The Prophotonix (UK) Ltd
Quality manual

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Quality Management System and Policy Commitment

Name	Title	Signature	Date:
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Paul Wharton	Group Quality Manager		24-4-14
Graham George	Production Manager		24-4-14
Mike Foster	Materials manager		24-4-14
Gary Marsh	Technical Manager		— " —
Tina Lea	Finance Manager		25-4-14
Peter Gottlieb	IT Manager		24-4-14

CHANGE CONTROL HISTORY

Version:	Date:	Summary of Changes
A	03-2009	Introduction
B	11-2010	Revised to new ProPhotonix format, quality policy statement incorporated, revised Procedures added to ISO9001 cross reference sheet.
C	01 - 2013	Added sect 4 – Infrastructure & Work environment. Removed references to QSMR.
D	24-10-2013	Amendments in response to audit findings & move to ISO 9001:2008. Document ref changed from PPXQM-001 to QP-0001

QUALITY POLICY STATEMENT

At Prophotonix Limited we believe that every member of the business shares the responsibility for quality and quality improvement. We also take the view that our quality management approach and its operation will enable us and our customers to continue to benefit from our ISO 9001:2008 certification.

Therefore:

- The Prophotonix Ltd management team, through their practices and standards, endeavor to lead by example. They will give complete commitment and allocate the necessary resources to the quality policies and programs initiated. The management team is charged with creating a clarity and unity of purpose within the Company and an environment in which the organization and its people can excel.

- All employees of the company are not only required to comply with and contribute to the provisions of the quality management system but are encouraged to embrace the fundamental attributes of the system and incorporate it into everyday activities. All employees are encouraged to make contributions to continuous quality improvement. Managers are responsible for ensuring that their workforce is instructed in, understand and comply with these requirements.

- Our aim is delight our customers and develop relationships with all suppliers both internal and external, working in partnership, developing mutually beneficial relationships built on trust, sharing of knowledge and integration. It is our aim to meet all supply chain requirements and to provide significant and measurable successes.

- We ensure that we can deliver the defined quality goals and targets by the establishment and implementation of management objectives and processes, which are monitored against the requirements of our customers' needs/expectations, our internal business management system, ISO9001:2008 and all applicable statutory and regulatory requirements. Progress against set goals and measurable targets is monitored and evaluated through a Management review process.

- Ultimate responsibility for the achievement of these objectives rests with the Managing Director supported by the management team with the responsibility and authority to implement company policies. The Group Quality Assurance manager is responsible for monitoring all aspects of the operation of this policy.

Jeremy Lane
Managing Director

COMPANY PROFILE

Photonic Products Ltd was founded in 1995, as a technically expert, market led specialist laser diode Distribution Company dedicated to complete customer satisfaction. From October 2010 the company name became ProPhotonix

Since 1995 the company has evolved dynamically to meet customer demand and now specialises in both the distribution of laser diodes and the custom design and manufacture of optoelectronic components based on semiconductor laser technology.

In November 2006 Photonics Products was purchased by Stocker Yale (now also known as ProPhotonix – name changed in June 2010), a USA Corporate group specialising in the design and manufacture of Laser, LED, and Fluorescent lighting Products.

ProPhotonix Engineers offer innovative, high quality product design and manufacture using the latest technology.

ProPhotonix has close links with major laser diode manufactures and access to direct technical support from the laser diode engineers of Opnext, Sanyo and Sony in Japan.

In-house capabilities include Laser Beam Profiling, Wavelength Measurement, Wavelength Selection, Laser Beam Analysis, Laser Power Measurement and a Turning and Milling Facility.

Product design, prototyping, assembly and testing is carried out in-house using only the highest grade materials, and applying strict ESD precautions. Comprehensive documentation packages can be supplied with custom designed products.

ProPhotonix laser diodes and optoelectronic components are used world-wide in alignment, positioning, measurement, levelling, scanning, therapeutic devices, biomedical instruments, DNA sequencing, free space optical communications and many other high-tech applications.

The Company Scope is to Design, Develop, Manufacture, Purchase and Distribute, Electro Optic Components.

From its foundation to the present day the company has always traded under the guiding principle:

“Adapting to customers’ needs to provide a Quality Product and Service is our Number one priority”

1	Scope

1.1	General

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard ISO 9001:2008.

