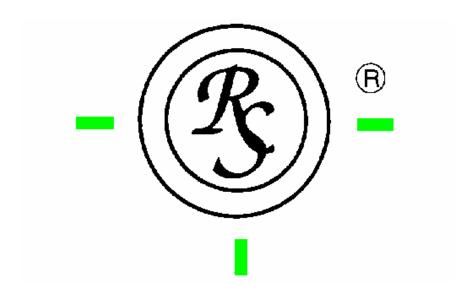
World Leaders in Unit Power Sights



# **QUALITY MANUAL**

# Copy no 1

Date of issue 24 January 2011

This quality manual is approved by the Board of Ring Sights Defence Group Ltd. It is accepted at all levels within the Company as formal company policy and is available to all employees.

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AMENDMENTS			
DATE	PARAGRAPH AMENDED	REASON	Issue No.
11/04/03	all	Complete reissue for ISO9001:2000	8.0
07/08/03	1.2 application	Error	8.0a
20/10/04	Title changes	Company title change	8.0b
26/11/04	Document Change Form	To reflect procedures	8.0c
04/05/05	VQ1 Vendor Questionnaire	Questions Amended	8.0d
05/08/05	New Skills Matrix TR1 Training DCF1	Added Skill Matrix added 2 new entries	8.0e
13/10/05	All	Updated and reissued	9.0
30/09/06	All	Updated and reissued following relocation	10.0
6/09/07	References added in Section 2 Computer back up process	Regulations added Added into document control	11.0
05/06/09	All	Updated to ISO9001:2008	12.0
	Not used	Not used	13.0
24/01/11	All	Company relocation	14.0
	-		

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### PROCESS OVERVIEW.

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### **PROCEDURES REQUIRED BY ISO9001**

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QP 2	CONTROL OF RECORDS	(4.2.4)
QP3	INTERNAL AUDIT	(8.2.2)
QP4	CONTROL OF NONCONFORMING PRODUCT	(8.3)
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# **PART TWO**

## **WORK INSTRUCTIONS**

IC1	Internal Communication	(5.5.3)
MP1	Management Review	(5.6)
TR1	Training	(6.2.2)
OF1	Order Review	(7.2)
DE1	Design & Development	(7.3)
SCE1	Evaluation of Suppliers/subcontractors	(7.4.1)
QA2000	Supplier Inspection Programme	(7.4.3)
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PU1	Purchase orders	(7.4.2)
CS1	Customer Satisfaction	(8.2.1)
DEFCON 129	MOD Packaging	

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# PART THREE FORMS IN USE

DCF1 Document Change Form

SA1 Sales Enquiry

OAF Order Analysis Form
BL2 Assembly Build List
CCO1 Certificate of Conformity

PF1 Project File Label

MRA1 Management Review Agenda QR002 Quality Deficiency Report

APL1 Audit Plan

APR1 Audit Preparation

ANCR1 Audit NCR AREP1 Audit Report

NEW New Employee induction form

SM1 Skills Matrix

SQ1 Supplier Questionnaire

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#### 0. INTRODUCTION

The Company to which this quality document refers is the business of:

Ring Sights Defence Group Ltd Ring Sights Dynamics Ltd Harbour Road Rye East Sussex TN31 7TE

hereinafter called The Company

Tel No. +44 (0) 1797 226279 +44 (0) 8700 422260 Fax No. +44 (0) 1797 272663 +44 (0) 8700 422261 E-Mail. defence@ringsights.com Web-site www.ringsights.com

The Company is primarily an optical weapon-sighting supplier.

#### 1. SCOPE

#### 1.1 GENERAL

The scope of this application covers the quality management system employed by the Company to meet the requirements of ISO9001: 2008 for the:

 Design and procurement of components and assemblies to meet customers' specifications, predominantly within the Defence Industry.

#### 1.2 APPLICATION

The Company does not carry out any of the manufacturing processes and therefore 7.5.2, 7.5.5 and 7.6 of the standard ISO9001: 2008 are excluded. However the Company does ensure control over sub-contractors by selection of assessed suppliers/sub-contractors and an adequate supplier inspection programme.

