

RGBLase LLC

The ISO 9001:2000
Quality Manual

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1 Approval and Revision

1.1 Approval

This Quality Manual has been approved for use throughout RGLase LLC:

Date of Initial Version: February 1, 2007
Name and Title of Approver: WenZhao Zhang (VP of Operation)
Date of Approval: February 5, 2007

1.2 Revision History

The following revisions have been made to this Quality Manual since its initial publication:

Revision Date	List of Changes	Author (Name & Date)	Approval (Name & Date)
01, 02/01/2007	Initial release	John Li	WZ Zhang
02, 04/05/2007	Update Company Mission statement and Quality Policy	John Li	WZ Zhang

2 Company

2.1 Introduction to RGLase LLC

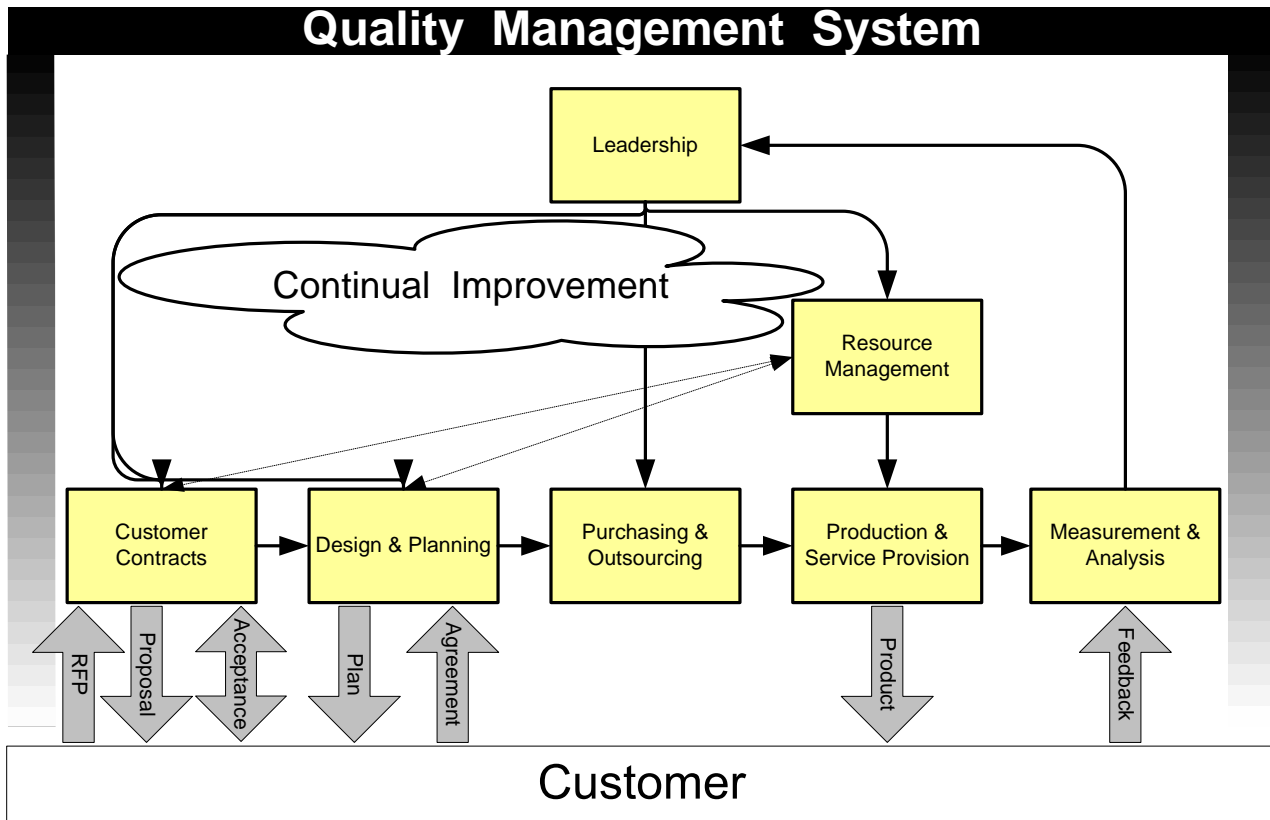
RGLase LLC was founded in September 2005. Our vision is to become the number one supplier for Laser Engine and Photonic Modules for scientific research application, bio-medical instrumentation and printing industry.

