



7799 McHenry Street, Meadville, PA, 16335

# *Quality Manual*

Based upon ISO 9001:2015

Issued by: 

Approved by: 

# Table of Contents

- 1.0 Introduction.....5
  - 1.1 Phoenix Laser Solutions.....5
  - 1.2 Phoenix Laser Quality Management System.....5
  - 1.3 The Scope .....5
- 2.0 Quality Policy.....5
- 3.0 Terms and Definitions .....6
- 4.0 Context of the organization .....6
  - 4.1 Understanding the organization and its context.....6
  - 4.2 Understanding the needs and expectations of interested parties .....6
  - 4.3 Determining the scope of the quality management system.....6
  - 4.4 Quality management system and its processes.....6
    - 4.4.1.....6
    - 4.4.2.....7
- 5.0 Leadership .....7
  - 5.1 Leadership and commitment .....7
    - 5.1.1 General .....7
    - 5.1.2 Customer Focus.....7
  - 5.2 Policy .....7
  - 5.3 Organizational roles, responsibilities and authorities.....8
- 6.0 Planning.....8
  - 6.1 Actions to address risks and opportunities .....8
  - 6.2 Quality objectives and planning to achieve them .....8
    - 6.2.1.....8
    - 6.2.2.....9
  - 6.3 Planning of Changes .....9
- 7.0 Support.....9
  - 7.1 Resources .....9
    - 7.1.1 General .....9
    - 7.1.2 People.....9
    - 7.1.3 Infrastructure .....9
    - 7.1.4 Environment for the operation of processes .....10
    - 7.1.5 Monitoring and measuring resources .....10

7.1.6	Organizational Knowledge .....	10
7.2	Competence .....	10
7.3	Awareness .....	11
7.4	Communication .....	11
7.5	Documented information.....	11
7.5.1	General .....	11
7.5.2	Creating and Updating .....	11
7.5.3	Control of documentation information.....	11
8.0	Operation .....	12
8.1	Operational planning and control .....	12
8.2	Requirements for products and services .....	12
8.2.1	Customer communication .....	12
8.2.2	Determining the requirements for products and services;.....	12
8.2.3	Review of the requirements for products and services .....	12
8.2.4	Changes to requirements for products and services .....	13
8.3	Design and development of products and services .....	13
8.3.1	General .....	13
	Phoenix Laser maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.....	13
8.3.2	Design and development planning.....	13
8.3.3	Design and development inputs.....	13
8.3.4	Design and development controls .....	14
8.3.5	Design and development outputs .....	14
8.3.6	Design and development changes.....	14
8.4	Control of externally provided processes, products, and services .....	14
8.4.1	General .....	14
8.4.2	Type and extent of control .....	15
8.4.3	Information for external providers .....	15
8.5	Production and service provision .....	16
8.5.1	Control of production and service provision.....	16
8.5.2	Identification and traceability .....	18
8.5.3	Property belonging to customers or external providers.....	18
8.5.4	Preservation .....	18

8.5.5	Post-delivery activities .....	19
8.5.6	Control of changes.....	19
8.6	Release of products and services .....	19
8.7	Control of nonconforming outputs .....	19
8.7.1	.....	19
8.7.2	.....	20
9.0	Performance Evaluation .....	21
9.1	Monitoring, Measurement, Analysis, and Evaluation .....	21
9.1.1	General .....	21
9.1.2	Customer satisfaction.....	21
9.2	Internal audit.....	21
9.2.1	.....	21
9.2.2	.....	21
9.3	Management Review .....	22
9.3.1	General .....	22
9.3.2	Management review inputs .....	22
9.3.3	Management review outputs.....	22
10.0	Improvement.....	23
10.1	General.....	23
10.2	Nonconformity and action .....	23
10.2.1	.....	23
10.2.2	.....	23
10.3	Continual improvement .....	23
11.0	Organization Chart .....	24

# Phoenix Laser Solutions Quality Management System

## 1.0 Introduction

### 1.1 Phoenix Laser Solutions

Phoenix Laser Solutions (PLS) develops, manufactures, and markets innovative laser welding techniques. Phoenix Laser Solutions (PLS), a privately-owned company, originated in Meadville, Pennsylvania and was founded in 2007, specializes in laser welding, engraving, waterjet, metallography, and EDM graphite parts for diverse industries.

