Quality Manual

This document is the Quality Manual that describes the Quality Management System implemented at LAZER-TECH Limited. This Quality Management System conforms to the requirements of the ISO 9001:2008 Quality Standard.

This document was issued, and is controlled by:

Quality Manager: _____ Date:_____

This document was approved by:

Quality Manager:_____ Date:_____

President:_____ Date:_____

Control Number __Uncontrolled Copy __

For a complete revision history, refer to the master copy stored in the Quality Assurance master file.

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1 Scope

This Quality Manual applies to all areas of Lazer-Tech Limited and all personnel at all levels within Lazer-Tech Limited that could have an effect on the quality of the product.

1.1 General

This Quality Manual:

- Provides an overview of the Quality Management System.
- Applies to all processes that could impact on the products we provide to our customers.
- Demonstrates that we have the ability to consistently provide product and services that meet customer and applicable regulatory requirements
- Aims to enhance customer satisfaction through the effective application of our Quality Management System, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.
- Describes a **Process Approach** where a number of linked activities are managed so that resources are used to transform inputs into outputs and where the outputs from some processes may be the inputs to other processes. We define this *process approach* as the application of a system of processes within our organization, together with the identification and interactions of these processes, and their management to produce the desired outcome.

This *process approach* emphasizes the importance of:

1. Understanding and meeting all requirements.
2. Considering processes in terms of added value.
3. Obtaining results of process performance and effectiveness.
4. Continually improving processes based on objective measurement.
5. Including customer current and future needs in the decision making process

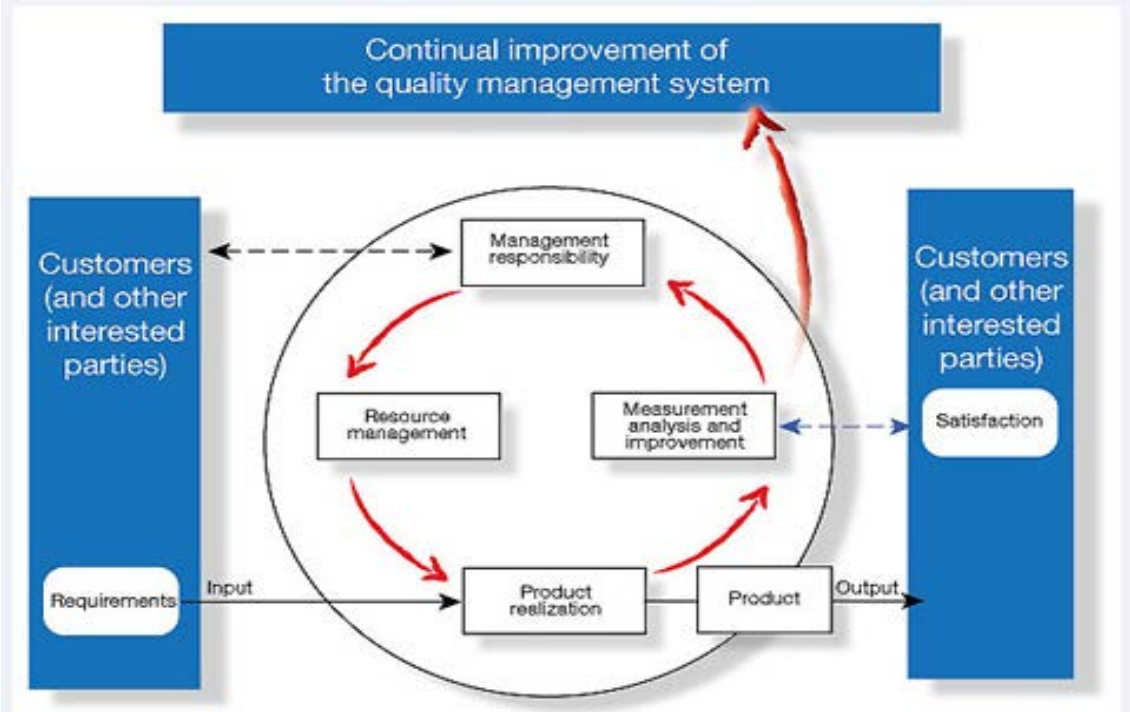
We employ the Plan-Do-Check-Act (PDCA) approach to process improvement. This approach includes:

Plan Establish the objectives and processes necessary to deliver results in accordance with customer requirements and our policies.