2.2 Mission

We dedicate on developing start of art products and providing the best service to our customer through continuous quality improvement and technology innovation.

2.3 Company Processes

We identified the key processes and their interaction at RGLase LLC and we fully integrated them in our ISO 9001:2000 quality management system. The flowchart below illustrates these processes and their interaction.



3 Scope and Exclusions

3.1 Scope

This Quality Manual documents our quality management system, and it demonstrates RGBLase LLC’s pursuit to consistently provide a product that meets customer and regulatory requirements.

This Quality Manual establishes compliance with ISO 9001:2000. It applies to all our business activities including our research and development, production, sales, marketing, installation and servicing activities as covered by this ISO 9001 Quality Manual (any applicable exclusions are listed below).

3.2 Exclusions

The following requirements of ISO 9001:2000 are excluded due to the nature of our company and our products in compliance with Paragraph 1.2 of ISO 9001:2000:

Chapter	Title	Justification for Exclusion
NA		

3.3 References

ISO 9001:2000:

All references to ISO 9001 in this manual refer to the requirements of ISO 9001:2000. Starting with Chapter 4 “Quality Management System”, the numbering system of this Quality Manual directly corresponds to the numbering system of the requirements section of ISO 9001:2000.

Quality Procedures:

We documented certain key processes of our quality management system through more detailed quality procedures as required by ISO 9001:2000. These Quality Procedures are part of our Quality Management System, and they are referenced in this Quality Manual as follows:

- Quality Procedure for Control of Documents (referenced in Chapter 4.2.3)
- Quality Procedure for Control of Records (referenced in Chapter 4.2.4)
- Quality Procedure for Internal Audits (referenced in Chapter 8.2.2)
- Quality Procedure for Control of Nonconforming Product (referenced in Chapter 8.3)
- Quality Procedure for Corrective Action (referenced in Chapter 8.5.2)
- Quality Procedure for Preventive Action (referenced in Chapter 8.5.3)

All Quality Procedures are established, documented, implemented and maintained.

4 Quality Management System

4.1 General Requirements

RGLase LLC has established, documented, and implemented a quality management system that meets the requirements of ISO 9001:2000. RGLase LLC maintains this Quality Management System and continually improves its effectiveness as required by ISO 9001:2000.

- a) Our Quality Management System identifies the processes needed for its operation and their application throughout RGLase LLC. These processes include processes for management activities, provision of resources, product realization and measurement.
- b) Our Quality Management System determines the sequence and the interaction of these processes.
- c) Our Quality Management System determines the criteria and methods needed to ensure that both the operation and control of these processes are effective.
- d) Our Quality Management System ensures the availability of resources and information necessary to support the operation and monitoring of these processes.
- e) Our Quality Management System ensures that these processes are monitored, measured and analyzed by us.
- f) Our Quality Management System ensures that necessary actions are implemented to achieve planned results and continual improvement of these processes.

RGLase LLC manages these processes in accordance with the requirements of ISO 9001:2000.

Where RGLase LLC chooses to outsource any process that affects how our products meet requirements, RGLase LLC ensures control over such processes. Our Quality Management System identifies the control of such outsourced processes (refer to Chapter 7.4).

4.2 Documentation Requirements

4.2.1 General

The documentation of our Quality Management System includes the following documents:

- a) The documented Quality Policy of RGLase LLC and the documented Quality Objectives of RGLase LLC.
- b) This Quality Manual.
- c) The documented Quality Procedures required by ISO 9001:2000 (see Chapter 3.3). All such Quality Procedures are established, documented, implemented and maintained.