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#### 2. NORMATIVE REFERENCE

The following references have been used:

BS EN ISO 9001: 2008 Quality Management System - Requirements

BS EN ISO 9000: 2005 Quality Management System - Fundamentals and

Vocabulary

BS EN ISO 9004: 2009 Managing for the sustained success of an

organisation – A Quality Management Approach

BS EN ISO 19011: 2002 Quality/Environmental Auditing Requirements

FIREARMS ACT: 1968 (as amended)

**Export Control Act 2002** 

Section 1, Section 5 Firearms

**OIEL Export Licences** 

HMC& E Export/Import of Firearms

**MOD Quality** 

**RADIOACTIVE SUBSTANCES ACT 1993** 

DAOS

#### 3. TERMS AND DEFINITIONS

The terms and definitions contained in ISO9000: 2005 are used.

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#### 4. QUALITY MANAGEMENT SYSTEM

#### 4.1 GENERAL REQUIREMENTS

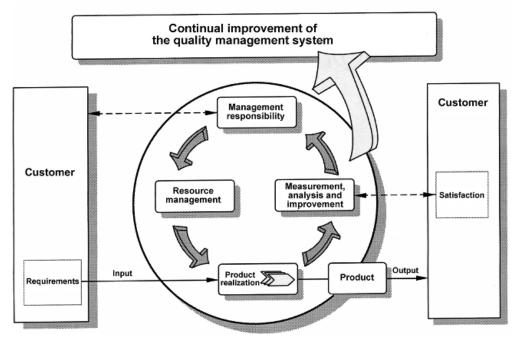
The Company has established, documented, implemented and maintains a quality management system and continually improves its effectiveness in accordance with the International Standard ISO9001:2008

#### The Company:

- Determines the processes needed for the quality management system and their application throughout the organisation;
- Determines the sequence and interaction of these processes;
- Determines criteria and methods needed to ensure that both the operation and control of these processes are effective;
- Ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- Monitors, measures, where applicable, and analyses these processes;
- Implements actions necessary to achieve planned results and continual improvement of these processes;

These processes are managed by the Company in accordance with the requirements of ISO9001:2008.

The model used is that contained in ISO 9001: 2008 Standard.



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#### 4.2 DOCUMENTATION REQUIREMENTS

#### 4.2.1 GENERAL

The Company has a documented quality management system, which includes:

- Documented statements of a quality policy and quality objectives;
- A quality manual;
- Documented procedures and records required by ISO9001:2008;
- Documents, including records needed by The Company to be necessary to ensure effective planning, operation and control of its processes;

#### 4.2.2 QUALITY MANUAL

The Company has established and maintains a quality manual that includes:

- The scope of the quality management system and exclusions;
- Documented procedures established for the quality management system or reference to them;
- A description of the interaction between the processes of the quality management system.

There are two hard copies of this quality manual in existence

Copy number one Managing Director

Copy number two Quality Consultant

A Master copy is held on computer in pdf format and all other copies are referenced to it.

The policies contained in this manual are mandatory.

The manuals are confidential and may not be removed from the premises nor communicated to anyone outside the organisation without the written authority of a Director.

#### 4.2.3 CONTROL OF DOCUMENTS (Procedure QP1 refers)

The Company has established a procedure for controlling new and revised documents required for the operation of the quality management system.

- Documents are approved for adequacy;
- Documents are periodically, reviewed updated and re-approved as necessary;
- Changes and the current revision status of documents are identified;
- Current versions of relevant documents are available at points of use;
- Documents remain legible and readily identifiable;
- Documents of external origin, determined by the company top be necessary for the planning and operation of the quality management system are identified and their distribution controlled;
- Obsolete documents are promptly removed or marked obsolete.

#### 4.2.4 CONTROL OF RECORDS (Procedure QP2 refers)

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system are controlled. The company hhas established a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records are legible, readily identifiable and retrievable.

#### 5. MANAGEMENT RESPONSIBILITY

#### 5.1 MANAGEMENT COMMITMENT

Top management of the Company provides evidence of their commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- Communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements;
- Establishing the quality policy;
- · Ensuring that quality objectives are established;
- Conducting Management reviews;
- Ensuring the availability of resources.

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#### 5.2 CUSTOMER FOCUS

Top management of the Company is committed to determining customer requirements with the aim of enhancing customer satisfaction.

