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## Introduction to the Quality Manual

### 1. INTRODUCTION

The purpose of this Quality Manual is to ensure that the Quality Policy and objectives of Poligas Ltd. as regards the manufacture and importation of medicinal industrial and associated gases , are in place. The objectives are achieved by compliance with the requirements of the Quality System documented in this manual and in the supporting Standard Operating Procedures.

### 2. SCOPE

The Quality Manual defines the Quality Policies, Procedures and Practices of Poligas Ltd. These objectives are achieved by working to a consistent and high standard in accordance with written procedures, and by the provision of specific quality improvement procedures and systems.

### 3. DEFINITIONS


**Quality:** The sum of all features and characteristics of a product or service that determine its ability to satisfy customer needs. The product manufactured must also satisfy the requirements of the marketing authorisation licence and product specifications.

**Quality Management system:** The sum of all that is necessary to implement an organisation's quality policy and meet quality objectives. It includes organisational structure, responsibilities, procedures, systems, processes and resources. Typically these features will be addressed in two documents - the quality manual and documented procedures.

**Quality Policy:** The overall quality intentions and directions of an organisation relating to Quality, as formally expressed by the management.


**Quality Manual:** A written description of the requirements of the Quality Management System which contains an outline structure of the system and includes or makes reference to, the documented procedures.

**Inspection:** The process of assessing an organisation, operation or activity against set criteria.

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**Licence:** For the purposes of this document, a licence is defined as an authorisation for the manufacture and importation of medicinal ,industrial , and associated gases.

**Standard Operating Procedure:** A written description of the operations to be carried out.

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## **1.0 Introduction to the Company**


### **1.1 Introduction to Poligas Ltd**

Poligas was established in Malta on 25<sup>th</sup> October 2004. It is a totally Maltese company with an authorized share capital of 100,000 in number shares of LM1.00. Polidano Holding Limited owns 9,998 of a total issued share capital of 10,000 – LM1.00 each. Mr.Charles Polidano (ID 506259M) and Mr Paul Polidano (ID 232165M) own 1 share each of the other 2 issued shares.

### **1.2 Poligas Ltd- the Plant**

The plant is highly automated and covers an area of approximately 2510 square meters. It was designed in such a way so as to be able to fulfil its role as a manufacturer and importer of compressed medical gases and associated gases used in the manufacture of pharmaceutical preparations both in cylinders and in bulk. The plant is divided into areas as follows:


- *The Air Separation Plant* which produces Liquid Oxygen by cryogenic distillation of atmospheric air. The air separation plant was purchased from Cosmodyne USA, and conforms to the Pressure Equipment Directive (PED) 97/23/EC
- Filling Plant – The unit is manufactured by Vanzetti Engineering Italy. The unit is in conformity with the following standards:-
  - The unit is according to Directive 89/392/CE;  
(Refer to file: Engineering European Directives)
  - Plant is in accordance to Directive 98/37/CE – 11 A;  
(Refer to file: Engineering European Directives)
  - Electromagnetic items compatible to 89/336/CE – 1;  
(Refer to file: Engineering European Directives)
  - Low tension items compatible to 73/23/CE – 111.  
(Refer to file: Engineering European Directives)
  - Other standards used DIN EN 414;  
(Refer to file: Engineering European Standards)
  - DIN EN 292;  
(Refer to file: Engineering European Standards)
  - DIN EN 418;  
(Refer to file: Engineering European Standards)
  - 1GC 11/82/D:

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(Refer to file: Engineering European Standards)

- *Storage Compound* consisting of a number of vertical storage tanks each dedicated to different medical and associated gases. These cryogenic tanks were manufactured by VRV Sp.A. The tank capacities vary in volume and all conforms to the specific requirements of the UNI, EN, DIN standards. All tanks are also covered by PED 97/23/EC: Refer to file Engineering European Legislation.
- *Electrical substation* to operate the plant in its entirety. It conforms fully to the provisions of the Electricity Supply Regulations of the Malta Resources Authority
- *Cylinders Awaiting Filling Area*, in which cylinders are waiting to be vacuumed and re-filled with compressed medical gases .
- *Approved Cylinders Area*, in which the processed cylinders are stored prior to delivery
- *Returned/Damaged/Expired Cylinders Area*: Cylinders which have failed visual inspection after manufacture, or which have been determined as having been returned to the plant as defective by clients, or which have been returned to the plant in the context of a full or partial recall are stored in this area
- *Quarantine Area*: Cylinders waiting for a decision regarding their subsequent approval or rejection are stored here. This decision is made immediately after manufacture through physical examination of cylinder integrity and through the evaluation of the quality of the compressed medical gases in accordance with European Pharmacopoeia monograph. Returned cylinders for which faults or damage are being claimed by clients are also stored here, prior to damage assessment and subsequent corrective action
- *Empty Cylinders Area*, in which cylinders which have been returned empty after use by Poligas Ltd. are stored and in which all previous batch number labels are removed.