- d) All such documents that RGLase LLC needs to ensure the effective planning, operation and control of our processes.
- e) All records that are required by ISO 9001:2000 (see Chapter 4.2.4).

The documentation of our Quality Management System may be of any form or type of medium. The extent of the documentation of our Quality Management System is dependent on the following factors:

- the size of RGLase LLC and the type of our activities,
- the complexity of our processes and their interactions, and
- the competence of our personnel.

4.2.2 Quality Manual

RGLase LLC has established this Quality Manual, which includes the following important sections:

- The scope of our Quality Management System in Chapter 3.1.
- Any exclusion including details and justifications in Chapter 3.2.
- Reference to our documented Quality Procedures in Chapter 3.3.
- A description of the interaction between the processes of our Quality Management System in Chapter 2.3.

The Quality Department is responsible for maintaining the quality manual

4.2.3 Control of Documents

RGLase LLC controls all documents that are required by our Quality Management System. Records are a considered a special type of document; records are controlled according to the requirements in Chapter 4.2.4.

RGLase LLC has established, documented, implemented and maintains a Quality Procedure titled "Quality Procedure for Control of Documents". This procedure defines the controls needed:

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

The Document Control Manager is responsible to maintain the Document Control Procedure, to ensure that relevant versions are available at points of use, to remove obsolete documents, and to control external documents. Documents are reviewed and approved, including re-approval as required, by the appropriate functional manager along with the Quality Manager.

4.2.4 Control of Records

RGLase LLC establishes and maintains records to provide evidence of conformity to requirements and of the effective operation of our Quality Management System. All such records are kept legible, readily identifiable and retrievable.

RGLase LLC has established, documented, implemented and maintains a Quality Procedure titled "Quality Procedure for Control of Records". This procedure defines the controls needed:

- a) for the identification of records,
- b) for the storage of records,
- c) for the protection of records,
- d) for the retrieval of records,
- e) for the retention time of records, and
- f) for the disposition of records.

The Document Control Manager is responsible to maintain the Records Control Procedure.

5 Management Responsibility

5.1 Management Commitment

Top management at RGLase LLC is not only committed to the development and implementation of our Quality Management System, but also to continually improving its effectiveness. Top management of RGLase LLC clearly demonstrates its commitment by:

- a) communicating to RGLase LLC the importance of meeting customer requirements, as well as statutory and regulatory requirements,
- b) establishing our Quality Policy (see detailed requirements in Chapter 5.3),
- c) ensuring the Quality Objectives are established,
- d) conducting management reviews of the Quality Management System, and
- e) ensuring the availability of resources.

5.2 Customer Focus

Top Management at RGLase LLC ensures that customer requirements are first determined and then met with the aim of enhancing customer satisfaction (see Chapters 7.2.1 and 8.2.1).

5.3 Quality Policy

Top management at RGLase LLC ensures

- a) that our Quality Policy is appropriate to the purpose of RGLase LLC,
- b) that our Quality Policy includes a statement that says that RGLase LLC is committed to comply with the requirements of ISO 9001:2000, and that RGLase LLC is committed to continually improve the effectiveness of our ISO 9001:2000 Quality Management System,
- c) that our Quality Policy provides a framework for establishing and reviewing quality objectives,
- d) that our Quality Policy is communicated and understood throughout RGLase LLC, and
- e) that our Quality Policy is reviewed for continuing suitability.

The stated quality policy is as follows:

RGLase LLC strives to be the number one supplier of Laser Engine & Photonic Products through a commitment to continuous quality improvement of our products, processes and people. Quality is integrated into all aspects of our business and forms the foundation of our customer satisfaction.

The Quality Manager is responsible for ensuring the quality policy is reviewed during the Management Review process.

5.4 Planning

5.4.1 Quality Objectives

Top management at RGLase LLC ensures that quality objectives are established throughout RGLase LLC at relevant functions and levels. These quality objectives meet the following requirements:

- They include (but are not limited to) objectives regarding meeting requirements for our products (see Chapter 7.1 a).
- They are measurable.
- They are consistent with our Quality Policy.