1.2	Application

Where any requirement of ISO 9001:2008 can not be applied due to the nature of our organization, its activities and its products, they will be considered for exclusion. An ISO 9001: 2008 requirement may be excluded only when both of the following conditions are met:

- The requirement must be within ISO 9001 clause 7, Product Realization.
- The exclusion may not affect our ability, nor absolves us from the responsibility, to provide product that meets customer and applicable regulatory requirements.

Prophotonix Ltd has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

1. Exclusion: ISO 9001: 2008 section 7. 5. 2, Validation of Processes for Production and Service Provision.
   Justification: There are no processes that can be validated prior to release.

2.0	Normative references

The following documents were used as reference during the preparation of the Quality Management System:

ISO9000:2005 Quality management Systems – Fundamentals and vocabulary.

3.0	Terms and definitions

Definitions unique to Prophotonix Ltd.

▪ Customer owned property - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.
▪ Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.
▪ Product – The end item result of meeting all contract terms and conditions.
▪ Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable.

Section 4: Quality management system

4.1 General Requirements

Prophotonix Ltd. has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS *Prophotonix Ltd.* has:

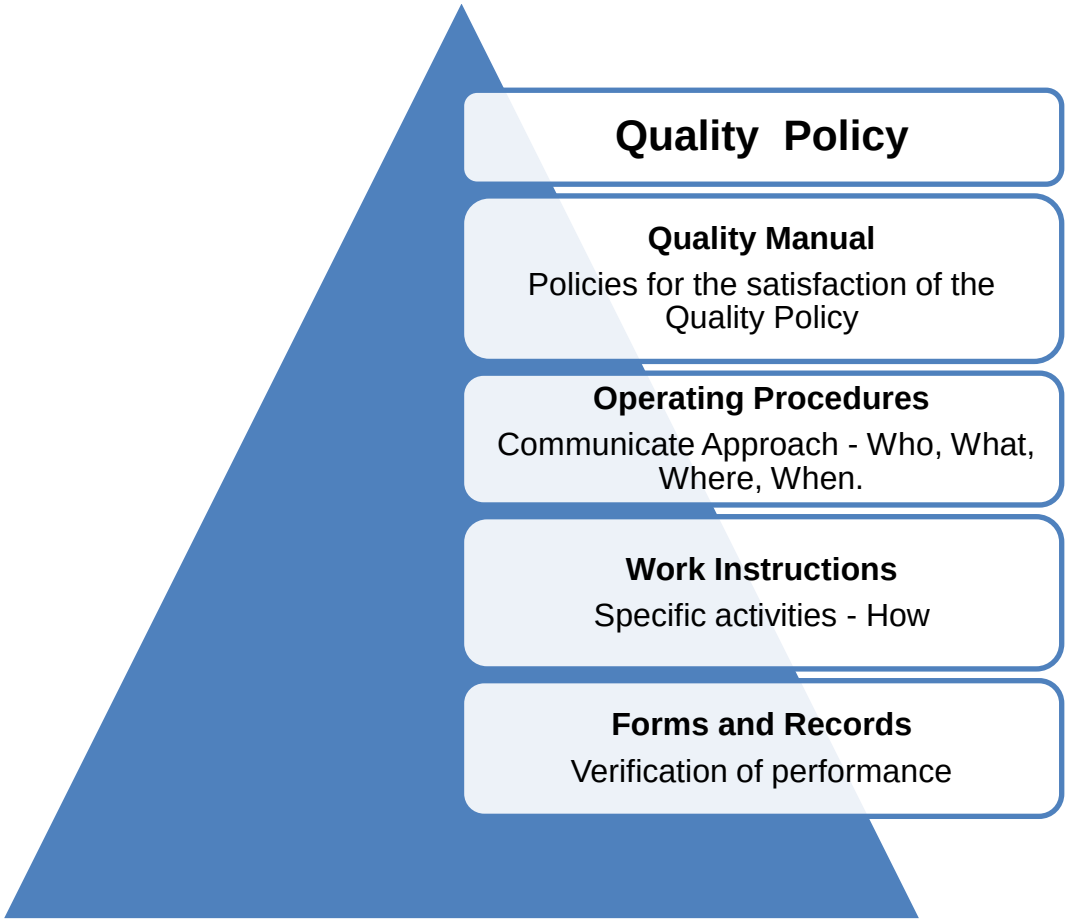
a) The processes needed for the QMS and their application throughout the organization have been determined,
b) The sequence and interaction of these processes has been determined,
c) Determined criteria and methods needed to ensure that the operation and control of the processes are effective.
d) Ensured the continuing availability of resources and information necessary to achieve planned results and continual improvement of these processes.
e) Established systems to monitor, measure and analyze these processes where applicable, and
f) Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.