These 5 areas are segregated, thus ensuring that no cylinder category misplacements are made. The safety provided by this segregation will be further enhanced by a supporting computer database system. Physical counting of

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cylinders in each of the five sections must correlate with the distribution calculated through the computerised stock control system.

*Acetylene Plant* , situated some 500 meters away from the main Poligas site for safety reasons. The building covers an uninhabited area of about 50 square meters and was custom built for its intended use. All quality principles described in this document reflect the current work practices and quality procedures adopted at the acetylene plant.

### 1.3 Filling


Filling will be carried out in re-usable cylinders of various sizes varying in capacity from 1-50 litres. The cylinders are made of very light weight material to reduce weight and are consequently less onerous to workers. These cylinders were manufactured by Worthington of Austria, are compliant with EN 1964-2 and conform to TPED 97/23 standards with all the data imprinted at the of each cylinder. In accordance with SABS 06-1957, the cylinders containing compressed medical gases are colour coded All cylinders having a water capacity of more than 10 litres have valve protection caps fitted. Three labels are attached to the shoulder of the tank. One shows the class of the gas, the name of the company, the name of the gas, the UN number, and the relevant warning/hazard notations. The second sticker indicates the batch number and the expiry date. The third label consists of patient's instructions before and after use. A heat shrink seal is fitted to the valve of the cylinder, confirming that it has been properly filled. Some industrial gases will also be supplied in bulk via road tanker.

### 1.4 The Products

Medical and industrial gases will be marketed either in steel cylinders of capacities varying from 1-35 litres or in bulk via road tanker. The quality of the gases manufactured will comply with European Pharmacopoeia standards and other international standards.

### 1.5 The Market

Poligas Ltd. is producing Medical and industrial gases for the Maltese market.

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## 2.0 The Quality Policy


### 2.1 Statement of Quality

At Poligas Ltd., we recognize that the quality, safety, efficacy and environmental responsibilities are crucial to our products together with the quality of our service. In manufacturing our products, it is our aim to protect and maintain public health by ensuring the quality, safety and efficacy of the manufacturing operations. This will be achieved by working to consistently high standards and by ensuring that all activities carried out by the company are all compliant with Good Manufacturing Practices (GMP). Furthermore, certificates of analysis will be issued for each batch of gas produced. Also, Poligas Ltd. is committed to ensure that the quality, integrity and purity of our products are maintained during the storage and distribution phases.

In order to achieve and maintain the desired quality level, Poligas Ltd., will establish and maintain a Documented Quality Management System. Poligas Ltd. will manufacture according to the licence conditions and in accordance with the Marketing Authorisation Licence. The system will be set up in such a way so as to ensure the continued improvement and upgrading of the quality not only of the company's product, but also of its services portfolio.

These goals will be achieved by ensuring that:

- Activities comply with regulatory and Quality System requirements
- Appropriate records are maintained at each stage of manufacture and storage and supply
- Handling/storage/transport conditions are observed
- Contamination by other products is avoided during manufacture, storage and delivery

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- Adequate stock turnover takes place
- The right products are delivered, efficiently
- There is an effective recall procedure
- Control of all operational requirements shall be by means of a documented Quality Management System (QMS).

In order to ensure the attainability of these goals, Poligas Ltd., is fully committed to the education and training of its employees at all levels, and will encourage and reward its staff with the opportunity for self improvement commensurate with their capabilities, and with their contribution to the success of the Company.

## 2.2 Review and Maintenance of the Quality Policy

The Chief Executive Officer together with Quality Assurance (Q.A.) Personnel, Environmental officer and Engineering Personnel ) undertake to regularly review the Quality Policy and Environmental policy, to ensure that it is implemented, and that it remains an effective tool in meeting the requirements of both local and International Legislation.

The Quality Assurance Manager has the authority and responsibility for implementing, managing and maintaining the Quality System Manual and Procedures. He/she also has the authority and the freedom to identify and investigate problems that affect the quality of the product, services, and Quality Management System.

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### **3.0 Management, Representation, Responsibility, Authority and Resources.**

#### **3.1 Representation**

The organizational structure of Poligas Ltd. is shown in Annex A to this Quality Manual.