The VP of Operation is responsible for establishing and maintaining the quality objectives.

5.4.2 Quality Management System Planning

Top management at RGLase LLC ensures

- a) that our Quality Management System has been planned so that the requirements set forth in Chapter 4.1 are met, and
- b) that the quality objectives are met.

Top management ensures that the integrity of our Quality Management System continues to be maintained at times when changes to our Quality Management System are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

Top management at RGLase LLC ensures that responsibilities and authorities are

- a) defined and
- b) communicated

throughout RGLase LLC.

5.5.2 Management Representative

Top management at RGLase LLC has appointed an ISO 9001 Management Representative (John Li). This Management Representative is a member of management who has the following responsibilities and authorities irrespective of other responsibilities:

- a) The Management Representative ensures that the processes needed for our Quality Management System are established, implemented and maintained.
- b) The Management Representative reports to our top management on the performance of our Quality Management System and any need for improvement.
- c) The Management Representative ensures that a general awareness of customer requirements is promoted throughout RGLase LLC.
- d) The Management Representative also serves as liaison with external parties on matters relating to our Quality Management System.

5.5.3 Internal Communication

Top management at RGLase LLC ensures that there are appropriate communication processes established throughout RGLase LLC. Top management further ensures that communication takes place regarding the effectiveness of our Quality Management System.

5.6 Management Review

5.6.1 General

Top management at RGLase LLC plans intervals at which it reviews our Quality Management System. Top management then reviews our Quality Management System at these intervals to ensure that the Quality Management System continues to be suitable, adequate and effective.

This review includes an assessment of opportunities for improvement and the need for changes to our Quality Management System, including our Quality Policy and the quality objectives.

RGLase LLC maintains records of these management reviews in compliance with Chapter 4.2.4.

5.6.2 Review Input

The following information serves as input to the management reviews of our Quality Management System:

- a) results of audits,
- b) customer feedback,
- c) process performance,
- d) product conformance to requirements,
- e) status of preventive and corrective actions,
- f) follow-up actions from previous management reviews,
- g) any changes that could affect our Quality Management System, and
- h) recommendations for improvement.

5.6.3 Review Output

The output from the management reviews of our Quality Management System includes the following:

- a) decisions and actions related to improving the effectiveness of the our Quality Management System and its processes,
- b) decisions and actions related to the improving our products relative to customer requirements, and
- c) decisions and actions related to resource needs.

6 Resource Management

6.1 Provision of Resources

RGLase LLC first determines and then provides the resources needed

- a) for the implementation and maintenance of our Quality Management System,
- b) for continually improving the effectiveness of our Quality Management System, and
- c) for the enhancement of customer satisfaction by meeting customer requirements.

6.2 Human Resources

6.2.1 General

RGLase LLC ensures that all our personnel who perform work that affects our product quality are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness and Training

RGLase LLC does the following regarding competence, awareness and training of our employees:

- a) RGLase LLC determines the necessary competence for personnel who perform work that affects our product quality.
- b) RGLase LLC provides the necessary training or takes other actions to satisfy these needs.
- c) RGLase LLC evaluates the effectiveness of the training or other actions taken.
- d) RGLase LLC ensures that all our personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- e) RGLase LLC maintains appropriate records of education, training, skills and experience in compliance with Chapter 4.2.4.

The Human Resources Department is responsible to determine competency requirements and to oversee the training process. Human Resources also maintains appropriate records of education, training, skills, and experience.

6.3 Infrastructure

RGLase LLC determines, provides and maintains the infrastructure necessary to achieve conformity to product requirements. This infrastructure includes, as applicable, the following:

- a) buildings, workspace and associated utilities,
- b) process equipment (this includes both hardware and software), and
- c) supporting services (such as transportation and communication).

6.4 Work Environment

RGLase LLC determines and manages the work environment that is necessary to achieve conformity to product requirements. The Human Resources Department is responsible to identify and control work environment requirements.