### 1.2 Phoenix Laser Quality Management System

Phoenix Laser Solutions quality management system (QMS) meets the requirements of ISO 9001:2015 and specific customer requirements.

Key for quality system requirements:

ISO9001:2015                      Selections in regular type apply across the organization.

The purpose of the Quality Manual is to document the quality system and policies and to inform Phoenix customers of the controls implemented to assure product quality. The Quality Manual provides for a quality management system to:

- a) Consistently provide products that meet customer and applicable requirements.
- b) Enhance customer satisfaction through effective application of the quality system, including processes for continual improvement of the system and assurance of conformity to customer and applicable requirements.

### 1.3 The Scope

The scope of this quality system is the following areas of Phoenix Laser Solutions,

- a) Laser Welding
- b) Cladding
- c) Laser Engraving
- d) Waterjet
- e) Machining

This manual and the quality system registration certificates are available for review at [www.phoenixlaser.com](http://www.phoenixlaser.com)

## 2.0 Quality Policy

Phoenix Laser Solutions is committed to providing quality products and service that meets customers' expectations of quality and value. Monitoring and continuously improve our processes to ensure overall customer satisfaction, achieve our quality objectives, and utilize best practices.

This quality policy has been established to guide the actions of all employees regarding quality. To ensure that it is understood and implemented at all levels of Phoenix Laser Solutions, the quality policy is explained and discussed during general orientation of new employees and is reviewed annually with all employees.

All employees are responsible for understanding their customers' and co-workers' requirements and the processes by which they are met, and for performing these processes as defined. In addition, all employees are empowered to initiate improvement actions within established change guidelines and are expected to participate in formal improvement initiatives to assure that changing customer and co-worker value expectations are continually met.

### 3.0 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

### 4.0 Context of the organization

#### 4.1 Understanding the organization and its context

Phoenix Laser determines external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. Phoenix Laser Solutions monitors and reviews information regarding these issues.

#### 4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services to meet customer and applicable requirements, Phoenix Laser determines, monitors, and reviews information in relation to:

- a) The interested parties that are relevant to the quality management system;
- b) The requirements of these interested parties that are relevant to the quality management system.

#### 4.3 Determining the scope of the quality management system

Phoenix Laser has considered the following and determined the scope of the quality management system;

- a) External and internal issues;
- b) Requirements of relevant interested parties;
- c) Products and services of the organization.

Phoenix Laser applies the requirements of ISO 9001:2015, as they are applicable with in the determined scope of the Quality Management System (QMS).

#### 4.4 Quality management system and its processes

##### 4.4.1

Phoenix Laser maintains and implements a documented quality management system (QMS) and continually improves its effectiveness in accordance with the requirements of the applicable quality system standards and specific customer requirements.

Phoenix Laser determines the processes needed for the QMS and their application throughout Phoenix Laser Solutions;

- a) determines the inputs required and the outputs expected from these processes;
- b) determines the sequence and interaction of these processes;
- c) determines and applies criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) assigns the responsibilities and authorities for these processes;
- f) addresses the risks and opportunities in these processes;
- g) evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results;
- h) improves the processes and the QMS.

#### 4.4.2

Phoenix Laser maintains documented information to support the operation of its processes and retains documented information to have confidence that the processes are being carried out as planned.

## 5.0 Leadership

### 5.1 Leadership and commitment

#### 5.1.1 General

Upper management provides evidence of its leadership and commitment to the development and implementation of the QMS and continually improving its effectiveness by:

- a) Taking accountability for the effectiveness of the QMS;
- b) Ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the context and strategic direction of the organization;
- c) Ensuring the integration of the QMS requirements into the Phoenix Laser business processes;
- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring the resources needed for the quality QMS are available;
- f) Communicating the importance of effective quality management and of conforming to the QMS requirements;
- g) Ensuring that the QMS achieves its intended results;
- h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) Promoting improvement;
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### 5.1.2 Customer Focus

Upper management ensures that customer requirements are determined, understood and met with the aim of enhancing customer satisfaction, by ensuring the establishment of processes for identification, review and implementation of customer requirements and monitoring of customer satisfaction.