Do Implement the processes.

Check Monitor and measure our processes and products against policies, objectives, and requirements for the product and report the results.

Act Take actions to continually improve process performance.



Model of a process-based quality management system

For information about how our processes are linked, refer to the Travelers that define the process sequence for a particular product and to *Process flow charts* (QA-124).

Note 1: As per ISO 9001:2008 the term “product” only applies to

a) Product intended for or required by a customer

b) Any intended output resulting from the product realization processes.

Note 2: Statutory and regulatory requirements can be expressed as legal requirements.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Listed below are the elements not applicable to Lazer-Tech Limited. These exclusions do not affect our ability or responsibility to provide the level of service that meets or exceeds customer requirements and applicable statutory and regulatory requirements.

ISO Element	Exclusion	Justification
7.3 Design and development	Design and Development	Lazer-Tech Limited has no responsibility for the design/development of customer's product or product flow. This element is the customer's responsibility. Lazer-Tech Limited has various service offerings available for the customer's selection and approval.
7.5.1 and 7.5.2	Service portions	We supply PCBs for use in electronic assembly, not finished products requiring a service component.

2 Normative References

The following referenced documents are indispensable for the application of this document.

ISO 9001:2008 International Quality System

ISO 9000:2005 Quality management systems- Fundamentals and vocabulary

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply.

4 Quality Management System

4.1 General Requirements

LAZER-TECH Limited has established, documented, implemented, and maintains a Quality Management System and continually improves its effectiveness in accordance with the requirements of ISO 9001:2008.

LAZER-TECH Limited has:

a) Determined the processes needed for the Quality Management System and their application throughout our organization. These processes include processes for management activities, provision of resources, product realization, and measurement. Refer to *index to procedures* (QA-002) for a list of all procedures and forms.

b) Determined the sequence and interaction of these processes. Refer to the flow sheet for the sequence and interaction of all processes related to a specific product and to *Process flow charts* (QA-124) for flow charts that show the interaction of processes.

c) Determined criteria and methods needed to ensure that both the operation and control of these processes are effective. Refer to the individual process documents or flow charts for the criteria and methods for a particular process.

d) Ensured the availability of resources and the information necessary to support the operation and monitoring of these processes through our planning process, the Human Resources department, and our training procedures. For more information about our planning process, refer to *Quality Plan* (QA-125).

e) Monitored, measured where applicable, and analyzed these processes. Refer to the Quality Manager for records of our monitoring, measuring, and analyzing activities.

f) Implemented actions necessary to achieve planned results and continual improvement of these processes. These actions include, but are not limited to, regularly scheduled Management Review meetings as described in *Management Review* (QA-111), handling and disposition of nonconforming product as described in *Control of Nonconforming Material* (QA-105) and taking corrective and preventive actions as described in *Corrective and Preventive Action process* (QA-113).

These processes are managed in accordance with the requirements in the ISO 9001:2008 standard.

Where we have outsourced (subcontracted) any processes that could affect product conformity to requirements, we identify and control these processes. The type and extent of control applied to these outsourced processes is defined. The methods for the defining and controlling outsourced processes are described in *Selecting, evaluating, and monitoring subcontractors* (QC-119). For a list of our approved suppliers, refer to *Approved vendors list* (QC-112)

Note 1: These processes needed for the Quality Management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis, and improvement. Refer to *index to procedures* (QA-002) for a list of all processes.

Note 2: An “outsourced process” is a process that Lazer-Tech Limited needs for its Quality Management System and which we choose to have performed by an external party.

Note 3: Ensuring control over outsourced processes does not absolve Lazer-Tech Limited of the responsibility of conformity to all customer, statutory, and regulatory requirements. The type and extent of control to be applied to the outsourced processes can be influenced by factors such as:

a) The potential impact of the outsourced process on our ability to provide product that conforms to requirements

b) The degree to which the control for the process is shared

c) The capability of achieving the necessary control through the application of good purchasing practices. (See *7.4 Purchasing* on page 19.)