7 Product Realization

7.1 Planning of Product Realization

RGLase LLC plans and develops the processes needed for product realization. This planning of product realization is consistent with the requirements of the other processes of our Quality Management System (see Chapter 4.1).

RGLase LLC determines the following, as appropriate, during the planning phase for product realization:

- a) quality objectives and requirements for the product;
- b) the need to establish
 - processes,
 - documents, and
 - provision of resources specific to the product;
- c) the following activities that are required by the specifics of the product and the criteria for product acceptance:
 - verification,
 - validation,
 - monitoring,
 - inspection and test;
- d) the records necessary to provide evidence that both the realization process and the resulting product meet requirements; these records are control in compliance with Chapter 4.2.4.

The output of this planning is in a form that is suitable for RGLase LLC's method of operations.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

RGLase LLC determines the following requirements that are related to our product:

- a) requirements that have been specified by our customers, including any such requirements for delivery and post-delivery activities,
- b) requirements that have not explicitly stated by our customers but that are necessary for the specified or intended use of our products (where the use is known),
- c) statutory and regulatory requirements related to our products, and
- d) any additional requirements that RGLase LLC determines.

The Sales Department is responsible for determining all customer requirements, whether specified; not stated, but necessary; or statutory and regulatory.

7.2.2 Review of Requirements Related to the Product

RGLase LLC reviews the requirements related to products prior to RGLase LLC's commitment to supply a product to the customer (e.g., prior to the submission of tenders, prior to the acceptance of contracts or orders, prior to the acceptance of changes to contracts or orders). This review is designed to ensure that:

- a) product requirements are defined,
- b) any differences of contract or order requirements to previously expressed contract or order requirements are resolved, and
- c) RGLase LLC has the ability to meet the defined requirements.

In situations in which it is impractical to formally review each individual order (e.g., in case of internet sales), RGLase LLC instead reviews the relevant product information such as catalogs or advertising materials.

The Sales Department maintains records that show the results of the review and the actions arising from the review in compliance with Chapter 4.2.4.

In cases in which our customers don't provide documented requirements, RGLase LLC confirms the customer requirements before acceptance.

In cases in which product requirements are changed, the Sales Department ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

RGLase LLC determines and implements effective arrangements for communicating with our customers regarding the following:

- a) product information,
- b) inquiries, contracts or order handling,
- c) handling of contract or order amendments, and
- d) customer feedback including customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

RGLase LLC plans and controls the design and development of our products. The Engineering Department is responsible for controlling all stages of the design process, and for maintaining the appropriate records. During this planning of design and development, RGLase LLC determines the following:

- a) the various stages of the design and development process,
- b) the review, verification and validation activities that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

RGLase LLC manages how the different groups that are involved in the design and development process interface with each other so that effective communication and clear assignment of responsibilities is ensured.

The output of design and development planning is updated, as appropriate, as the design and development process progresses.

7.3.2 Design and Development Inputs

RGLase LLC determines the inputs related to product requirements. These inputs include:

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements those are essential for the design and development.

RGLase LLC reviews these inputs for adequacy, and ensures that all requirements are complete, unambiguous and not in conflict with each other.

RGLase LLC maintains records of these inputs in compliance with Chapter 4.2.4.

7.3.3 Design and Development Outputs

RGLase LLC provides the outputs of the design and development process in a form that enables verification against the design and development input. RGLase LLC approves these outputs prior to release and ensures that these outputs meet the following conditions:

- a) The outputs meet the input requirements for design and development.
- b) The outputs provide appropriate information for purchasing, production and service provision.
- c) The outputs either contain or reference the criteria for product acceptance.
- d) The outputs specify the product characteristics that are essential for its safe and proper use.

7.3.4 Design and Development Review

RGLase LLC performs systematic reviews of the design and development at suitable stages in accordance with our design and development plan (see Chapter 7.3.1). These reviews:

- a) evaluate if the results of design and development are able to meet requirements, and
- b) identify any problems and propose necessary actions.