### 5.2 Policy (reference section 2.0 of this manual)

Upper Management ensures that the quality policy:

- a) Is appropriate to the purpose and context of Phoenix Laser and supports its strategic direction;

- b) Provides a framework for setting quality objectives;
- c) Includes a commitment to satisfy applicable requirements;
- d) Includes a commitment to continual improvement of the quality management system.

The quality policy is maintained as a documented information in F-1017. The policy is communicated, understood and applied within the organization.

### 5.3 Organizational roles, responsibilities and authorities

Upper management defines and communicates responsibilities and authorities for relevant roles within Phoenix Laser through organization charts, position descriptions, and operating policies and procedures. This includes responsibilities and authorities for;

- a) Ensuring that the quality management system conforms to the requirements of the applicable international standards;
- b) Ensuring that the processes are delivering their intend outputs;
- c) Reporting on the performance of the QMS and on opportunities for improvement to top management;
- d) Ensuring the promotion of customer focus throughout Phoenix Laser;
- e) Ensuring that the integrity of the QMS maintains when changes to the QMS are planned and implemented.

## 6.0 Planning

### 6.1 Actions to address risks and opportunities

Upper management ensure that when planning for the QMS, Phoenix Laser shall consider the issues referred to in 3.1 and the requirements referred to in 3.2 and determine the risks and opportunities that need to be addresses to:

- a) Give assurance that the quality management system can achieve its intended result(s);
- b) Enhance desirable effects;
- c) Prevent, or reduce, undesired effects;
- d) Achieve improvement.

Phoenix Laser upper management shall plan:

- a) Actions to address these risks and opportunities;
- b) How to:
  - a. Integrate and implement the actions into QMS processes
  - b. Evaluate the effectiveness of these actions.

### 6.2 Quality objectives and planning to achieve them

#### 6.2.1

Upper management ensures that quality objectives, including those needed to meet product requirements, and to deploy the quality policy, are established and documented at relevant functions and levels within the organization. They will be updated as found appropriate by management.

Phoenix Laser Quality objects are:



- a) consistent with the quality policy;
- b) measurable;
- c) consider applicable requirements;
- d) are relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) are monitored;
- f) are communicated;
- g) are updated as appropriate.

## 6.2.2

When planning how to achieve its quality objectives, Phoenix Laser determines:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

## 6.3 Planning of Changes

Upper management ensures that the integrity of the QMS is maintained when changes to the QMS are planned and implemented. Changes to the quality system are approved by applicable customers, if required, prior to implementation. When planning changes Phoenix Laser considers:

- a) The purpose of changes and their potential consequences;
- b) The integrity of the QMS;
- c) The availability of resources;
- d) The allocation or reallocation of responsibilities and authorities.

## 7.0 Support

### 7.1 Resources

#### 7.1.1 General

Phoenix Laser determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS. Phoenix Laser considers:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

#### 7.1.2 People

Phoenix Laser determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

#### 7.1.3 Infrastructure

Phoenix Laser determines, provides, and maintains the infrastructure necessary for the operation of its processes; and to achieve conformity of products and services to include:

- a) building and associated utilities;
- b) equipment, including hardware and software;

- c) transportation resources;
- d) information and communication technology.

#### 7.1.4 Environment for the operation of processes

Phoenix Laser determines and manages the work environment needed to achieve conformity to product requirements. Additionally, Phoenix Laser strives to ensure productive, quality-oriented employees by providing appropriate compensation and a safe and healthy work.