4.2 Documentation Requirements

4.2.1 General

Our Quality Management System documentation includes:

a) Documented statements of quality policy and quality objectives. Refer to Policy on page 12 (*see Quality policy 5.3*) for this information.

b) A Quality Manual

c) Documented procedures as required by ISO 9001:2008. Refer to *index to procedures* (QA-002) for a list of all documented procedures and related forms.

d) Documents, including records, determined by Lazer-Tech Limited to be necessary to ensure the effective planning, operation, and control of our processes. Refer to *index to procedures* (QA-002) for a list of these processes and their related documents and forms.

Note 1: All documented procedures are established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

Note 2: The documentation may be in any form or type of medium that is suitable for the applicable activity.

Refer to *Control of Documents* (QA-101) for more information.

4.2.2 Quality Manual

Our Quality Manual includes:

a) The scope of the Quality Management System. See Scope 1 on page 5.

b) References to the documented procedures established for the quality system, referenced throughout this manual and summarized in

c) *11 Associated* Documents on page 28.

d) A description of the interactions between the processes and the Quality Management System, which are further described in each procedure.

4.2.3 Control of Documents

We control all documents required by the Quality Management System. Records are a special type of document and are controlled according to the description in *4.2.4 Control* of Records on page 11.

A documented procedure (C*ontrol of Documents*, QA-101) describes the controls needed to:

a) Approve documents for adequacy prior to issue or use

b) Review and update, as necessary, and re-approve documents

c) Ensure that changes and the current revision status of documents are identified

d) Ensure that relevant versions of applicable documents are available at points of use

e) Ensure the documents remain legible and readily identifiable

f) Ensure that documents of external origin that we have determined to be necessary for the planning and operation of our Quality Management System are identified and their distribution controlled

g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

For more information about how we control documents, refer to: *Control of Documents* (QA-101).

4.2.4 Control of Records

Records established to provide evidence of conformity to requirements and of the effective operation of the Quality Management System are controlled.

We establish and maintain records to provide evidence of conformity to requirements and of the effective operation of the Quality Management System.

Records remain legible, readily identifiable and easily retrievable.

A documented procedure, *Control of Records* (QA-115) describes how we control the identification, storage, protection, retrieval, retention time, and disposition of records.

5. Management Responsibility

5.1 Management Commitment

Top management (see 5.5.1 Responsibility and Authority on page 14 for the definition of Top Management) provides evidence of its commitment to the development and implementation of the Quality Management System and continually improving its effectiveness by:

a) Communicating to the organization the importance of meeting customer, as well as statutory and regulatory, requirements.

b) Establishing the Quality Policy

c) Ensuring that Quality Objectives are established

d) Conducting Management Reviews

e) Ensuring the availability of resources.

5.2 Customer Focus

Top Management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction. Refer to section *7.2 Customer-Related* Processes on page 17 and *8.2.1* Customer Satisfaction on page 24 for more information.

5.3 Quality Policy

LAZER-TECH Limited is dedicated to producing high quality printed circuit boards that will meet or exceed customer requirements and to continually improve the effectiveness of the Quality Management System.

Top Management ensures that the quality policy:

a) Is appropriate to the purpose of our organization

b) Includes a commitment to comply with requirements and continually improve the effectiveness of the Quality Management System

c) Provides a framework for establishing and reviewing quality objectives

d) Is communicated and understood within the organization

e) Is reviewed for continuing suitability at the Management Review meetings.

5.4 Planning

5.4.1 Quality Objectives

Top Management ensures that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. These quality objectives are measurable and consistent with the quality policy.

LAZER-TECH Limited's quality objectives are consistent with our Quality Policy and our commitment to continual improvement. Our objectives are measurable. Our fundamental quality objectives include:

a. Complete customer satisfaction.

b. Continual improvement.

c. Continued employee satisfaction.

For a more detailed description of our current measurable Quality Objectives and our status at meeting these objectives, refer to the minutes of our Quality Management Review meetings.

5.4.2 Quality Management System Planning

Top management ensures that:

a) The planning of the quality management system is carried out in order to meet the requirements described in *4.1 General* Requirements on page 8 as well as the quality objectives.

b) The integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Top management ensures that responsibilities and authorities are defined and communicated within the organization.