Representatives of those functions concerned with the design and development states under review are participants in the reviews.

RGLase LLC maintains records of the results of the reviews and of any necessary actions in compliance with Chapter 4.2.4.

7.3.5 Design and Development Verification

RGLase LLC performs a design and development verification in accordance with the planned requirements (see Chapter 7.3.1). Verification is designed to ensure that the design and development outputs meet the design and development input requirements.

RGLase LLC maintains records of the results of the verification and of any necessary actions in compliance with Chapter 4.2.4.

7.3.6 Design and Development Validation

RGLase LLC performs a design and development validation in accordance with the planned requirements (see Chapter 7.3.1). Validation is designed to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use (where known). Wherever practicable, RGLase LLC completes validation prior to the delivery or implementation of the product.

RGLase LLC maintains records of the results of the validation and of any necessary actions in compliance with Chapter 4.2.4.

7.3.7 Control of Design and Development Changes

RGLase LLC identifies any design and development changes and maintains records. RGLase LLC reviews, verifies and validates (as appropriate) these changes, and approves them prior to their implementation. The review of design and development changes includes an evaluation on the effect of the changes on constituent parts and product already delivered.

RGLase LLC maintains records of the results of the review of changes and of any necessary actions in compliance with Chapter 4.2.4.

7.4 Purchasing

7.4.1 Purchasing Process

RGLase LLC ensures that the products we purchase conform to our specified purchase requirements. In order to achieve this, RGLase LLC applies certain controls to our suppliers and to the purchased products; the type and extend of these controls depend on the effect that the purchase product has on our product realization or on our final product.

RGLase LLC evaluates and selects our suppliers based on their ability to supply products in accordance with our requirements. RGLase LLC establishes criteria that we use for the selection, evaluation and re-evaluation of our suppliers.

Purchasing Department maintains records of the results of the evaluations and of any necessary actions in compliance with Chapter 4.2.4.

7.4.2 Purchasing Information

RGLase LLC describes the products to be purchased and includes the following, as appropriate, in the purchasing information:

- a) requirements for the approval of product, procedures, processes and equipment,

- b) requirements for qualification of personnel, and
- c) quality management system requirements.

Prior to communicating the purchase information to the supplier, RGLase LLC ensures that the purchase requirements are adequate.

7.4.3 Verification of Purchased Product

RGLase LLC establishes and implements inspection or other activities that are necessary to ensure that our purchased products meet our specified purchase requirements.

In cases in which RGLase LLC or our customers intend to perform this verification at our supplier's premises, RGLase LLC states the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

RGLase LLC carries out our production and service provision under controlled conditions which include the following, as applicable:

- a) Information that describes the characteristics of the product is available.
- b) Necessary work instructions are available.
- c) Suitable equipment is used.
- d) Monitoring and measuring devices are available and used.
- e) Monitoring and measuring activities are implemented (see Chapter 7.5.2 for an exception).
- f) Release, delivery and post-delivery activities are implemented.

The Production Department is responsible for controlling all phases of product and service provision and for maintaining appropriate records.

7.5.2 Validation of Process for Production and Service Provision

In such special situations in which we cannot use monitoring or measurement activities to verify the output of our production and service provision, RGLase LLC validates the processes of such production and service provision. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

The process validation is designed to demonstrate that these processes are able to achieve the planned results.

RGLase LLC establishes arrangements for these processes which include, as applicable:

- a) defined criteria for review and approval of the processes;
- b) approval of equipment and qualification of personnel;
- c) use of specific methods and procedures;
- d) requirements for records (refer to Chapter 4.2.4), and
- e) revalidation.

7.5.3 Identification and Traceability

RGLase LLC identifies our product, where appropriate, by suitable means throughout the product realization.

RGLase LLC identifies the product status with respect to monitoring and measurement requirements. In cases in which traceability is a requirement, The Production Department controls the unique identification of the product and maintains records in compliance with Chapter 4.2.4.