The type and extent of control applied to any outsourced processes or services is defined within the Quality Management System.

4.2	Documentation requirements
4.2.1	General

The QMS documentation includes:

- A documented Quality Policy.
- This Quality Manual.
- Documented Procedures and records required by ISO9001:2008
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records.



Ref Docs:- QMS Documentation Log
Documentation control procedure (QP-0002)

4.2.2	Quality manual

This Quality Manual has been prepared to describe the *Prophotonix Ltd* QMS. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section.

4.2.3	Control of Documents

All of the QMS documents are controlled according to the Document & data Control Procedure. This procedure defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and updating as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified.
- Ensuring that relevant versions of applicable documents are available at points of use.
- Ensuring that documents remain legible and readily identifiable.
- Ensuring that documents of external origin are identified and their distribution controlled, and
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

Ref Docs:- Documentation and data control procedure (QP-0002)

4.2.4	Control of records

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the Control of Quality Records Procedure. This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

Ref Docs:- Documentation and data control procedure (QP-0002)

Section 5: Management Responsibility

5.1 Management Commitment

The managing Director and the Group Quality manager are actively involved in implementing and maintaining the quality management system (QMS). The Management Group has provided the vision and strategic direction for the growth of the QMS and established quality objectives and the quality policy.
To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

- Communicate the importance of meeting customer, statutory, and regulatory requirements.
- Establish quality objectives
- Establish the quality policy.
- Conduct monthly management reviews.
- Conduct an in depth annual Quality management review.
- Ensure the availability of resources.

Ref Docs:- Quality Management Review (QP-0001)

5.2 Customer focus

Prophotonix Ltd. strives to identify current and future customer needs to meet customer requirements and exceed customer expectations. The sales team ensures that customer requirements are understood and met, *through compliance with documented customer communication procedures.* Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization.

Ref Docs:- Sales and Marketing Procedure (QP-0004)

5.3 Quality Policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent positions throughout the offices, production areas and in reception.
Management reviews the Quality policy at each annual Quality Management Review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is documented at page 3 of this document, Quality Policy Statement.

5.4 Planning

5.4.1 Quality Objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

Ref Docs:- Quality Management review Procedure

5.4.2 Quality management system planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

5.5 Responsibility, Authority and communication

5.5.1 Responsibility and authority

An organization chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

Ref docs:- Org Chart @ Annex 1

5.5.2 Management representative

The Group Quality Assurance Manager has responsibility and authority that includes:

- Ensuring that processes needed for the quality management system are established and implemented.
- Report to top management on the performance of the quality management system, and note needed improvements.
- Promote awareness of customer requirements throughout the organization.
- Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

5.5.3	Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication.

5.6	Management review
5.6.1	General

Management reviews the QMS Annually. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

Ref Docs:- Quality Management Review (QP-0001)

5.6.2	Review input

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

- Results of audits
- Status of preventive and corrective actions
- Customer Feedback
- Process/service performance
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for improvement

Ref Docs:- Quality Management Review (QP-0001)

5.6.3 Review output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes.
- Improvement of product related to customer requirements.
- Improvement in the level of service provided to our customers.
- Resource needs.
- Establishment of Company Objectives and Improvement plan.

Responsibility for required actions is assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

Ref Docs:- Quality Management Review (QP-0001)

Section 6: Resource Management

6.1 Provision of resources

Prophotonix Ltd. has implemented a Quality Management System that complies with the ISO 9001:2008 standard and enhances levels of customer satisfaction. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

6.2 Human resources

6.2.1 General

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience.
Appropriate qualifications, along with required training, provide the competence required for each position.