#### 7.1.5 Monitoring and measuring resources

##### 7.1.5.1 General

Phoenix Laser determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

Phoenix Laser ensures that the resources provided for monitoring and measurement are suitable for the specific type of monitoring and measurement activities being undertaken. The resources are maintained to ensure their continuing fitness for purpose.

##### 7.1.5.2 Measurement Traceability

When measurement traceability is a requirement, or is an essential part of providing confidence in the validity of measurement results, measuring equipment is:

- a) calibrated or verified, or both at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results.

Phoenix Laser determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose and takes appropriate action as necessary.

#### 7.1.6 Organizational Knowledge

Phoenix Laser determines the knowledge necessary for the operation of processes and to achieve conformity of products and services. Phoenix Laser strives to maintain this knowledge and make available to the correct persons at the extent needed to ensure continuances of processes. Phoenix Laser reviews changing needs and trends and considers its current knowledge and determines whether to acquire any necessary additional knowledge and required updates. Phoenix Laser reviews skill levels and needs within processes ongoing and adjusts to future needs and requirements.

## 7.2 Competence

Personnel performing work directly or indirectly affecting conformity to product requirements are competent based on appropriate education, training, skills, and experience.

Phoenix Laser assures that personnel are adequately prepared for their responsibilities. Upper management:

- a) determines the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable, provides training or takes other actions to achieve the necessary competence,
- c) evaluates the effectiveness of the actions taken,
- d) ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and maintains appropriate records of education, training, skills, and experience.

### 7.3 Awareness

Phoenix Laser ensures that persons performing work are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) the implications of not conforming with quality management system requirements;

### 7.4 Communication

Phoenix Laser has established appropriate internal and external communication processes and communicates information regarding the QMS including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

### 7.5 Documented information

#### 7.5.1 General

Phoenix Laser quality management system includes:

- a) documented information required by the relevant international standards;
- b) documented information determined to be necessary for the effectiveness of the QMS.

#### 7.5.2 Creating and Updating

When creating and updating documentation information, Phoenix Laser ensures appropriate:

- a) identification and description (title, date, owner, document number)
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

#### 7.5.3 Control of documentation information

##### 7.5.3.1

Documented information required by the QMS and by relevant international standards is controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

### 7.5.3.2

A documented process is maintained to define the controls needed:

- a) to ensure proper distribution, access, retrieval and use;
- b) to ensure proper storage and preservation, including preservation of legibility;
- c) to ensure control of changes;
- d) to ensure that documents of external origin that are necessary as determined by Phoenix Laser for the planning and operation of the QMS are identified and their distribution controlled
- e) for retention and disposition;

## 8.0 Operation

### 8.1 Operational planning and control

### 8.2 Requirements for products and services

#### 8.2.1 Customer communication

Phoenix Laser determines and implements effective arrangements for communicating with customers in relation to:

- a) providing information in relation to products and services;
- b) handling enquiries, contract, or order handling, including changes;
- c) customer feedback, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

#### 8.2.2 Determining the requirements for products and services;

When determining the requirements for the products and services to be offered to customers, Phoenix Laser ensures that:

- a) the requirements for the products and services are defined
  - a. any applicable requirements;
  - b. those considered necessary by Phoenix Laser;
- b) the claims for the products and services offered, can be met.

#### 8.2.3 Review of the requirements for products and services

Phoenix Laser reviews the requirements related to products and services, during quotation or order review/entry. This review is conducted prior to Phoenix Laser commitment to supply a product to the customer and includes:

- a) requirements specified by customer, including the requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) requirements specified by Phoenix Laser;
- d) statutory and regulatory requirements applicable to the products and services;

Where the customer provides no documented statement of requirement, Phoenix Laser confirms the customer requirements before acceptance via a written document provided to the customer.

Where product requirements are changed, Phoenix Laser ensures that the relevant documents are amended and that relevant personnel are made aware of the changed requirements.

#### 8.2.3.2

Documented information is retained on the results of the review and on any new requirements for the products and services.

#### 8.2.4 Changes to requirements for products and services

Phoenix Laser ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

### 8.3 Design and development of products and services

#### 8.3.1 General

Phoenix Laser maintains a design and development process that is appropriate to ensure the subsequent provision of products and services.