#### 5.3 QUALITY POLICY

The Managing Director has issued this policy and declares that the Company is committed to complying with requirements and meeting or exceeding customers' quality needs.

Top management is committed to continually improving the effectiveness of the quality management system.

Top management provides a framework for establishing and reviewing quality objectives.

This policy is displayed within the Company and reviewed, regularly for continuing suitability.

Shaun Elliott 24 January 2011

#### 5.4 PLANNING

#### 5.4.1 QUALITY OBJECTIVES

The Company has set objectives to provide products that are suitable and fit for purpose and provided to suit customers' requirements. The quality objectives are measurable and consistent with the quality policy.

#### 5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

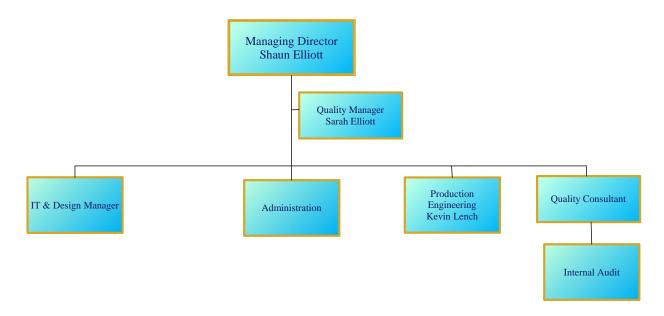
The Company has a business plan covering the anticipated demand for its products and for the levels of resources, both material and personnel needed to achieve the objectives in 5.4.1.

The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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### 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

### 5.5.1 RESPONSIBILITY AND AUTHORITY



January 2011

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#### Authorised By Sarah Elliott

#### 5.5.2 MANAGEMENT REPRESENTATIVE

The Company management has appointed the Sarah Elliott as the management representative who irrespective of other responsibilities has defined authority for:

- Ensuring that the processes needed by the quality management system are established, implemented and maintained;
- Reporting on the performance of the quality management system and the need for improvement;
- Ensuring the promotion of awareness of customer requirements throughout the organisation.

#### 5.5.3 INTERNAL COMMUNICATION

The Company ensures that appropriate communication processes are established within the organisation and that communication takes place regarding the effectiveness of the quality management system.

#### 5.6 MANAGEMENT REVIEW

#### 5.6.1 GENERAL

The Company reviews the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained.

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#### 5.6.2 REVIEW INPUTS

The input to management review includes information on:

- Results of Audits;
- Customer feedback;
- Process performance and product conformity;
- Status of preventive and corrective and actions;
- Follow-up actions from previous management reviews;
- Changes that could affect the quality management system;
- Recommendations for improvement.

#### 5.6.3 REVIEW OUTPUTS

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

- Improvement of the effectiveness of the quality management system and its processes;
- Improvement of the product related to customer requirements;
- Resource needs.

#### 6. RESOURCE MANAGEMENT

#### 6.1 PROVISION OF RESOURCES

The Company determines and provides the resources needed:

- To implement and maintain the quality management system and continually improve its effectiveness;
- To enhance customer satisfaction by meeting customer requirements.

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#### 6.2 HUMAN RESOURCES

#### 6.2.1 GENERAL

Personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

#### 6.2.2 COMPETENCE, TRAINING AND AWARENESS

#### The Company:

- Determines the necessary competence for personnel performing work affecting conformity to product requirements;
- Where applicable, provides training or takes other actions to achieve the necessary competence;
- Evaluates the effectiveness of the actions taken;
- Ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives;
- Maintains appropriate records of education, training, skills and experience.

#### 6.3 INFRASTRUCTURE

The Company has determined, provides and maintains the infrastructure needed to achieve conformity of product including:

- Buildings, workspace and associated utilities;
- Process equipment, both hardware and software;
- Supporting services such as transport, communication or information systems.

#### 6.4 WORK ENVIRONMENT

The Company determines and manages the work environment needed to achieve conformity to product requirements.

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#### 7. PRODUCT REALISATION

#### 7.1 PLANNING OF PRODUCT REALISATION

The Company plans and develops the processes needed for product realisation. Planning of product realisation is consistent with the requirements of the other processes of the quality management system.

