectiveness of the quality system.

Auditees are the people within a department to be audited. Auditors are persons performing the audit and are independent of the work being performed. A minimum of one auditor on the internal audit team has formal Internal Auditor Training.

Audit results consisting of noted conformances, nonconformances, and opportunities for improvement are recorded and shared with the personnel responsible for the area being audited. The audit team leader initiates corrective actions on audit findings as necessary. The person identified as responsible will resolve corrective actions according to the corrective action procedures. The corrective action activities will verify and record the actions taken and ensure the effectiveness of the corrective action.

8.2.3 Monitoring and Measurement of Processes

All employees are authorized to suggest techniques for the monitoring and measurement of the quality management system processes. Area management is responsible for determining what methods are needed and capable of demonstrating achievement of planned process results. Measurements affecting quality include, but are not limited to accuracy, timeliness, development, and cost reduction.

Department supervisors are responsible for ensuring processes of Lion Precision meet the desired results and that appropriate corrective actions are taken as needed.

8.2.4 Monitoring and Measurement of Product

Lion Precision has documented and maintained processes for ensuring our products meet specified requirements. Inspection and testing activities are detailed in procedures, work instructions, and/or design plans.

Incoming products are not used until inspected or verified to conformance to specified requirements as documented in the appropriate procedures or documentation. The extent of inspection and test of product is determined by the quality control exercised by the supplier as demonstrated through delivery of conforming and nonconforming product.

Procedures are documented and maintained for in-process inspection and testing. Procedures or work instructions detail the process points where inspection and testing will occur. Product will not be released to the next step until documented in-process inspection and test requirements have been met.

Finished products complete final inspection and testing according to documented procedures, work instructions, or quality plan to ensure specified requirements are met.

Products that fail any inspection or test are removed from the process, identified and segregated according to the nonconforming product process.

Records are established and maintained to verify all documented inspection and test procedures have been completed and whether the product has passed or failed. Records must include the acceptance criteria for product release.

Inspection and test records identify the inspection person responsible for the release of the product.

8.3 Control of Nonconforming Product

The Control of Nonconforming Product process ensures nonconforming product is not used in the production process or delivered to customers. The nonconforming product is segregated and dispositioned according to documented procedures. Nonconforming product identified in final inspection and test is segregated until the problem is properly resolved and the product meets specified requirements. Documented procedures provide decision criteria on communication about nonconformance and who is to be notified.

Each employee is responsible for identifying and initiating the nonconforming process for nonconforming parts. The Manager of Operations and Inventory Control are responsible for ensuring nonconforming product is handled according to the nonconforming product procedure, identifying trends, monitoring effectiveness of the nonconforming procedures, and disposition of product.

Procedures are documented and maintained describing the responsibility for review and authority for the disposition of nonconforming product.

Nonconformances are documented and logged in the Nonconforming Product Notice (NPN) database.

Nonconforming product may be reworked, retested, rejected, scrapped, or accepted with or without repair (Use As Is).

Any nonconformance to specified requirements in a contract is reported to the customer. The customer has the final decision in accepting the product. Should the customer accept the nonconforming product, the product is identified as such and records are established to document the actual condition.

Any product that requires rework is tested and/or inspected according to documented procedures before it is released.

8.4 Analysis of Data

Data collected is analyzed and actions are taken as appropriate to ensure the effectiveness of Lion Precision's quality system and to determine where continual improvement can be made. Examples of analysis include, but are not limited to, shipping performance, product performance, supplier performance, customer feedback, audits, and control of nonconforming product.

Department supervisors are responsible for the analysis of data for their department. The ISO Coordinator is responsible for the analysis of data for the quality system. This data is reviewed at scheduled intervals by management and records are kept.

Lion Precision manufactures parts in small quantities with 100% of product tested for those requiring product calibrations. Because of this, statistical control of product is not universally conducted. However, there are times when products are monitored and the data analyzed. These analyses are performed by department supervisors and are reviewed by management.

8.5 Improvement

8.5.1 Continual Improvement

Continual improvement is incorporated into the quality system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective actions, preventive actions, and management reviews.

Actions taken toward continual improvement are discussed in management review and recorded in the minutes. Changes made to the system are documented as appropriate. Continuous improvement is observed through examination of measurements done in association with quality objectives.

8.5.2 Corrective Action

The Corrective Action procedure describes the corrective feedback mechanism at Lion Precision. The degree of investigation into identified problems is directly related to the magnitude of the situation and the potential of the problem surfacing at the customer's site.

All employees are responsible for ensuring quality; including initiating corrective action requests or implementing corrective actions. The ISO Coordinator is responsible for monitoring and ensuring corrective actions are closed in a timely manner. Department supervisors are responsible for initiating activities to implement the corrective action, as well as determine the root cause. The Management Representative is responsible for approving the corrective actions to verify closure.

Corrective action procedures include the following actions:
The capturing and proper handling of designated customer complaints and nonconformities.
Root cause analysis and recording of nonconformities in process, product, or any aspect of the quality system.
Determination of the process for the actions required to eliminate the cause of nonconformities.
Control(s) to ensure that corrective action has taken place and is effective.

8.5.3 Preventive Action

The Preventive Action procedure describes the preventive action feedback mechanism at Lion Precision. The degree of investigation into potential problems is directly related to the magnitude of the situation and the potential of the problem surfacing at the customer's site.

All employees are responsible for ensuring quality; including initiating preventive action requests or implementing preventive actions. The ISO Coordinator is responsible for monitoring and ensuring preventive actions are closed in a timely manner. Department supervisors are responsible for initiating activities to implement the preventive action. The Management Representative is responsible for approving the preventive actions to verify closure.

Procedures are documented and maintained for preventive action. Preventive action procedures include the following activities:

- Determination of the problem-solving process for preventive action.
- Implementation of a problem-solving process with metrics for measuring the program's effectiveness as appropriate.
- Actions taken based on the results of preventive actions are reviewed to ensure the preventive action taken is in place and effective.
- Data collection from: Processes
  Work Operations
  Audit Results
  Quality Records
  Service Reports
  Customer Correspondence

SUPPORTING DOCUMENTATION:

Document Reference	Document Title
QM-APP1	Lion Precision Organization Chart
QM-APP4	Lion Precision Process Map