The Quality Assurance Manager is the nominated representative with the responsibility for implementing and maintaining the Quality System and reporting upon its effectiveness. He/she must also ensure that the system is understood, accepted and established among the various staff strata within the organization.

#### **3.2 Responsibility and Authority**

It is the responsibility of all the managers to ensure that all the requirements of the Quality System Manual and Standard Operating Procedures have been fully implemented and maintained. They must also ensure that all the staff understands the requirements of the Standard Operating Procedures that affect their tasks as well as the parameters and specifications to which they are required to work. The managers must also ensure that their staff has the necessary procedures, work instructions, training, specifications, tools and equipment to effectively carry out their assigned tasks. Each employee of the company is responsible for maintaining the specified standards of work at all times.

The following staff responsibilities, authority and inter-relationships are defined and documented below.


##### **3.2.1 Managing Director**

- Reviews and approves all major projects and capital expenditure exceeding Lm10,000 in value.

##### **3.2.2 Chief Executive Officer**

- Business policy and financial projections.
- Planning and marketing strategy.
- Marketing and selling activities.
- Overall direction and management of the business.



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- Enquiries and contracts, administration and records.
- Overall responsibility for Human Resource Management and industrial relations.
- Reviews and approves all major projects and capital expenditure.
- Ensures that products and services are supplied to specifications and within cost and delivery targets.
- Overall responsibility for giving guidance and direction for maintaining a business that yields profit, but that in no way jeopardizes the safety of the operators or the health of the end user of the compressed medical gas.
- Maintains all accounting, financial affairs and records.


### 3.2.3 Enviromental Officier

It shall be the duty of the qualified person to:

- Ensure that the licence conditions are adhered to;
- Ensure that the conditions for manufacture of products are in accordance with the requirements of the product specifications;
- Maintain records;
- Ensure that a quality system is maintained by the licensee in accordance with principles of Good Manufacturing Practice and ISO9001:2008
- Ensure that each batch of medicinal products has been manufactured, tested and complies in all respects with any requirement established by local Legislation;
- Be permanently and continuously at the disposal of the holder of the manufacturer's licence.
- Releases the products for sale or distribution.

### 3.2.4 Quality Assurance / Quality Control Manager

- Administers and controls the day to day running of the Quality Management System.
- Updates, issues and controls the Quality System Manual and the Standard Operating Procedures.
- Overall responsibility for the formal recording, investigating and reporting of customer complaints and returned products.
- Liaises with both customers and Certification Body regarding Quality Assurance issues.

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- Ensures that the requirements of ISO 9001:2000 are fully addressed and that the system is effectively implemented, maintained and reviewed.
- Informs the Chief Executive Officer of any system element or incident that will prevent Poligas Ltd. from meeting any contractual requirements, or that will breach the documented Quality System.
- Provides and manages a system of Internal Audits using adequately trained staff all of whom are independent of the activity being audited.
- Initiates and controls processes to prevent recurrence or occurrence of non-conforming products or services.
- Prepares reports on the state of Quality in the company every 3-4 months.
- Holds management reviews as indicated in the appropriate procedure.
- Acts as a direct liaison between customers and partners on technical matters.
- Identifies staff training needs, organises training, and maintains training records.
- Ensures that products are manufactured in accordance with the Manufacturing Licence and the Marketing Authorisation Licence.

### 3.2.5 Plant Engineer

- Overall responsibility for mechanical and electrical problem solving within the manufacturing plant
- Overall responsibility for overseeing manufacture, storage and warehousing of all products and materials.
- Overall responsibility for implementing processes that ensure safe and satisfactory state of the gas cylinders and their appropriate handling
- Overall responsibility for training operators in plant operating and cylinder handling techniques
- Overall responsibility for training staff in safety techniques with special reference to the handling of cryogenic substances
- Overall responsibility for the management of the plant.

### 3.2.6 Assistant Administrator

- Working under the direct supervision of the Chief Executive Officer, he/she records receipts and issues of empty and filled cylinders in stock, and
- Records receipts and issues of other goods relating to the business as a whole.
- Working under the direct supervision of the Chief Executive Officer he attends to the day to day accounting matters with respect to sales made by the company.
- Processing of orders.

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- Issue of invoices and delivery notes.
- Inputting stocks into database.
- Keeping both hard and soft copies of all the documentation.
- Answer phone calls, e-mails, faxes and other correspondence.
- Receiving customer complaints.
- Stock taking.

### 3.2.7 Senior Operator


- Answering directly to the Engineer he is responsible for the daily running of the manufacturing plant in its entirety.
- He is responsible for filling the cylinders with compressed medical oxygen at the filling station
- He supervises the work of the other operators
- Fills relevant Standard Operating Procedure Forms.