6.2.2 Competence, training and awareness

Qualifications are reviewed upon employment, when an employee changes positions or the requirements for a position change. *Human Resources* maintain records of employee qualifications. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job. All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
Training and evaluation are conducted according to the Training Policy and procedure.

Ref Docs:- Training Policy and Procedure (QP-0008)
Production Training Procedure (QP-0008PT)

6.3 Infrastructure

The Managing Director with the assistance of the management team will determine, manage and provide suitable facilities to perform appropriate business tasks and functions. The degree of adequacy with which the current business Infrastructure meets requirements is assessed on an on-going basis.
Facilities are defined below:-

Total accommodation = 910m²

Office accommodation & Meeting rooms = 320m²
Production/Assembly/Stores/Areas = 364m²
Common areas = 140m²
Engineering Dev Lab = 84m²

1. Air conditioning – Office, stores and Assembly areas.
2. Desk top computers – Sufficient for all office staff and for all production/stores staff to have easy access as and when required.
3. Computer server.
4. Miscellaneous test equipment, jigs, tooling and sufficient workstations.
5. All usual services.
6. Secure stores.

Ref Docs:- N/A

6.4 Work environment

The Work Environment is to comply with all current and relevant health and safety legislation. In addition the working environment must be appropriate for the expected tasks.
Whilst Office and general areas have no specific environmental requirements beyond those required by National Legislation the assembly and stores areas are required to meet the following standards:-

1. Temperature control – To be maintained within normally accepted levels for the work place.
2. Humidity – Is not controlled.
3. Clean room Std – No specific clean room standard is applied but through daily general cleaning and weekly programmed workstation cleaning the assembly and stores areas are maintained at an appropriate level of cleanliness
4. Lighting – Sufficient and appropriate lighting to allow all staff to accomplish tasks comfortably.

Section 7: Product Realization

7.1 Planning of product realization

Planning is required before new products are implemented. This planning may take place as a design project, or according to the Technical, Design and Development Procedure (QP-0006). During this planning, management or assigned personnel identify:

- The quality objectives and requirements for the product
- Processes, documentation and resources required
- Verification, validation, monitoring, inspection and test requirements
- Criteria for product acceptance.

The output of quality planning may include documented quality plans, processes, Procedures and other design outputs.

Ref Docs:- Technical, Design and Development Procedure (QP-0006)
Sales and Marketing procedure (QP-0004)

7.2 Customer related processes

7.2.1 Determination of requirements related to the product

Prophotonix Ltd. determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer
- Required for delivery and post-delivery activities
- Not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Additional requirements determined by *Prophotonix Ltd.*

Customer requirements are determined according to the Sales Process Procedure (QP-0012).

Ref Docs:- Technical, Design and Development Procedure (QP-0006)
Sales and Marketing procedure (QP-0004)

7.2.2 Review of requirements related to the product

Prophotonix Ltd. has a process in place for the review of requirements related to the product. The review is conducted before the order is accepted. The process ensures that:

- Product requirements are defined.
- Contract or order requirements differing from those previously expressed are resolved.
- *Prophotonix Ltd.* has the ability to meet the defined requirements
- Records are maintained showing the results of the review and any actions arising from the review.
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- When product requirements are changed, *Prophotonix Ltd.* communicates changes to relevant personnel and amends relevant documents.

Ref Docs:- Technical, Design and Development Procedure (QP-0006)
Sales and Marketing procedure (QP-0004)

7.2.3 Customer communication

Prophotonix Ltd. has implemented effective procedures for communicating with customers in relation to:

- Product Information
- Inquiries, contracts and order handling, including amendments
- Customer feedback, including customer complaints

7.3 Design and development

7.3.1 Design and development planning

The Technical, Design and Development Procedure (QP-0006) details the process for controlling the development process. The applicable department plans the design and development according to this procedure. The design plan includes:

- Design and development stages
- Required design reviews
- Verification and validation methods appropriate to each design and development stage
- Responsibilities and authorities for design and development
- Identification of the technical interfaces required for the project
- Updating of the design plan as the project progresses

Ref Docs :- Technical, Design and Development Procedure (QP-0006)