In planning product realisation, the Company determines the following as appropriate:

- Quality objectives and requirements for the product;
- The need to establish processes and documents, and to provide resources specific to the product;
- Required verification, validation, monitoring, mmeasurement, inspection and test activities specific to the product and the criteria for acceptance;
- Records needed to provide evidence that the realisation process and resulting product meets requirements;

#### 7.2 CUSTOMER RELATED PROCESSES

# 7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

The Company determines:

- Requirements specified by the customer; including the requirements for delivery and post delivery activities;
- Requirements not stated by the customer but necessary for specified or intended use, where known;
- Statutory and regulatory requirements applicable to the product;
- Any additional requirements considered necessary by the Company.

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#### 7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT

The Company carries out a review related to the requirements of the product. This review is conducted prior to the Company's commitment to supply the product and ensures that:

- Product requirements are defined;
- Contract or other terms differing from those previously expressed are resolved;
- The organisation has the ability to meet the defined requirements.

Records of the review and actions arising from the review are maintained. Where the customer provides no documented statement of requirement, the customer's requirements are confirmed by the Company before acceptance.

When product requirements are changed the Company ensures that relevant documents are amended and relevant personnel are made aware of the changed requirements.

#### 7.2.3 CUSTOMER COMMUNICATION

The Company determines and maintains effective arrangements for communicating with customers in relation to:

- Product information;
- Enquiries, contracts or order handling, including amendments;
- Customer feedback, including customer complaints.

#### 7.3 DESIGN AND DEVELOPMENT

#### 7.3.1 DESIGN AND DEVELOPMENT PLANNING

The Company plans and controls the design and development of product

During the design and development planning, the Company determines

- The design and development stages;
- The review, verification and validation that are appropriate to each design and development stage;
- The responsibilities and authorities for design and development.

The Company manages the interfaces between different groups involved in the design and development to ensure effective communication and clear assignment of responsibility.

Planning output is updated as appropriate, as the design and development progresses.

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#### 7.3.2 DESIGN AND DEVELOPMENT INPUTS

Inputs relating to product requirements are determined and records maintained. These 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.

The inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.

#### 7.3.3 DESIGN AND DEVELOPMENT OUTPUTS

The outputs of design and development are in a form suitable for verification against design and development input and are approved prior to release.

Design and development outputs:

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

#### 7.3.4 DESIGN AND DEVELOPMENT REVIEW

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements:

- To evaluate the ability of then results of design and development to meet requirements;
- To identify any problems and propose necessary actions.

Participants in these reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained.

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#### 7.3.5 DESIGN AND DEVELOPMENT VERIFICATION

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs meet the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

#### 7.3.6 DESIGN AND DEVELOPMENT VALIDATION

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of the validation and any necessary actions are maintained.

#### 7.3.7 CONTROL OF DESIGN AND DEVELOPMENT CHANGES

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of the design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions are maintained.

#### 7.4 PURCHASING

#### 7.4.1 PURCHASING PROCESS

The Company has a procedure for controlling purchasing and for selecting and evaluating suppliers and sub-contractors who are capable of supplying the Company's needs.

Records of the results of evaluation are maintained.

#### 7.4.2 PURCHASING INFORMATION

The Company produces purchase orders, which clearly describe the product or service ordered.

Purchase orders are reviewed for adequacy and approved prior to release.

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#### 7.4.3 VERIFICATION OF PURCHASED PRODUCT OR SERVICES

The Company carries out verification at suppliers' premises, as required, to ensure that the product meets specified purchase requirements. The intended verification arrangements and the method of product release is specified in purchasing documents. This verification, where contractually specified, will be extended to MOD QAR or other representatives.

The Company also carries out a supplier inspection programme to ensure that There is ongoing compliance to quality and product requirements.

#### 7.5 PRODUCT PROVISION

#### 7.5.1 CONTROL OF PRODUCT PROVISION

The Company sub-contracts this element but supervises the controlled conditions at the suppliers premises, through the supplier inspection programme.

These supervised controlled conditions include:

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

#### 7.5.2 VALIDATION OF PROCESSES FOR PRODUCT PROVISION

The sub-contractor carries out this function, as required.

