The Prophotonix (Irl) Ltd
Quality manual

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Revision: D

3020 Euro Business Park,
Little Island, Cork,
Ireland
Tel: +353 (0)21 5001313
Fax: +353 (0)21 4297749
e-mail:

DOCUMENT APPROVAL

Name	Title	Signature	Date:
Paul Wharton	Group Quality Assurance Manager		8/11/13
Simon Stanley	Managing Director		8/11/13

Quality Management System and Policy Commitment

Name	Title	Signature	Date:
Simon Stanley	Managing Director		8/11/13.
Paul Wharton	Group Quality Manager		8/11/13
Linda McCormack	Production Manager		8/11/13
Sean O'Sullivan	Operations Manager		8/11/13
Kevin Lee	Finance Manager		8/11/13.

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

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.

Simon Stanley
Managing Director

COMPANY PROFILE

Prophotonix (IRL) Limited is located at 3020 Euro business Park Little Island, Cork and is a subsidiary of ProPhotonix, which is headquartered in Salem, New Hampshire, USA. (see : www.prophotonix.com). Prophotonix was founded in 1946 as Stocker & Yale, Inc. StockerYale introduced diverse lighting applications to the optical and metrology industries.

Today, Prophotonix is an independent designer and manufacturer of structured light lasers, and LED technologies. Through this diverse product mix, the company serves a wide range of markets including the machine vision, industrial inspection, defense, telecommunication, sensors, and medical markets.

The company in Cork was set up in 1994 (originally known as CorkOpt) and was acquired by StockerYale Corp in 2000 in order to provide LED solutions to the illumination side of the StockerYale business.

To remain an innovative leader, and to continue growing its high-technology markets, Prophotonix invests a significant portion of its earnings into research and development. The company is committed to growing its photonics based business solutions so that its worldwide customers can successfully compete in today's highly competitive technology markets.

Prophotonix operates a paperless filing system called the Alpha System. This system was designed to give the following benefits:

1. Supports our business model. The system has been designed to follow our processes and strategies.
2. Customer focused. By having the customer at the top of the filing tree ensures that all documents, design work, etc. are customer specific.
3. Quality orientated. By having master documents released as PDF's. Then by linking to these released documents in the BOM ensures that the released documents can't be modified and prevents duplication.
4. Flexible. It is an evolving system that can be easily adapted to the company's changing needs. It also standardises the filing of any documents relating to the design / production of all products.
5. Easy to use. By having all folders created automatically, means that each set of folders follow the same structure. In addition document templates, such as BOM's, are also automatically placed in their relevant folder.

Scope

Design, Development and Manufacture of Optoelectronic Components and solutions.

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:

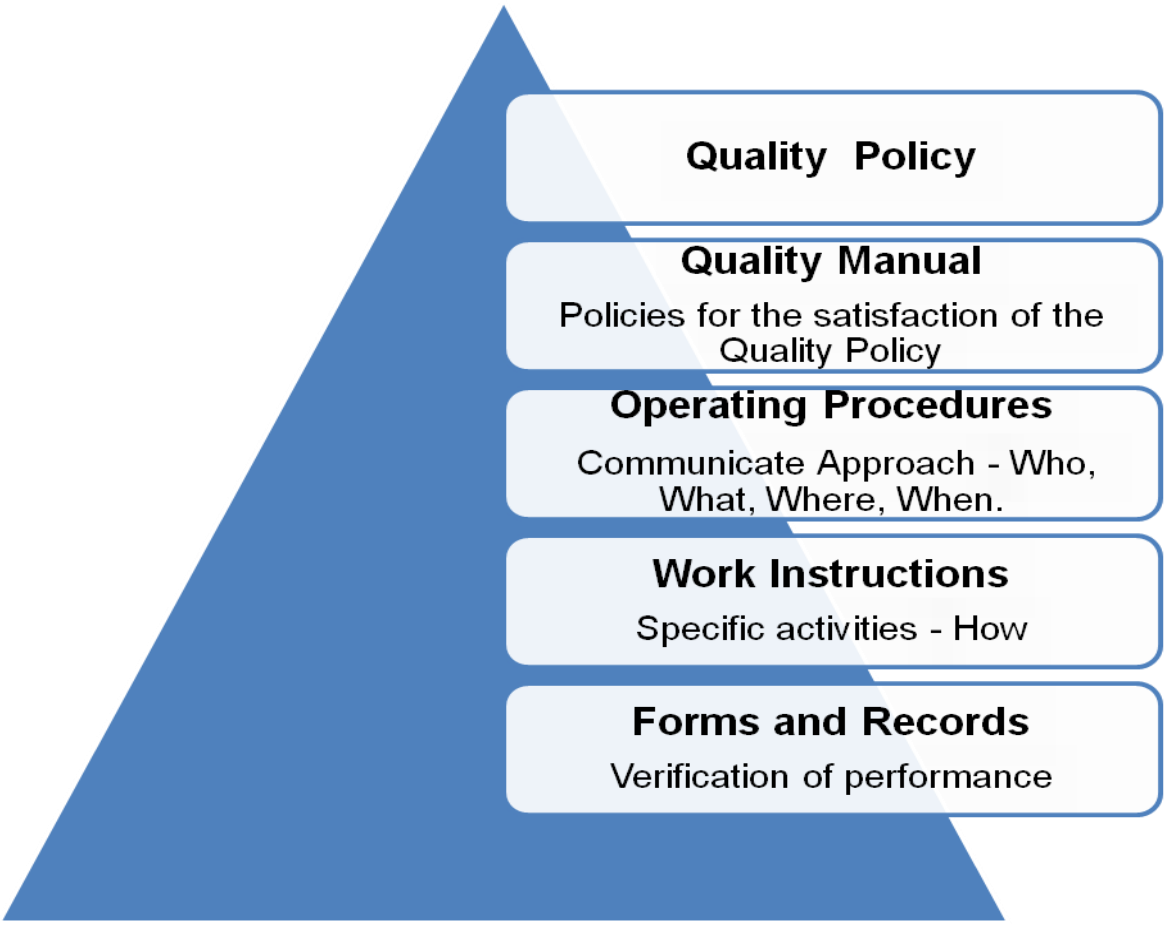
a) The processes needed for the QMS and their application throughout the organization have been determined,
b) The sequence and interaction of these processes has been determined,
c) Determined criteria and methods needed to ensure that the operation and control of the processes are effective.
d) Ensured 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:- Document Control Index
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 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:- Control of Quality Records (QP-0016)

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-0010)
Quality Objectives (QF-0017)

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:- Customer Satisfaction form (QF-0044)
Sales Process Procedure (QP-0012)

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 Objectives (QF-0017)

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 – See Appendix 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.

The QA organisation has the authority to ensure that that non-compliant material/product is segregated and that appropriate disposition action is taken.

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 Monthly. This review assesses the continuing QMS for 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-0010)
Quality Objectives (QF-0017)

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-0010)

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-0010)

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 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-0024)

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 & at management review meetings.
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:- Equipment Maintenance Log

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 Design review procedure (QP-0008). 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:- Product Specification Form (QF-0008)
Enquiry Review Form (QF-0009)
Design Review Procedure (QP-0008)
Design Review Form (QF-0012)

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:- Sales Process Procedure (QP-0012)
Enquiry Review Form (QF-0009)
Design Review Procedure (QP-0008)

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:- Contract Review Form (QF-0010)
Design Review Procedure (QP-0008)

7.2.3 Customer communication

Prophotonix Ltd. has implemented an 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 Design Review Procedure (QP-0008) 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 :- Design Review Procedure (QP-0008)

7.3.2 Design and development inputs

Inputs relating to product requirements are determined and documented according to the Design review Procedure (QP-0010). 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:- Product Specification Form (QF-0008)
Enquiry Review Form (QF-0009)
Design Review Procedure (QP-0008)
Design Review Form (QF-0012)

7.3.3 Design and development outputs

Outputs of design and development are documented according to the Design review Procedure (QP-0010). 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:- Design Review Procedure (QP-0008)
Design Review Form (QF-0012)

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:- Design Review Procedure (QP-0008)
Design Review Form (QF-0012)

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 design Review procedure (QP-0010).

Ref Docs:- Design Review Procedure (QP-0008)
Design Review Form (QF-0012)

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 Design Review Procedure (QP-0010).