7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Technical, Design and Development Procedure (QP-0006). All inputs are reviewed for adequacy and completeness and to resolve any ambiguous inputs. Inputs include:

- Functional and performance requirements
- Applicable statutory and regulatory requirements
- Where applicable, information derived from previous similar designs
- Other requirements essential for design and development

Ref Docs:- Technical, Design and Development Procedure (QP-0006)
Sales and Marketing procedure (QP-0004)

7.3.3 Design and development outputs

Outputs of design and development are documented according to the Technical, Design and Development Procedure (QP-0006). They are documented in a format that enables verification against the inputs, and are approved prior to release. Outputs include:

- Meet the input requirements
- Provide appropriate information for purchasing, production and for service provision
- Contain or reference product acceptance criteria
- Specify the characteristics of the product that are essential for its safe and proper use.

Ref Docs:- Technical, Design and Development Procedure (QP-0006)

7.3.4 Design and development review

The design plan specifies suitable stages of the project to conduct design and development review. Reviews take place according to the design and development procedure; results of design review are recorded in minutes of the design review meetings which are maintained as a quality record. Design reviews:

- Evaluate the results of design and development activities and determine if they fulfil requirements.
- Identify any problems and propose necessary actions.
- Include representatives of functions concerned with the design and development stage being reviewed.

Ref Docs:- Technical, Design and Development Procedure (QP-0006)

7.3.5 Design and development verification

Design verification is planned and performed to ensure that the design and development outputs have satisfied the design and development input requirements. Records of the results of the verification and any necessary actions are maintained according to the Technical, Design and Development Procedure (QP-0006).

Ref Docs:- Technical, Design and Development Procedure (QP-0006)

7.3.6 Design and development validation

Design and development validation is performed according to the design plan to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Validation is completed prior to delivery whenever practicable. Records of the validation activities are maintained according to the Technical, Design and Development Procedure (QP-0006).

Ref Docs:- Technical, Design and Development Procedure (QP-0006)

7.3.7 Control of design and development changes

The Drawing Control Procedure (QP-0007) defines a process for identifying, recording, verifying, validating and approving design changes. The review of design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

Ref Docs:- Technical, Design and Development Procedure (QP-0006)
Documentation and data Control Procedure (QP-0002)

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure, Materials Management (QP-0005) is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

Ref Docs:- Materials Management (QP-0005)

7.4.2 Purchasing information

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

- Requirements for approval of product, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

Ref Docs:- Materials Management (QP-0005)

7.4.3 Verification of purchased product

The Materials Management (QP-0005) describes the process used to verify that purchased product meets specified purchase requirements. If *Prophotonix Ltd* or the customer, perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

Ref Docs:- Materials Management (QP-0005)

7.5	**Production and service provision**
7.5.1	**Control of production and service provision**

Prophotonix Ltd. plans and carries out production and service provision under controlled conditions according to documented procedures. Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product
- The availability of work instructions
- The use of suitable equipment
- The availability and use of monitoring and measuring devices
  The implementation of monitoring and measurement
- The implementation of release, delivery and post-delivery activities

7.5.2	**Validation of processes for production and service provision**

- See Para 1.2 of this document

Ref Docs:- N/A

7.5.3 Identification and traceability

All Product is identified with respect to monitoring and measurement requirements. Prophotonix Ltd. controls and records the identification of the product/Material throughout product realisation where ever traceability is a specified requirement.

Ref Docs:- Example Product Traveller Card below

PRO PHOTONIX

Standard Batch Card Form

Customer:	**GE Healthcare**					
Customer Order No:	**SO1400296**	**Works Order No:**		**WO1400544**		
Our Part No/Version	**300-0375-00**	**Revision Number**		**L**		
Qty:	**50**	**Due Date:**		**08/05/2014**		
Patch lead:		Module Power		0.92 mW		
Orientation:		Wavelength:		635 nm		
Laser Driver lead:	058/154/068	**Power:**	Min 0.85	Typ 0.92	Max 0.99	
Power Meter and Head: CAL 019 / 021						