#### 7.5.3 IDENTIFICATION AND TRACEABILITY

The relevant parts of the product are identified by suitable means throughout product realisation processes at the suppliers' premises.

The Company provides traceability by the control of the unique identification of product and maintains records.

#### 7.5.4 CUSTOMER PROPERTY

The Company has a procedure to ensure care with customer property while under it's control. If any property is lost or damaged or otherwise found to be unsuitable, the company will report this to the customer and maintain records.

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#### 7.5.5 PRESERVATION OF PRODUCT

The company preserves the product and materials used in the provision of the product during internal processing and delivery to the customer. As applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies to constituent parts of the product.

#### 7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

The Company, through the supplier inspection programme, supervises the process at the suppliers' premises that controls, calibrates and maintains those monitoring and measuring equipment used to demonstrate conformance of product to specified requirements.

The Company, through the supplier inspection programme, provides methods of handling, preservation and storage that protect measuring equipment from damage or deterioration. Equipment used for making meaningful measurements will be calibrated and traceable to a National or International Standard.

Measuring and monitoring devices are used in a manner that ensures that measurement uncertainty, including adequacy and precision is known and is consistent with the required measurement capability.

#### The Company:

- Calibrates or verifies, or both at specified intervals or prior to use against equipment traceable to international or national standards;
- Have identification in order to determine its calibration status;
- Determines the method of calibration of monitoring and measuring devices;
- Records of the results of calibration and verification are maintained;
- Ensures environmental conditions are suitable for calibrations, measurements, inspections and tests;
- Safeguards monitoring and measuring devices from adjustments that would invalidate the calibration;
- Assesses the validity of previous inspection and test results when a device is found to be out of calibration and take appropriate actions.

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#### 8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

#### 8.1 GENERAL

The Company plans and implements the monitoring, measurement, analysis and improvement processes needed:

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

#### 8.2 MONITORING AND MEASUREMENT

#### 8.2.1 CUSTOMER SATISFACTION

The Company has established a process for obtaining and monitoring information and data on customer perception for satisfaction and/or dissatisfaction.

#### 8.2.2 INTERNAL AUDIT (Procedure QP3 refers)

The Company conducts internal audits, at planned intervals to determine whether the quality management system:

- Conforms to the planned arrangements and to the requirements of the International Standard ISO9001:2008;
- Is effectively implemented and maintained.

The Company plans the audit programme, taking into consideration the importance of the activities and areas to be audited as well as the results of previous audits.

The selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process; auditors do not audit their own work. A documented procedure is established to define the responsibilities and requirements for planning and conducting audits and for reporting results.

Records of the audits and their results are maintained.

The management responsible for the area being audited ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow up activities include the verification of actions taken and the reporting of verification results. Where planned results are not achieved, correction and corrective action is taken, as appropriate.

#### 8.2.3 MONITORING AND MEASUREMENT OF PROCESSES

The Company 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.

#### 8.2.4 MONITORING AND MEASUREMENT OF PRODUCT

The Company monitors and measures the characteristics of the product to verify that product requirements have been met. The necessary inspection and testing activities and the records to be kept are defined. Product completion does not take place until planned arrangements have been carried out. Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorising release of product for delivery to the customer

# 8.3 CONTROL OF NONCONFORMING PRODUCT (Procedure QP4 refers)

The Company ensures that any product, which does not conform to requirements, is identified and controlled to prevent its unintended use or delivery.

Where applicable, the Company deals with non-conforming product by one or more of the following ways:

- By taking action to eliminate the detected non-conformity;
- By authorising its use by a relevant authority and where applicable by the customer;
- By taking action to preclude its original intended use or application.
- By taking action appropriate to the effects or potential effects of the non-conformity when nonconforming product is detected after delivery or use has started.

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

Records of the nature of non-conformities and any subsequent actions, including concessions obtained, taken are maintained.

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#### 8.4 ANALYSIS OF DATA

The Company 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 effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from relevant sources.

The analysis of data provides information relating to:

- Customer satisfaction:
- Conformity to product requirements;
- Characteristics and trends of processes including the opportunity for preventive action;
- Suppliers.

#### 8.5 IMPROVEMENT

#### 8.5.1 CONTINUAL IMPROVEMENT

The Company 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 (Procedure QP5 refers)

The Company takes action to eliminate the causes of nonconformity to prevent recurrence.