Ref Docs:- Design Review Procedure (QP-0008)
Design Review Form (QF-0012)

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:- Documentation Control Procedure (QP-0002)

7.4 Purchasing

7.4.1 Purchasing process

A documented procedure (QP-0011) 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:- Purchasing Procedure (QP-0011)

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:- Purchasing Procedure (QP-0011)

7.4.3 Verification of purchased product

The Purchasing procedure (QP-0011) 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:- Purchasing Procedure (QP-0011)

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

Prophotonix Ltd. validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.
Validation demonstrates the ability of these processes to achieve planned results.
Prophotonix Ltd. has documented the process for validation including:

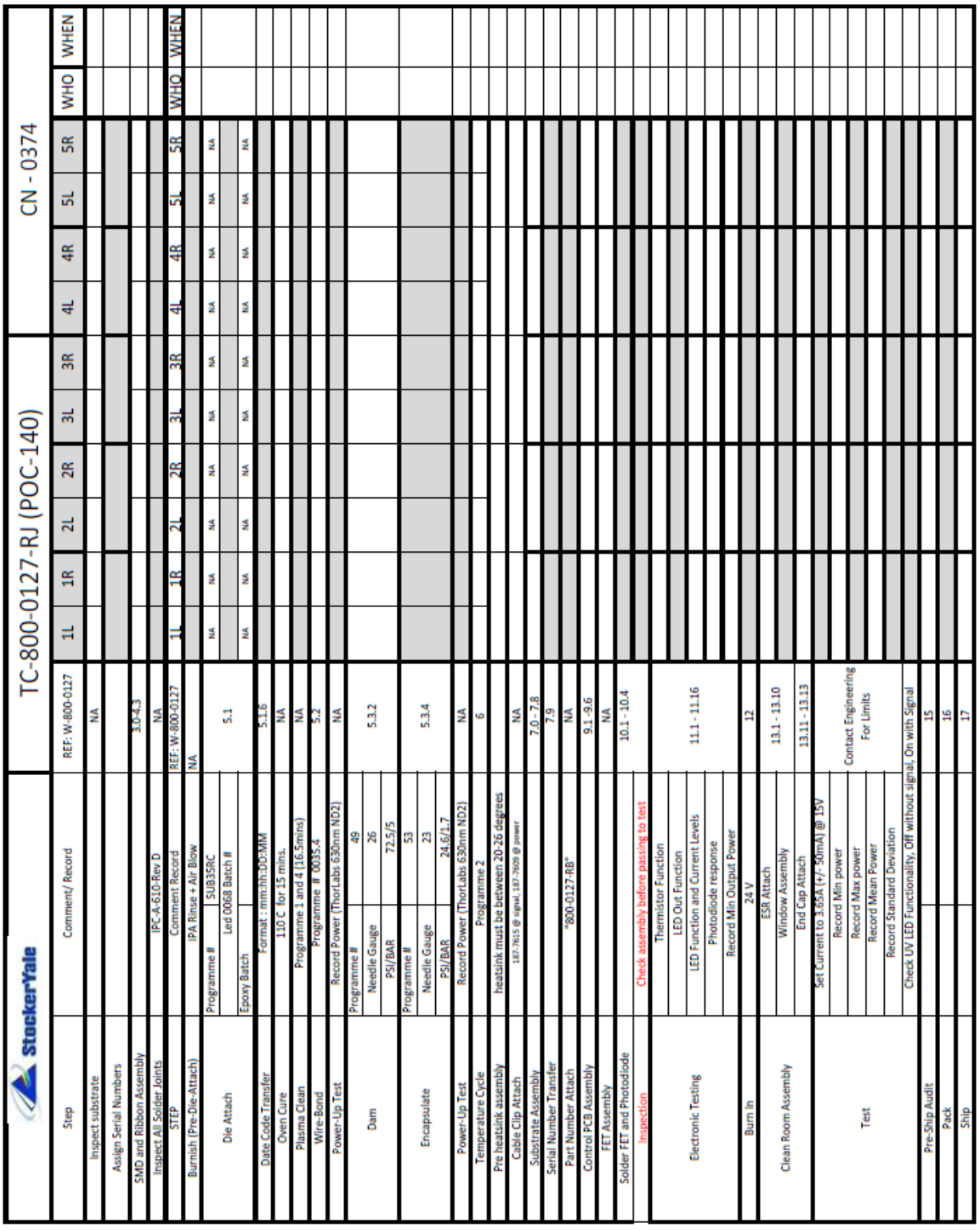
- Defined criteria for review and approval of the processes
- Approval of equipment and qualification of personnel
- Use of specific methods and procedures
- Requirements for records
- Revalidation