Top management at LAZER-TECH Limited is committed to the development and implementation of the Quality Management System and continually improving its effectiveness. *Top Management* at LAZER-TECH Limited consists of the President, Research and Technology Manager, Quality Manager and Engineering Manager.

Refer to the Quality Manager for the current organization chart.

The Quality Manager is responsible for coordinating the implementation, monitoring, and continual improvement the Quality Management System and the related processes. The Quality Manager reports directly to the President.

The Engineering Manager is responsible for analysing unique customer requirements and come up with manufacturing solutions to meet their requirements and work with the Engineering Department, management, production and quality staff to resolve any engineering issues with customers.

The Research and Technology Manager is responsible for the status of SR & ED projects and for investigating and implementing new processes and equipment.

The President is responsible for production, all supervisors, sales team and contracts for consultants and to define and implement a strategy that assures the success of the company by delegating management responsibilities to an appropriate management staff.

All Managers and Supervisors are responsible for ensuring that personnel that report to them are aware of the requirements of the Quality Management System and comply with these requirements.

All personnel are responsible for complying with all aspects of the Quality System, and for suggesting and implementing improvements to the Quality System in accordance with the methods described in this Quality Manual.

Refer to *Job Descriptions* (AD-010) and the Human Resources department for more information.

5.5.2 Management Representative

Top Management has appointed a member of Lazer-Tech's management who, irrespective of other responsibilities, has responsibility and authority that includes:

a) Ensuring that processes needed for the Quality Management System are established, implemented, and maintained.

b) Reporting to top management on the performance of the Quality Management System and any need for improvement

c) Ensuring the promotion of awareness of customer requirements throughout the organization.

Note: The responsibility of a management representative includes liaison with external parties on matters relating to the Quality Management System.

The member of the management team appointed as the Management Representative is:

Quality Manager 416-291-7727 EXT: 227

5.5.3 Internal Communications

Top Management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the Quality Management System. Due to the size of our organization, most communication is verbal, by e-mail, daily production/quality meetings, and by ad hoc meetings as required. The effectiveness of the Quality Management System is discussed at the regularly scheduled Management Review meetings.

5.6 Management Review

5.6.1 General

Top Management reviews our Quality Management System at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System, including the quality policy and quality objectives.

The Quality Manager maintains records of Management Reviews.

5.6.2 Review input

The input to Management Review includes information about:

- **a)** Results of audits
- **b)** Customer feedback
- **c)** Process performance and product conformity
- **d)** Status of preventive and corrective actions
- **e)** Follow up actions from previous management review meeting
- **f)** Changes that could affect the quality management system
- **g)** Recommendations for improvement
- **h)** Health and Safety

5.6.3 Review Output

The output from the Management Review includes any decisions and actions relating to:

- **a)** Improvement of the effectiveness of the Quality Management System and its processes
- **b)** Improvement of product related to customer requirements

c) Resource needs.

6 Resource Management

6.1 Provision of Resources

LAZER-TECH Limited determines and provides the resources needed to:

a) Implement and maintain the Quality Management System and continually improve its effectiveness

b) Enhance customer satisfaction by meeting customer requirements

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements are competent based on appropriate education, training, skills and experience. The area supervisor, in consultation and agreement with the Quality Manager, and the President defines the level of education, training, skills, and experience necessary for the work to be performed.

Note: Lazer-Tech Limited takes into account that conformity to product requirements can be affected directly or indirectly by personnel performing any task within the Quality Management System.

6.2.2 Competence, Training, and Awareness

LAZER-TECH Limited:

a) Determines the necessary competence for personnel performing work affecting conformance to product requirements (as described 6.2.1 above).

b) Where applicable, provides training or takes other actions to achieve the necessary competence.

c) Evaluates the effectiveness of the actions taken.

d) Ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives.

e) Maintains appropriate records of education, training, skills, and experience.

Refer to *Employee training* QA-117 for more information about our training program and our employee records for evidence of competence and awareness of personnel.

6.3 Infrastructure

LAZER-TECH Limited determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes:

a) Buildings, workspace, and associated utilities. Refer to the Quality Manager for a floor plan showing the location of equipment using their unique identification.

b) Process equipment (both hardware and software)

c) Supporting services (such as transport, communication, and information systems).