Standard Instructions (1)		**Packing Instructions (2)**	
Working volts	5V	Laser Warning Label	Yes
Lead Length	129 mm	Individual Packaging	
Pot Values		Instruction Leaflet	
Lock Optics Off	Yes	Lens Cap	Yes
Focal Distance	1m	Product Label	Yes
Beam Size		Focus Key	
Modulation		Test Certificate	
Isolator Link		C of C	
Potting Compound	Yes Clear Compound	Pin Assignment Sheet	
Record File Address	Yes	Anti Static Label	
Module Soak Sheet		Graph Required	

Kitted by: SAM Date:	Assembled by: Process: Date:	Assembled by: Process: Date
Assembled by: Process: Date:	Tested by: Date:	Potted by: Date:
Production Checked by: Date:	QA Check by: Date:	Shipped by: Date:
Comments: Serial numbers to be found at R:\Production\Report File\GE module test reports By date then works order (i.e. 19_03_10 WO0901110 300-0375-00.xls)		
ALL SCRAP PARTS TO BE RETURNED WITH FINISHED PARTS AND A COMPLETED NCM REPORT FORM		
(1) Fit Anti Static Foam to Laser Diode Pins		
(2)The following items must be included when packing this order		

Full Check Serial No:

Document Reference:	**PPXF 007-1**	**Issue: C**	**November 2010**

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7.5.4 Customer property

Prophotonix Ltd. exercises care with customer property while it is under the organization's control or being used. Customer property is identified upon receipt and kept segregated within the stores by locating in an area identified by the customers name. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

Ref Docs:- N/A

7.5.5 Preservation of product

Prophotonix Ltd. preserves the conformity of product during internal processing through to delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product. Preservation instructions are detailed in product work instructions and Procedure for packing finished product including customer specific labeling.

Ref Docs:- Customer Shipping Instruction File

7.6 Control of monitoring and measuring equipment

A documented procedure Calibration Procedure (QP-0002) details the process used to ensure that the control of monitoring and measurement equipment is managed and carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- Calibrated or verified or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.
- Adjusted or re-adjusted as necessary.
- Identified to enable the calibration status to be determined.
- Safeguarded from adjustments that would invalidate the measurement result.
- Protected from damage and deterioration during handling, maintenance and Storage.

In addition, a review is carried out to assess records the validity of the previous measuring results when the equipment is found not to conform to requirements.
Prophotonix Ltd. takes 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, the ability of computer software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Ref Docs:- Calibration Procedure (QP-0009)

Section 8: Measurement, Analysis and Improvement

8.1 General

Prophotonix Ltd. plans and implements the monitoring, measurement, analysis and improvement processes as needed.

- To demonstrate conformity of the product.
- To ensure conformity of the quality management system.
- To continually improve the effectiveness of the quality management system.

These processes include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, Prophotonix Ltd monitors information relating to customer perception. The method for obtaining and using this information is detailed in the Sales and Marketing Procedure (QP-0004). The survey is carried out by the sales and marketing dept based in Cork IAW. the Cork Customer Satisfaction Survey procedure (QP-0027), see Annex 2.
Further analysis is carried out of customer complaints and returned goods data.

Ref Docs:- Sales and marketing procedure (QP-0004)

8.2.2 Monitoring and measurement

Prophotonix Ltd. conducts internal audits at planned intervals to determine whether the quality management system:

- Conforms to the planned arrangements (see 7.1) to the requirements of this International Standard and to the quality management system requirements established by the organization.
- Is effectively implemented and maintained.

An audit program has been designed and implemented. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Quality Audit procedure (QP-0010).
The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Ref Docs:- Quality Audit Procedure (QP-0010)

8.2.3	Monitoring and measurement of processes

Prophotonix Ltd. 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, to ensure conformity of the product. The determination of suitable methods is carried out as part of the Technical, Design and Development Procedure (QP-0006).

Ref docs:- Technical, Design and Development Procedure (QP-0006)

8.2.3	Monitoring and measurement of product

Prophotonix Ltd. monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in Work Instructions or traveller cards.
Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

Ref docs:- See para 7.5.3 above
Production procedure (QP-0007)

8.3	Control of non-conforming product

Prophotonix Ltd. ensures that product which 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 the documented procedures.