#### 8.3.2 Design and development planning

During the design and development planning, Phoenix Laser considers:

- a) nature, duration, and complexity of the design and development activities;
- b) required process stages, including applicable design and development reviews;
- c) required design and development verification and validation activities;
- d) responsibilities and authorities involved in the design and development process;
- e) internal and external resource needs for the design and development of products and services;
- f) need to control interfaces between persons involved in the design and development process;
- g) need for involvement of customers and users in the design and development process;
- h) requirements for subsequent provision of products and service;
- i) level of control expected for the design and development process by customers and other relevant interested parties;
- j) documented information needed to demonstrate the design and development requirements have been met.

#### 8.3.3 Design and development inputs

In determining the requirements essential for the specific type of products and services to be designed and developed. Phoenix Laser considers:

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) customer requirement
- d) standards or codes of practice that Phoenix Laser has committed to implement;
- e) potential consequences of failure due to the nature of the product and services.

Inputs are adequate for design and development purpose, complete and unambiguous. All conflicting design and development inputs are resolved. Documented information on design and development inputs are retained.

#### 8.3.4 Design and development controls

- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) documented information of these activities is retained.

#### 8.3.5 Design and development outputs

Phoenix Laser ensures that design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

Phoenix Laser retains documented information on design and development inputs.

#### 8.3.6 Design and development changes

Phoenix Laser identifies, reviews, and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

Documented information is retained on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

### 8.4 Control of externally provided processes, products, and services

#### 8.4.1 General

Phoenix Laser ensures that externally provide processes, products and services conform to requirements.

Phoenix Laser determines the controls to be applied to externally provided processes, products and services when:

- a) products and services from external providers are intended for incorporation into Phoenix Laser products and services;
- b) products and services are provided directly to the customer by external providers on behalf of Phoenix Laser;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by Phoenix Laser.

Criteria is determined and applied for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. Documented information is retained on these activities and any necessary actions arising from the evaluations.

#### 8.4.1.1 Phoenix Laser Solutions

- a) defines the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
- b) maintains a register of its external providers that includes approval status (e.g., approved, conditional, disapproved) and the scope of approval (e.g., product type, process family);
- c) periodically reviews external provider performance including process, product and service conformity, and on-time delivery performance;
- d) defines the necessary actions to take when dealing with external providers that do not meet requirements;
- e) defines the requirements for controlling documented information created by and/or retained by external providers.

#### 8.4.2 Type and extent of control

Phoenix Laser ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers by:

- a) ensuring that externally provided processes remain within the control of its quality management system;
- b) defining both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) taking into consideration:
  1. the potential impact of the externally provided processes, products, and services on Phoenix Laser's ability to consistently meet customer and applicable statutory and regulatory requirements;
  2. the effectiveness of the controls applied by the external provider;
  3. the results of the periodic review of external provider performance;
- d) determining the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

#### 8.4.3 Information for external providers

Phoenix Laser ensures the adequacy of requirements prior to their communication to the external provider:

- a) the processes, products and services to be provided [including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions)];
- b) the approval of:
  - a. products and services;
  - b. methods, processes and equipment;
  - c. the release of products and services;
- c) competence, including and required qualification of persons;
- d) the external providers interactions with Phoenix Laser;
- e) control and monitoring of the external providers performance to be applied by Phoenix Laser;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers premises.
- g) design and development control;
- h) special requirements, critical items, or key characteristics;
- i) test, inspection, and verification (including production process verification);
- j) the use of statistical techniques for product acceptance and related instructions for acceptance by the organization;
- k) the need to:
  - a. implement a quality management system;
  - b. use customer-designated or approved external providers, including process sources (e.g., special processes);
  - c. notify the organization of nonconforming processes, products, or services and obtain approval for their disposition;
  - d. prevent the use of counterfeit parts;
  - e. notify Phoenix Laser of changes to the processes, products, or services, including changes of their external providers, location of manufacture, and obtain the organization's approval.
  - f. flow down the external providers applicable requirements including customer requirements;
  - g. provide test specimens for design approval, inspection/verification, investigation, or auditing;
  - h. retain documented information, including retention periods and disposition requirements;
- l) the right of access by Phoenix Laser, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
- m) ensuring that persons are aware of:
  - a. their contribution to product service conformity;
  - b. their contribution to product safety;
  - c. the importance of ethical behavior.

## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

Phoenix Laser maintains production and service provision under controlled conditions, including as applicable:

- a) the availability of documented information that defines:



- a. the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
- b. the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
  - a. ensuring that documented information for monitoring and measurement activity for product acceptance includes:
    - 1. criteria for acceptance and rejection;
    - 2. where in the sequence verification operations are to be performed;
    - 3. measurement results to be retained (at a minimum an indication of acceptance or rejection);
    - 4. any specific monitoring and measurement equipment required and instructions associated with their use;
  - b. ensuring that when sampling is used as a means of product acceptance, the sampling plan is justified and appropriate for use.]
- d) the use of suitable infrastructure and environment for the operation of processes;
- e) the appointment of competent persons, including any required qualification;
- f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery and post-delivery activities.
- i) [the establishment of criteria for workmanship;
- j) the accountability for all products during production;
- k) the control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- l) the determination of methods to measure variable data;
- m) the identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
- n) the availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- o) the provision for the prevention, detection, and removal of foreign objects;
- p) the control and monitoring of utilities and supplies to the extent they affect conformity to product requirements;
- q) the identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

#### 8.5.1.1 Control of equipment, tools, and software programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are maintained.

Storage requirements are defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks.

#### 8.5.1.2 Validation and control of special processes

For processes where resulting output cannot be verified by subsequent monitoring or measurement, Phoenix Laser establishes arrangements for these processes including, as applicable:

- a) definition of criteria for the review and approval of the processes;
- b) determination of conditions to maintain the approval;
- c) approval of facilities and equipment;
- d) qualification of persons;
- e) use of specific methods and procedures for implementation and monitoring the processes;
- f) requirements for documented information to be retained.

#### 8.5.1.3 Production process verification

Phoenix Laser maintains production process verification activities to ensure the production process can produce products that meet requirements.

Phoenix Laser's system uses a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling can produce parts and assemblies that meet requirements. This process is repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

Phoenix Laser maintains documented information on the results of production process verification (FAI).

#### 8.5.2 Identification and traceability

Phoenix Laser uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The status of outputs is identified with respect to monitoring and measurement requirements throughout production and service provision. Phoenix Laser controls the unique identification of the outputs when traceability is a requirement and retains the documented information necessary to enable traceability.

#### 8.5.3 Property belonging to customers or external providers

Phoenix Laser exercises care with customer property while it is under Phoenix Laser's control or being used by Phoenix Laser. Phoenix Laser identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the product and services. If the customers' or external providers' property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer or external provider and records maintained.

#### 8.5.4 Preservation

Phoenix Laser preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

Preservation of outputs includes, when in applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:

- a) cleaning;
- b) prevention, detection, and removal of foreign objects;
- c) special handling and storage for sensitive products;

- d) marking and labeling, including safety warnings and cautions
- e) shelf life control and stock rotation;
- f) special handling and storage for hazardous materials.

#### 8.5.5 Post-delivery activities

Phoenix Laser meets requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the following are considered:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback;
- f) [collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
- g) control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
- h) controls required for work undertaken external to the organization (e.g., off-site work);
- i) product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

When problems are detected after delivery, Phoenix Laser takes appropriate action including investigation and reporting.

#### 8.5.6 Control of changes

Phoenix Laser reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. Documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review is retained.

#### 8.6 Release of products and services

Phoenix Laser implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Phoenix Laser retains documented information on the release of the products and services. The documented information includes:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

#### 8.7 Control of nonconforming outputs

##### 8.7.1

Phoenix Laser ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

Phoenix Laser takes appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This applies to nonconforming products and services detected after delivery of products, during or after the provision of services.