Top Management, along with the Area Supervisors, and other personnel as applicable, determine, provide, and maintain the infrastructure.

6.4 Work Environment

LAZER-TECH Limited determines and manages the work environment needed to achieve conformity to product requirements.

The Top Management, along with the Engineering, Process Engineering, Quality and Production Supervisors, Human Resources, and other personnel as applicable determine and manage the work environment.

Note: At Lazer-Tech Limited the term “work environment” relates to those conditions under which work is performed including physical, environmental, and other factors (such as noise, temperature, humidity, lighting, or weather).

7 Product Realization

7.1 Planning of Product Realization

LAZER-TECH Limited plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the Quality Management System.

In planning product realization, LAZER-TECH Limited determines the following as appropriate:

a) Quality **objectives** and **requirements** for the product based on the requirements from the customer

b) The need to establish **processes** and **documents**, and provide **resources** specific to the product. These are documented on the Engineering sheet and engineering records.

c) Required **verification**, **validation**, **monitoring**, **measuring**, **inspection**, and **test** activities specific to the product and the **criteria for product acceptance.** These are documented on the traveler.

d) **Records** needed to provide evidence that the realization processes and resulting product meet requirements. These records are the completed Flow-sheets signed and dated by the operators at each stage of the realization process.

The output from the planning is in a form suitable for our methods of operation. For product, this output is the traveler that lists the sequence of processes, inspections, and tests required to make the product.

Note 1: A document specifying the processes of the quality management system in this manual (including the product realization processes, see Lazer-Tech Limited Operations flowchart Appendix B) is referred to as our quality plan for that product.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

LAZER-TECH Limited determines:

a) Requirements specified by the customer, including the requirements for delivery. (Normally we are not involved in post-delivery activities.)

b) Requirements not stated by the customer but necessary for specified or intended use, where known (such as IPC standards for circuit boards).

c) Statutory and regulatory requirements applicable to the product and process.

d) Any additional requirements considered as necessary by our organization.

Note: Lazer-Tech Limited is not involved in post-delivery activities, for example actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 Review of Requirements Related to the Product

LAZER-TECH Limited reviews the requirements related to the product. This review is conducted before we commit to supply product to the customer (that is, before submission of tenders, acceptance of contracts or orders, or acceptance of changes to contracts or orders) and ensures that:

a) Product requirements are defined

b) Contract or order requirements differing from those previously expressed are resolved

c) We have the ability to meet the defined requirements

Records of the results of the review and actions arising from the review are maintained by Quality Manager and are kept in Quality Office.

Where the customer provides no documented statement of requirements, we confirm the customer requirements with the customer (normally by telephone call or e-mail) before acceptance of the order, and maintain a record of this confirmation.

Where product requirements are changed, we ensure that the relevant documents are amended and the relevant personnel are made aware of the changed requirements.

For more information, refer to *Contract Review* QA-103 and *Engineering* QC-100.

7.2.3 Customer Communication

LAZER-TECH Limited has determined and implemented effective arrangements for communicating with customers in relation to:

a) Product information

b) Enquiries, contracts, or order handling, including amendments

c) Customer feedback, including customer complaints.

Normal communications with the Customer may be directly through Sales for pricing, order status, customer satisfaction, or (with the agreement and awareness of Sales) through Engineering for technical issues or through the Quality Manager for quality-related issues. Communication may be by telephone, fax, or e-mail depending on the nature of the communication. Records of relevant communications are maintained.

7.3 Design and Development

LAZER-TECH Limited is not involved in the design or development of products. We make printed circuit boards based on the design provided by our customers and to their specifications and requirements. Therefore we do not have a Design and Development process.

7.4 Purchasing

7.4.1 Purchasing Process

LAZER-TECH Limited ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

LAZER-TECH Limited evaluates and selects suppliers based on their ability to supply product in accordance with our requirements. Criteria for selection, evaluation, and re-evaluation have been established. Records of the results of evaluations and any necessary actions arising from the evaluations are maintained.

For more information about our Purchasing process, refer to *Purchasing procedure* (QA-104). For information about how we select suppliers, refer to *Selecting, evaluating, and monitoring subcontractors* (QC-119). For a list of our approved suppliers, refer to *Approved Suppliers list* (QC-112).