7.5.4 Customer Property

Whenever we use our customers' property or whenever we have our customers' property under our control, RGLase LLC exercises care with such customer property (which can also include intellectual property). RGLase LLC identifies, verifies, protects and safeguards customer property that has been provided for use or incorporation into our product.

If despite all our care any customer property is lost, damaged or otherwise found unsuitable for use, RGLase LLC reports this to the customer and maintains records in compliance with Chapter 4.2.4.

The Production Department is responsible for controlling and recording customer property. The Sales Department is responsible for all communication with the customer regarding their property.

7.5.5 Preservation of Product

The Production Department is responsible for preserving the conformity of our products and their constituent parts during internal processing and during delivery to the intended destination. This preservation includes:

- identification,
- handling,
- packaging,

- storage, and
- protection.

7.6 Control of Monitoring and Measuring Devices

In order to provide evidence that our products conform to determined requirements (see Chapter 7.2.1), RGLase LLC determines the monitoring and measuring activities to be undertaken, as well as the monitoring and measuring devices needed.

RGLase LLC establishes processes that ensure that monitoring and measurement can be carried out, and that monitoring and measurement is performed in a manner that is consistent with the monitoring and measurement requirements. The Quality Department is responsible for all aspects related to the system of controlling monitoring and measurement.

Where necessary to ensure valid results, measuring equipment

- a) is calibrated or verified at specified intervals or prior to use; this calibration or verification is done against measurement standards that are traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded;
- b) is adjusted or re-adjusted as necessary; when measuring equipment is found not to conform to requirements, RGLase LLC assesses and records the validity of previous measuring results; RGLase LLC takes appropriate action on the equipment and any product that is affected;
- c) is identified to enable the calibration status to be determined;
- d) is safeguarded from adjustments that would invalidate the measurement results;
- e) is protected from damage and deterioration during handling, maintenance and storage.

RGLase LLC maintains records of the results of calibration and verification in compliance with Chapter 4.2.4.

In cases in which we use computer software in the monitoring and measurement of specified requirements, RGLase LLC confirms the software's ability to satisfy the intended application. This is done prior to the initial use and reconfirmed as necessary.

8 Measurement, Analysis and Improvement

8.1 General

RGLase LLC has planned and implemented the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate that our products conform to requirements, and

- b) to ensure that our Quality Management System conforms to requirements, and to continually improve its effectiveness.

This includes the determination of applicable methods, including statistical techniques, and the extent of their use. The Quality Department is responsible for systems related to monitoring, measurement, analysis and improvement.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Customer satisfaction is one of the key indicators of the performance of our Quality Management System. RGLase LLC, therefore, monitors information relating to our customers' perception as to whether RGLase LLC has met customer requirements.

RGLase LLC has determined and established the methods used to obtain and to use this information.

8.2.2 Internal Audit

RGLase LLC has established, documented, implemented and maintains a Quality Procedure titled "Quality Procedure for Internal Audit". This Quality Procedure defines the responsibilities and requirements for the planning and conducting of internal audits, for the reporting of audit results, and for maintaining records in compliance with Chapter 4.2.4.

This procedure also defines how internal audits are conducted at planned intervals in order to determine the following information on our Quality Management System:

- a) Does our Quality Management System conform to the planned arrangements (see Chapter 7.1)?
- b) Does our Quality Management System conform to the requirements of ISO 9001:2000?
- c) Does our Quality Management System conform to the requirements established by RGLase LLC?
- d) Is our Quality Management System effectively implemented and maintained?

This procedure also defines how RGLase LLC plans an audit program under consideration of the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit program defines the audit criteria, scope of audits, frequency of audits, and the audit methods. RGLase LLC selects our auditors and conducts our audits as to ensure that the audit process is objective and impartial. Auditors never audit their own work.

This procedure also defines how the management of the areas being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes, and how RGLase LLC conducts follow-up activities which include the verification of actions taken, and the reporting of the verification results (see Chapter 8.5.2).

8.2.3 Monitoring and Measurement of Processes

RGLase LLC applies suitable methods for the monitoring and, where applicable, measurement of the processes of our Quality Management System in order to demonstrate that these processes achieve the planned results.