Ref Docs:- Identification and Management of special processes (QP-0025)

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



StockerYale — TC-800-0127-RJ (POC-140) — CN - 0374

Step	Comment/ Record	REF: W-800-0127	1L	1R	2L	2R	3L	3R	4L	4R	5L	5R	WHO	WHEN
Inspect substrate		NA												
Assign Serial Numbers														
SMD and Ribbon Assembly		3.0-4.3												
Inspect All Solder Joints	IPC-A-610-Rev D	NA												
STEP	Comment Record	REF: W-800-0127	1L	1R	2L	2R	3L	3R	4L	4R	5L	5R	WHO	WHEN
Burnish (Pre-Die-Attach)	IPA Rinse + Air Blow	NA												
Die Attach	Programme # SUB35RC	5.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
	Led 0068 Batch #													
	Epoxy Batch		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA		
Date Code Transfer	Format : mmchh:DD:MM	5.1.6												
Oven Cure	110 C for 15 mins.	NA												
Plasma Clean	Programme 1 and 4 (16.5mins)	NA												
Wire-Bond	Programme # 0035.4	5.2												
Power-Up Test	Record Power (ThorLabs 630nm ND2)	NA												
Dam	Programme # 49	5.3.2												
	Needle Gauge 26													
	PSI/BAR 72.5/5													
Encapsulate	Programme # 53	5.3.4												
	Needle Gauge 23													
	PSI/BAR 24.6/1.7													
Power-Up Test	Record Power (ThorLabs 630nm ND2)	NA												
Temperature Cycle	Programme 2	6												
Pre heatsink assembly	heatsink must be between 20-26 degrees													
Cable Clip Attach	187-7615 @ signal, 187-7609 @ power	NA												
Substrate Assembly		7.0 - 7.8												
Serial Number Transfer		7.9												
Part Number Attach	"800-0127-RB"	NA												
Control PCB Assembly		9.1 -9.6												
FET Assembly		NA												
Solder FET and Photodiode		10.1 - 10.4												
Inspection	Check assembly before passing to test													
Electronic Testing	Thermistor Function	11.1 - 11.16												
	LED Out Function													
	LED Function and Current Levels													
	Photodiode response													
	Record Min Output Power													
Burn In	24 V	12												
Clean Room Assembly	ESR Attach	13.1 - 13.10												
	Window Assembly													
	End Cap Attach	13.11 - 13.13												
Test	Set Current to 3.65A (+/- 50mA) @ 15V	Contact Engineering For Limits												
	Record Min power													
	Record Max power													
	Record Mean Power													
	Record Standard Deviation													
	Check UV LED Functionality, Off without signal, On with Signal													
Pre-Ship Audit		15												
Pack		16												
Ship		17												

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 managed in accordance with Customer Property procedure (QP-0026) which details the Identification, verification, protection and safeguarding of customer property. 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:- Control of Customer Property (QP-0026)

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 (SOP-0008)

Ref Docs:- Procedure for packing finished product including customer specific labeling (SOP-0008)

7.6 Control of monitoring and measuring equipment

A documented procedure (QP-0022) 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-0022)

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 Customer Satisfaction Survey Procedure (QP-0027).
Further analysis is carried out of customer complaints and returned goods data.

Ref Docs:- Customer Satisfaction Survey Procedure (QP-0027)

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-0015).
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-0015)

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 design review process.

Ref docs:- Design Review Procedure (QP-0008)

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
Monitoring and Measuring of Process Data in Production (QP-0018)

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:- Non-Conformance Control Procedure (QP-0005)

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-0010)

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 (QP-0014) 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:- Corrective and Preventive Action Procedure (QP-0014)

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:- Corrective and Preventive Action Procedure (QP-0014)

9 Appendix 1 - ORGANISATION CHART