Phoenix Laser nonconformity control process is maintained as documented information including the provisions for:

- a) defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- b) taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
- c) timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- d) defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.

Phoenix Laser deals with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession [by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products is only implemented:

- a) after approval by an authorized representative of the organization responsible for design or by persons having delegated authority from the design organization;
- b) after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap is conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements is verified when nonconforming outputs are corrected.

#### 8.7.2

Phoenix Laser retains documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the nonconformity.

## 9.0 Performance Evaluation

### 9.1 Monitoring, Measurement, Analysis, and Evaluation

#### 9.1.1 General

Phoenix Laser determines:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when monitoring and measuring is performed;
- d) when the results from monitoring and measurement shall be analyzed and evaluated.

Phoenix Laser evaluates the performance and the effectiveness of the quality management system. Phoenix Laser retains appropriate documented information as evidence of the results.

#### 9.1.2 Customer satisfaction

Phoenix Laser monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled. Phoenix Laser monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled.

#### 9.1.3 Analysis and evaluation

Phoenix Laser analyzes and evaluates appropriate data and information arising from monitoring and measurement. The results of analysis are used to evaluate:

- a) Conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

## 9.2 Internal audit

### 9.2.1

Phoenix Laser conducts internal audits at planned intervals to determine whether the quality management system:

- a) conforms to the planned arrangements, applicable QMS standards, customer requirements, applicable statutory and regulatory authority requirements and the QMS requirements established by Phoenix Laser, and
- b) is effectively implemented and maintained.

### 9.2.2

Phoenix Laser includes the following in the internal audit program:

- a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of the previous audits;
- b) define the audit criteria and scope for each audit;

- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective action without undue delay;
- f) retain documented information as evidence of the implementation of the audit program and the audit results.

### 9.3 Management Review

#### 9.3.1 General

Top management reviews the organization's management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with Phoenix Laser's strategic direction.

#### 9.3.2 Management review inputs

Management review is planned and carried out, taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the QMS;
- c) information on the performance and effectiveness of the quality management system, including trends in:
  - a. customer satisfaction and feedback from relevant interested parties;
  - b. the extent to which quality objectives have been met;
  - c. process performance and conformity of products and services;
  - d. nonconformities and corrective actions;
  - e. monitoring and measurement results;
  - f. audit results;
  - g. the performance of external providers;
  - h. on-time delivery performance;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) opportunities for improvement;

#### 9.3.3 Management review outputs

The outputs of the management review include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs;
- d) risks identified.

Phoenix Laser retains documented information as evidence of the results of management reviews.

## 10.0 Improvement

### 10.1 General

Phoenix Laser determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These opportunities include:

- a) improving products and service to meet requirements as well as to address future needs and expectations;
- b) correcting, preventing or reducing undesired effects;
- c) improving the performance and effectiveness of the QMS.

### 10.2 Nonconformity and action

#### 10.2.1

When a nonconformity occurs, including any arising from complaints, LORD:

- a) reacts to the nonconformity and, as applicable:
  - a. takes action to control and correct, it;
  - b. deal with the consequences;
- b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - a. reviewing and analyzing the nonconformity;
  - b. determining the causes of the nonconformity;
  - c. determining if similar nonconformities exist, or could potentially occur;
- c) implements any action needed;
- d) reviews the effectiveness of any corrective action taken;
- e) updates risks and opportunities determined during planning, if necessary;
- f) makes changes to the QMS, if necessary.
- g) flows down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
- h) takes specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Phoenix Laser maintains documented information that defines the nonconformity and corrective action management processes.

#### 10.2.2

Phoenix Laser retains documented information as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

### 10.3 Continual improvement

Phoenix Laser continually improves the suitability, adequacy, and effectiveness of the QMS. Phoenix Laser considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities to address as part of continual improvement.

Phoenix Laser monitors the implementation of improvement activities and evaluates the effectiveness of the results.

### 11.0 Organization Chart