In cases in which the Quality Management Processes do not achieve planned results, RGLase LLC applies correction and corrective action, as appropriate, to ensure that our products conform to requirements.

8.2.4 Monitoring and Measurement of Product

RGLase LLC monitors and measures the characteristics of our products at appropriate states of the product realization process and in accordance with planned arrangements (see Chapter 7.1) in order to verify that product requirements have been met. RGLase LLC maintains records (in compliance with Chapter 4.2.4) providing evidence of conformity to acceptance criteria; these records, also indicate the person(s) authorizing the release of our products.

Unless otherwise approved by a relevant authority and, where applicable, by the customer, RGLase LLC ensures that product release and service delivery do not proceed until the planned arrangements (see Chapter 7.1) have been satisfactorily completed.

8.3 Control of Nonconforming Product

RGLase LLC ensures that those products that do not conform to product requirements are identified and controlled so that their unintended use or delivery is prevented.

RGLase LLC has established, documented, implemented and maintains a Quality Procedure titled "Quality Procedure for Control of Nonconforming Product" which defines the controls and related responsibilities and authorities for dealing with nonconforming products.

This procedure defines how RGLase LLC deals with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity. When a nonconforming product is corrected, it is subject to re-verification to demonstrate its conformity to requirements.
- b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.
- c) By taking action to preclude its original intended use or application.

The procedure also defines the action taken when a nonconforming product is detected after delivery or after use has started. Action taken is appropriate to the effects, or potential effects, of the nonconformity.

The procedure also defines how records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained in compliance with Chapter 4.2.4.

8.4 Analysis of Data

RGLase LLC 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 our Quality Management System can be made. This data includes data generated as a result of our monitoring and measurement activities and from other relevant sources.

The analysis of data is designed to provide information relating to

- a) customer satisfaction (see Chapter 8.2.1),
- b) conformity to product requirements (see Chapter 7.2.1)
- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

The Quality Department is responsible for determining the data requirements and for coordinating with other departments to collect and subsequently analyze the data in order to make improvements.

8.5 Improvement

8.5.1 Continual Improvement

RGLase LLC continually improves the effectiveness of our Quality Management System. In order to achieve continual improvement, RGLase LLC makes use of

- our Quality Policy,
- our Quality Objectives,
- our audit results,
- the analysis of data,
- corrective and preventive actions, and
- management review.

8.5.2 Corrective Action

RGLase LLC has established, documented, implemented and maintains a Quality Procedure titled "Quality Procedure for Corrective Action" which defines how RGLase LLC takes corrective actions to eliminate the cause of nonconformities in order to prevent those nonconformities from recurring.

This procedure defines the requirements for the following steps of the corrective action process:

- a) Review of the nonconformities including customer complaints;
- b) Determination of the causes of the nonconformities;
- c) Evaluation of the need for action to ensure that nonconformities do not recur;
- d) Determination of the actions needed; actions are appropriate to the effects of the encountered nonconformities;
- e) Implementation of the action;
- f) Establishment and maintenance of records of the results of the actions taken in compliance with Chapter 4.2.4;
- g) Review of the corrective action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.

8.5.3 Preventive Action

RGLase LLC has established, documented, implemented and maintains a Quality Procedure titled "Quality Procedure for Preventive Action" which defines how RGLase LLC takes preventive action to eliminate the causes of potential nonconformities in order to prevent the occurrence of those potential nonconformities.

This procedure defines the requirements for the following steps of the preventive action process:

- a) Determination of potential nonconformities and their causes;
- b) Evaluation of the need for action to ensure that these potential nonconformities will not occur;
- c) Determination of the actions needed; actions are appropriate to the effects of the potential problems;
- d) Implementation of the action;
- e) Establishment and maintenance of records of the results of the actions taken in compliance with Chapter 4.2.4;
- f) Review of the preventive action taken.

The Quality Department is responsible for maintaining the procedure and the associated records.