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate:

- **a)** Requirements for approval of product, procedures, processes and equipment
- **b)** Requirements for qualification of personnel
- **c)** Quality Management System requirements

LAZER-TECH Limited ensures the adequacy of specified purchase requirements before communicating them to the supplier. For more information, refer to *Purchasing procedure* (QA-104).

7.4.3 Verification of Purchased Product

LAZER-TECH Limited has established and implemented the inspection and other activities necessary for ensuring that purchased product meets the specified purchase requirements. For more information, refer to *Inspection and test procedure* (QA-108) and *Receiving inspection* (IN-112).

Where we, or our customers, intend to perform verification at the supplier's premises, LAZER-TECH Limited states the intended verification arrangements and method of product release in the purchasing information. For more information, refer to *Purchasing procedure* (QA-104).

7.5 Production and Service Provision

Note: LAZER-TECH Limited does not do service. For that reason, reference to service provision is not included in this section.

7.5.1 Control of Production

LAZER-TECH Limited plans and carries out production under controlled conditions. *Controlled conditions* include (as applicable):

- **a)** The availability of information that describes the characteristics of the product
- **b)** The availability of work instructions, as necessary
- **c)** The use of suitable equipment
- **d)** The availability and use of monitoring and measuring equipment
- **e)** The implementation of monitoring and measurement
- **f)** The implementation of product release, delivery, and post-delivery activities.

The President, or designate, in consultation with Engineering and Quality defines the production sequence for any product and prints out a traveler that shows a sequential list of all process steps required for that product. The flow-sheet provides evidence (by operator signature and date) that the product has been processed through each step.

For more information, refer to *Process control* (QA-107) and *Production control* (QA-121).

7.5.2 Validation of Processes for Production Provision

LAZER-TECH Limited validates any production processes where the resulting output cannot be verified by subsequent monitoring or measurement, and as a consequence, deficiencies become apparent only after the product is in use.

Validation demonstrates the ability of these processes to achieve the planned results.

LAZER-TECH Limited has established arrangements for these processes including as applicable:

a) Defined criteria for review and approval of the process

b) Approval of equipment and qualification of personnel

c) Use of specific methods and procedures

d) Requirements for records (**see 4.2.4**)

e) Revalidation

For more information refer to *Installing new process equipment and developing preventive maintenance plan* (QA-123).

7.5.3 Identification and Traceability

Where appropriate, LAZER-TECH Limited identifies the product by suitable means throughout product realization.

LAZER-TECH Limited identifies the product status with respect to monitoring and measurement requirements throughout product realization through entries on the Flow-sheet.

Where traceability is a requirement, we control and record the unique identification of the product and maintain records **(see 4.2.4).**

Note: Configuration management includes a unique “job number” for each product that identifies the customer, part number, engineering level, and release level”.

For more information, refer to *Product identification and traceability* (QA-106)

7.5.4 Customer Property

LAZER-TECH Limited exercises care with customer property while it is under our control or is being used by our organization. We identify, verify, protect, and safeguard customer property provided for use or incorporation into the product (including intellectual property). If any customer property is lost, damaged, or

otherwise found to be unsuitable for use, this information is reported to the customer and records are maintained **(see 4.2.4).**

Note: “Customer property” can include intellectual property and personal data.

For more information, refer to *Controlling customer-supplied material* (QA-102).

7.5.5 Preservation of Product

LAZER-TECH Limited preserves the conformity of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. This preservation includes: identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of the product.

For more information, refer to *Handling, storage, packaging, preservation, and delivery* (QA-119).

7.6 Control of Monitoring and Measuring Equipment

LAZER-TECH Limited determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

LAZER-TECH Limited has established processes to ensure that monitoring and measurement can be carried out, and are carried out, in a manner that is consistent with the monitoring and measuring requirements.

Where necessary to ensure valid results, measuring equipment is:

a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification is recorded as part of the calibration record. **Note: See section 4.2.4.**

b) Adjusted or re-adjusted as necessary

c) Have identification (usually with a stick-on label) in order to determine its calibration status.

d) Safeguarded from adjustments that would invalidate the measurement result

e) Protected from damage and deterioration during handling, maintenance, and storage.