Ref docs:- QA Procedure (QP-0003)

8.4 Analysis of data

Prophotonix Ltd. determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other relevant sources.
The analysis of data provides information relating to

- Customer satisfaction
- Conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers

Ref docs:- Management Review (QP-0001)

8.5 Improvement

8.5.1 Continual Improvement

Prophotonix Ltd continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

Prophotonix Ltd. takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.
A documented procedure QA Procedure (QP-0003) defines requirements for

- Reviewing nonconformities (including customer complaints
- Determining the causes of nonconformities
- Evaluating the need for action to ensure that nonconformities do not recur
- Determining and implementing action needed
- Records of the results of action taken (see 4.2.4)
- Reviewing corrective action taken

Ref docs:- QA Procedure (QP-0003)

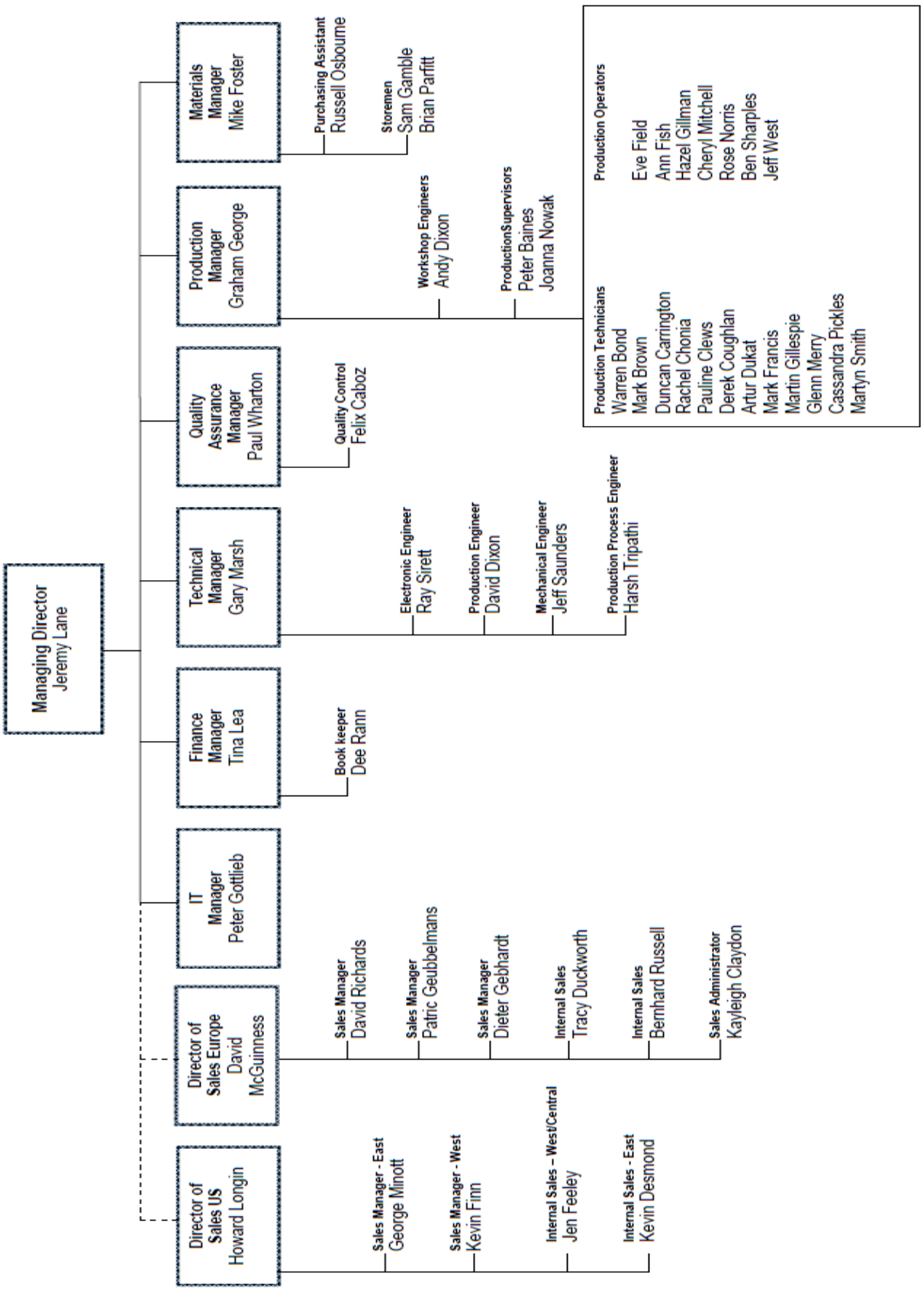
8.5.3	Preventive action

Prophotonix Ltd. determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.
A documented procedure (PPXP 003) defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing preventive action taken