Corrective action is appropriate to the effects of the nonconformities encountered.

A documented procedure is established to define 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;
- Recording the results of action taken;
- Reviewing effectiveness of the corrective action taken.

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#### 8.5.3 PREVENTIVE ACTION (Procedure QP6 refers)

The Company determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action is appropriate to the effects of the potential problems.

A documented procedure is established to define requirements for:

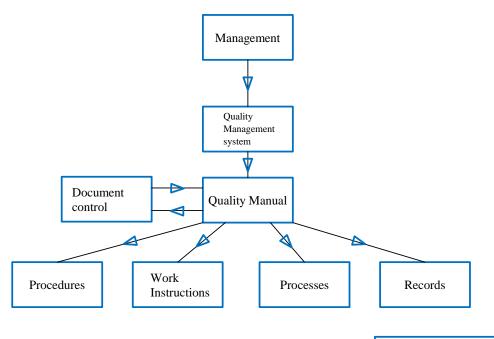
- Determining potential nonconformities and their causes;
- Evaluating the need for action to prevent occurrence of nonconformities;
- · Determining and implementing action needed;
- Recording the results of action taken;
- Reviewing the effectiveness of the preventive action taken.

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### Authorised By Sarah Elliott Ring Sights Management Review 5.6 Continual improvemt 8.5 Design & Developmen t 7.3 Internal Sub-Contractor Product data 7.5 & 7.6 Customer satisfaction 8.2.1 Documents & audit 8.2.2 Records Corrective & preventive action 8.5.2 & 8.5.3 Resources 6.1-6.4 Inspection data & nonconformance reports 8.3 Calibration & equip control 7.6 Training & competence 6.2.2

Management Review



Quality System Overview

Despatch to

Customer

#### Receive Estimates& 7.2.1 Ring Sights Quotations sales order 7.2.2 7.2.3 Communicate with Customer Yes ISO9001:2008 7.3 Sub-Contractor Yes Design and Development Selection & Evaluation of Suppliers Purchase Order Management Receive order Sub-contractor Responsibility 7.4.2 Plan Measurement Analysis and improvement Production Resource Management 7.5-7.6 Purchase Materials Product Realisation Control of Monitoring and Measuring Product Realisation Equipment Records Identification & Invoice Customer Monitoring & Nonconforming Problems and Traceability Measurement Product Data Procedures Product

Release

7.4.3

Purchaser

verification

Ok?

Yes

Pack and label

### Authorised By Sarah Elliott

### **ISO9001 Mandatory Procedures**

ISO Clause	Procedure	
4.2.3	QP1	Control of Documents
4.2.4	QP2	Control of Records
8.2.2	QP3	Internal Audit
8.3	QP4	Control of Non-Conforming Product
8.5.2	QP5	Corrective Action
8.5.3	QP6	Preventive Action

#### **QP1 CONTROL OF DOCUMENTS**

#### QP1.1 Issue

All controlled documents have as a minimum:

- Title
- Date and Authorisation
- In addition they can have an issue Number.

The quality manual is authorised on the amendments page.

All controlled documents are reviewed and authorised before issue. Documents can be in any form, hard copy, electronic etc. Documents of external origin are check for amendment status before use.

Obsolete documents are removed promptly from points of issue or otherwise prevented from unintentional use. One copy of the obsolete document will be marked 'obsolete' and retained for record purposes.

#### QP1.2 Changes

No controlled document may be changed or destroyed, without authority.

Should it be found necessary to change a document, for any reason, then the document change procedure is as follows:

A document control *form* DCF is completed and this is the record that the change has been authorised. The change is incorporated into the document concerned. The completed DCF is filed as a quality record.

#### QP1.3 Computer Back-up

The computer system has a raid array of disks to ensure data integrity. Computer back-up takes place automatically using a tape system. Data tapes are protected in a fire-proof safe.

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#### **QP2 CONTROL OF RECORDS**

The Company has a means for identification, collection, indexing, access, filing, storage, maintenance, retrieval, and disposing of records.

Quality records are kept for a minimum of two years, unless otherwise required by regulation and are protected in suitable facilities to prevent damage, loss and deterioration. Redundant paper records are recycled.