LAZER-TECH Limited assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. LAZER-TECH Limited takes the appropriate action on the equipment and any product affected.

Records of the results of calibration and verification are maintained.

When used in the monitoring and measurement of specified requirements (such as for electrical test and automated optical inspection (AOI)), the ability of computer software to satisfy the intended application is confirmed. This confirmation is undertaken prior to the initial use and reconfirmed as necessary.

Note: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

For more information, refer to *Maintaining inspection, measuring, and test equipment* (QA-109).

8 Measurement, Analysis, and Improvement

8.1 General

LAZER-TECH Limited plans and implements the monitoring, measurement, analysis, and improvement processes needed to:

a) Demonstrate conformity to product requirements

b) Ensure conformity of the Quality Management System

c) Continually improve the effectiveness of the Quality Management System

These processes include the determination of applicable methods, including statistical techniques, and the extent of their use. For more information, refer to *Quality Plan* (QA-125).

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of our Quality Management System, LAZER-TECH Limited monitors information relating to customer perception as to whether we have met customer requirements. The methods for obtaining and using this information are determined and then reviewed on a periodic basis.

Note: Monitoring customer perception includes obtaining input from sources such as Customer satisfaction surveys (Survey Monkey http://www.surveymonkey.com/s/YCQL93Q), customer data on delivered product quality, user opinion surveys, lost business analysis, customer compliments, warranty claims and dealer reports.

Refer to the minutes from Management Review meetings for information about our current methods of measuring customer satisfaction and current satisfaction levels.

8.2.2 Internal Audit

LAZER-TECH Limited conducts internal audits at planned intervals to determine whether the Quality Management System:

a) Conforms to the planned arrangements, to the requirements of ISO 9001:2008, and to the Quality Management System requirements that we have established

b) Is effectively implemented and maintained

Our audit programme is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and reporting results, and maintaining records, are defined in a documented procedure. See *Internal Quality Audits* (QA-116).

Records of Audits and their results are maintained by Quality Manager and kept in Quality Office filing cabinet in a binder.

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue time delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Note: Refer to ISO 19011 for further guidance.

8.2.3 Monitoring and Measurement of Processes

LAZER-TECH Limited applies suitable methods for monitoring and, where applicable, measurement of the Quality Management System processes. These methods demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, correction and corrective action is taken, as appropriate.

Note: When determining suitable methods, Lazer-Tech considers the type and extent of monitoring and measurement appropriate to each of its processes in relation to their impact on the conformity of product requirements and on the effectiveness of the quality management system.

For more information about process monitoring and measuring, refer to *Process Control* (QA-107) and *Chemical process monitoring and control* (CAP01). For more information about nonconforming material and corrective action, refer to *Corrective /Preventive Action (QA-113) and Control of Nonconforming Material* (QA-105).

8.2.4 Monitoring and Measurement of Product

LAZER-TECH Limited monitors and measures the characteristics of the product to verify that product requirements have been met. This verification is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained.

Records indicate the persons authorizing release of the product for delivery to the customer. The traveler shows the signature and dates that all processes and inspections are performed, also yield information.

The release of product does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority (either the President or the Quality Manager) and, where applicable, by the customer.

For more information, refer to *Inspection and test procedure* (QA-108).

8.3 Control of Nonconforming Product

LAZER-TECH Limited ensures that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

The controls and related responsibilities and authorities for dealing with nonconforming product are defined in a documented procedure. Refer to *Control of Nonconforming Material* (QA-105) for more information.

Where applicable, Lazer-Tech Limited deals with nonconforming product by one or more of the following ways:

a) Taking action to eliminate the detected nonconformity

b) Authorizing its use, release, or acceptance under concession by a relevant authority either the Quality Manager or the President and, where applicable, by the customer

c) Taking action to preclude its original intended use or application

d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected, it is subjected to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained by the Quality Manager and kept in filing cabinet in Quality Office in a binder **(see 4.2.4).**

8.4 Analysis of Data

LAZER-TECH Limited determines, collects, and analyzes appropriate data to demonstrate the suitability and effectiveness of our Quality Management System and to evaluate where continual improvement of the effectiveness of the Quality Management System can be made. This data includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

a) Customer satisfaction **(see 8.2.1).**

b) Conformity to product requirements **Note: See 8.2.1.**

c) Characteristics and trends of processes and products including opportunities for preventive action **Note: See 8.2.3 and 8.2.4**

d) Suppliers. **Note: See 7.4**

For more information about how we collect, analyze, and report data, refer to *Management review* (QA-111) and *using statistical techniques* (QA-118).