Ref docs:- QA Procedure (QP-0003)

9 Appendix 1 - ORGANISATION CHART



Appendix 2



Quality Procedure

Document:	QP-0023	Date:	13/03/13
Revision:	2.0	History:	See back of document
Description:	Customer Satisfaction Survey		

Approval	Name	Date
Originator	P Wharton	8/11/13

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1.0 Scope

1.1 The scope of this document is to outline the procedure for an annual survey of customer satisfaction

2.0 Applicable Documents

2.1 Customer satisfaction survey form. See below

3.0 Aim:

3.1 The aim of this procedure is to provide prophotonix Ireland the means of determining levels of customer satisfaction and reporting to senior management.

4.0 Procedure:

4.1 The customer database is maintained using the online 'SalesForce' program, which is then linked into the Alliance system procedure for releasing new monitoring and measuring devices at Prophotonix.

4.2 An annual telephone survey is carried out targeting customers selected from the above database. A minimum of 15 customers will be interviewed and these should be a mix of customers including a mix of high, mid and low value purchasers.

4.3 An annual telephone survey is carried out targeting customers selected from the above database. A minimum of 15 customers will be interviewed and these should be a mix of UK customers including a mix of high, mid and low value purchasers.

4.4 Questions are asked from the from the template form QF-0044 – Customer satisfaction form. Copy at appendix 1.

4.5 The results of the survey are promulgated to the senior management team and presented at the annual quality review.

Document history

Rev	CN #	Date	Person	Description
1.0	0287	13/03/13	TE	Release
2.0	0287	8/11/13	PW	Update

Appendix 1

PRO PHOTONIX	QF-0044	Customer Satisfaction Form	R1.0	CN:0287

Customer - Company		Customer Contact	
Prophotonix Contact		Date	

We would be grateful if you could spare a few minutes to complete this Customer Satisfaction Questionnaire to help us ensure that our standard of customer care exceeds expectations wherever possible.

Please tick the appropriate box to indicate your degree of satisfaction.

Where: 1 = Excellent, 2 = Good, 3 = satisfactory, 4 = Poor

TOPIC	1	2	3	4	COMMENTS/SUGGESTIONS
RESPONSIVENESS: How do you rate our sales teams' responsiveness in dealing with you?					
PROFESSIONALISM: How do you rate the professionalism of our sales team in dealing with you?					
TECHNICAL SUPPORT: If you received any technical support, how do you rate 1) the technical competence of our Engineers and 2) their response time?					
PRODUCT QUALITY: How do you rate our products and services in terms of 1)quality and 2) performance?					
DELIVERY: How do you rate 1) our delivery on time performance and 2) our commitment to meet your delivery expectations?					
COMPETITIVENESS: How do you rate the competitiveness of our products? Do they represent good value?					
OVERALL: How do you rate Prophotonix?					
Do you have any comments or suggestions that would help us to improve our quality of customer service?					

PRO PHOTONIX	QF-0044	Customer Satisfaction Form	R1.0	CN:0287

Please note: The following questions do not require a rating.

Company Confidential

Were your goods packaged to your specifications and satisfaction?	
Does the ProPhotonix's product range meet all of your LED and Laser Module needs? Do you have specific requirements that we should explore to complete our product line?	
What do you **like** about our products and services,? *Please give as many examples as you can.*	
What do you **dislike** about our products and services? *Please give as many examples as you can.*	
What could you source from us but choose to procure from a different supplier? What are the factors influencing your decision?	
How thoroughly do you believe we understand your business and are able to add value to you?	
What could we do to satisfy your requirements even more?	
Do you measure our performance internally? How does Prophotonix rate?	
In the next 3-5 years how do you expect your business to change? What support can we provide to ensure that our businesses grow together?	

Customer signature..... Date.....