Quality records consist of:

#### ISO Clause

4.2.3	Control of Documents
4.2.4	Control of Records
5.6.1	Management Review
6.2.2	Competence, Awareness and Training
7.1	Planning of Product Realisation
7.2.2	Review of Requirements related to the Product
7.3.	Project File & Design and Development records
7.4.1	Purchasing Process
7.5.3	Identification & Traceability
7.5.4	Customer Property
7.6	Control of Monitoring & Measuring Devices
8.2.2	Internal Audit
8.2.4	Monitoring & Measurement of Product
8.3	Control of Non-Conforming Product
8.5.2	Corrective Action
8.5.3	Preventive Action
Plus	
	Technical files
	Accounts
	Legal Files
	Sales Files

General Files

Master Record Index

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#### **QP3 INTERNAL AUDIT**

Audits will be carried out to ensure that the Quality Management System is being operated and is effective. Audits of each element must be carried out **Once** per annum, unless indications are such that more frequent audits are required, to keep the quality management system in good working order.

#### The Audit Plan

Form Aud1 (Quality audit forward plan) will be used to plan future internal audits and to notify all concerned that an audit is to be carried out and on what date. The plan notifies the areas of audit against a pre-determined timescale.

#### Preparation

Prior to the commencement of the audit a form Aud 2 (Quality audit preparation) will be used to select elements of the system to be examined. This form constitutes part of the audit records and is for guidance of the auditor and is used as a checklist.

#### **Opening Meeting**

This meeting between the auditor and auditee will agree:

- a) What is to be audited?
- b) What is to happen if non-conformities are found?

#### Investigation & Examination

This is the objective evaluation of the elements of the quality system by the auditor. Areas that may be examined will include:

- Organisational structures;
- Administration and operational procedures;
- Personnel, equipment and operational resources;
- Work areas, operations and processes;
- Documentation, reports and records.

#### Identify Nonconformities & Agree Actions

Elements that do not conform will be noted on form Aud 3 (Audit NCR) in the section headed Non-conformity. If actions to correct the non-conformity can be agreed, then these are noted in the actions required including a time scale section. If corrective actions cannot be agreed then a solution will be developed at the closing meeting.

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#### **Closing Meeting**

Findings of the audit will be discussed and corrective actions (if not already agreed) will be agreed including a time scale.

The Audit Report

This report on form Aud 4 will contain the findings that were discussed at the closing meeting and will have copies of non-conformance reports attached.

#### QP4 CONTROL OF NON-CONFORMING PRODUCT

**Incoming Goods** 

Incoming products are inspected to the level required.

Products that do not comply with specified requirements are set aside.

The Delivery Note is stamped 'REJECTED'. The reason for non-conformity and the action taken, including any contact or communication with the supplier is recorded on the Non-Conforming Product Form.

The completed Delivery Note is forwarded to accounts to be matched with the relevant Purchase Order and processed in accordance with instructions on the Delivery Note.

Issue 14.0 Date of Issue: 24 January 2011

#### Authorised By Sarah Elliott

#### **QP5 CORRECTIVE ACTION**

The majority of actions will be carried out in conjunction with the supplier at the supplier's premises.

Corrective action is designed to eliminate the cause of non-conformity by preventing recurrence.

The following requirements are particularly relevant:

- reviewing non-conformities, including customer complaints;
- · determining the causes of non-conformities
- evaluating the need for action to prevent recurrence
- · determining and implementing the actions needed

Where a corrective action is required it is monitored to ensure that it is effective. Where the corrective action does not eliminate the problem, an alternative is implemented. The quality manager will normally co-ordinate these activities.

Records of the results of actions taken are kept.

#### **QP6 PREVENTIVE ACTION**

Preventive action is designed to eliminate the cause of potential nonconformities to prevent occurrence.

The following requirements are particularly relevant:

- determining potential non-conformities and their causes;
- evaluating the need for action to prevent occurrence;
- determining and implementing the actions needed;
- reviewing preventive actions.

The output from the management review will normally indicate the need for preventive action. Any such preventive action that is implemented is monitored to assess its effectiveness.

The quality manager will normally co-ordinate these activities.

Records of the results of actions taken are kept.

End

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