8.5 Improvement

8.5.1 Continual Improvement

LAZER-TECH Limited strives to continually improve the effectiveness of our Quality Management System through the use of our Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive action, and management review.

For evidence of our continual improvement, refer to the minutes from our Management Review meetings available from the Quality Manager.

8.5.2 Corrective Action (8.5.2)

LAZER-TECH Limited takes action to eliminate the causes of nonconformities in order to prevent reoccurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

Refer to *Control of nonconforming material* (QA-105) for information about how we handle and resolve product non-conformances found during production.

Our documented procedure *Corrective and Preventive Action* (QA-113), defines the requirements for:

- **a)** Reviewing nonconformities (including customer complaints)
- **b)** Determining the causes of nonconformities
- **c)** Evaluating the need for actions to ensure that nonconformities do not recur
- **d)** Determining and implementing action needed
- **e)** Recording the results of actions taken **(see 4.2.4)**
- **f)** Reviewing the effectiveness of the corrective actions taken

Refer to *Control of nonconforming material* (QA-105) and *Corrective and Preventive Action* (QA-113) for more information.

8.5.3 Preventive Action

LAZER-TECH Limited determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problem.

Our documented procedure *Corrective and Preventive Action* (QA-113), defines the requirements for:

a) Determining potential nonconformities and their causes

b) Evaluating the need for actions to prevent the occurrence of nonconformities

c) Determining and implementing action needed

d) Recording the results of actions taken **(see 4.2.4)**

e) Reviewing the effectiveness of the preventive actions taken.

Refer to *Corrective and Preventive Action* (QA-113) for more information.

9 Audit

It is the responsibility of the Quality Manager, or designates, to conduct periodic audits at planned intervals to ensure the Quality Management System:

a. Conforms to the planned arrangements, to the requirements of ISO 9001:2008, and to the Quality Management System requirements that we have established for our organization.

b. Is effectively implemented and maintained.

Note: Auditors do not audit their own work

10 Definitions

For definitions of quality terms used in this manual, refer to ISO 9000-2005, *Quality management systems - Fundamentals and vocabulary*.

11 Associated Documents

Procedure Number	Title
QA-002	Index to procedures
QA-003	Workmanship standards
QA-101	Control of documents
QA-102	Controlling customer-supplied material

Procedure Number	Title
QA-103	Contract review
QA-104	Purchasing procedure
QA-105	Control of Non-conforming material
QA-106	Product identification and traceability
QA-107	Process control
QA-108	Inspection and test procedures
QA-109	Maintaining inspection, measuring, and test equipment
QA-111	Management review
QA-113	Corrective/Preventive action
QA-115	Control of records
QA-116	Internal quality audits
QA-117	Employee training
QA-118	Using statistical techniques
QA-119	Handling storage, packaging, preservation, and delivery
QA-121	Production Control
QA-122	Equipment maintenance
QA-123	Installing new process equipment and developing pm plan
QA-124	Process flow charts
QA-125	Quality plan
IN-112	Receiving inspection

Procedure Number	Title
QC-100	Engineering
CAP01	Chemical process monitoring and control
QC-112	Approved vendors list
QC-119	Selecting ,evaluating & monitoring subcontractors
AD-010	Job descriptions

12 Associated Forms

None referenced in this document.

13 Records:

Records shall be retained consistent with the procedure for Control of Records (QA-115).

Revision Date	Description	Sections Affected
Nov. 11/ 10	Updated to remove Quality Managers name. Changed procedure QA-101 title to Control of Documents and changed procedure QA-115 title to Control of Records as per ISO Standard. Change QA-001 to QM-001.	All Sections
Apr.22/11	Updated to merge responsibilities of General Manager to President	Section 5.5.1
Oct.31/11	Added survey monkey to customer satisfaction measurements	Section 8.2.1
Aug.28/15	Re format	All

End of Document

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