### 3.2.8 Quality Inspector

- Places the seal on filled medical oxygen cylinders that have passed Quality Control.
- Places the required labels on the filled medical oxygen cylinder gases
- Assists the Quality Assurance Manager.
- Fills the relevant Standard Operating Procedure Forms.
- Labels all the areas in the plant under the supervision of the Engineer and Quality Assurance Manager. Replaces old labels with new labels if the labels require any replacement.
- Maintains records and updates of the standard operating procedures located in various positions at the plant.
- Responsible to check that all cylinders and equipment are stored in their appropriate place.
- Handling of cylinders: Placing all the cylinders in their allocated area and filling of non-conformance forms for damaged cylinders.

### 3.2.9 Operators

- Under the direct supervision of the Engineer & Senior Operator they perform filling of the compressed medical oxygen cylinders

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- Loading and unloading of the cylinders on the truck

### **3.2.10 Truck Drivers**

- Answering directly to the Assistant Administrator, he is responsible for the timely, efficient and safe delivery of medical oxygen cylinders when this is to be delivered to clients.

### **3.2.11 Housekeeper**

- Answering directly to the Engineer, he is responsible for cleaning of the premises in accordance with protocols pre-established by the Quality Assurance Manager.


## **3.3 Resources**

The management team ensures that adequate resources are provided for work in progress and any accepted contracts/orders. These resources include materials, equipment, adequately trained personnel, outside expertise, management resources, time and financial budget allocation.

Review of resources requirements are carried out formally at management reviews and also at contract reviews. The requirements for resources are also continuously monitored informally to ensure performance meets targets, the company's organizational goals and the customer's specifications, expectations and needs.

All employees are trained and their capabilities reviewed formally to ensure that their knowledge of the processes they handle is up to the standard required by the Company, and in line with all operating procedures. Management at Poligas Ltd. must ensure that each person employed at Poligas Ltd. is aware of his/her responsibility for the application of the Quality System within the span of his or her responsibility

Additional verification is provided by a planned programme of internal audits and, where appropriate, verification checks have been instituted as part of the Standard Operating Procedures in order to check the processes themselves as well as the quality of the product.

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### 3.4 Quality System Assurance

A systematic organisation for the assurance of the Quality of the operations of Poligas Ltd. shall be established and maintained within the company. The procedures used shall be documented where necessary to safeguard quality and shall be the result of planning refined by experience of the operation. This Quality System will provide the

- Organisational Structure
- Responsibilities
- Procedures
- Processes
- Resources for implementing *QUALITY* management.


Implementation and maintenance of a formal Quality Management System provides the structure to meet many of the requirements set out in Title VII of Directive 2001/83/EC. (Refer to file: Pharmaceutical European Legislation). The Quality System shall consist of procedures designed to:

- Encourage safe practices.
- Assure Quality.
- Ensure storage conditions are observed at all times.
- Ensure adequate and timely turnover of products.
- Ensure traceability of all faulty products and an effective recall procedure.
- Contribute to the goals of the company.
- Utilise the skills and knowledge of the staff to the full.

### 3.5 Management Review

The Quality Assurance Manager will call a review meeting on a biannual basis as specified in Self Inspection/Internal Audits (SOPQA/08/06/00). This is a formally recorded event with minutes recorded and dated by the Quality Assurance Manager, and records maintained and signed by the Chief Executive Officer.

The overall purpose of the management review is to ensure the continued effectiveness and suitability of the Quality Management System.

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## 4.0 Organisation of the Quality System

### 4.1 Organisational Structure

The Quality Management System of Poligas Ltd. is subdivided into 2 levels of documentation as follows:

- **LEVEL 1** The Quality System Manual.
- **LEVEL 2** The SOPs and appropriate checklists.

These two levels, accompanied by the appropriate records, have been designed to meet all the stipulations of the Maltese Medicines Authority and the relevant clauses of the ISO 9001:2000 standards.

### 4.2 The Quality System Manual- Definition of Company Quality Policy


The Quality System Manual defines the Company Quality Policy in relation to each clause of the standard ISO 9001:2008. It states our policy to meet the requirements of certification bodies and clients. It lays the foundations for the Quality Management System as implemented at Poligas Ltd.

Each clause of the Quality System Manual is implemented via the Standard Operating Procedures.


#### 4.2.1 SOPs and Checklists

The Standard Operating Procedures prescribe the actual details of how the Company operates. These are written in a straightforward manner to meet the needs of internal staff. The listed operating procedures prescribe in detail how the requirements of the Quality Management System and the customers' requirements will be met.

They will also convey knowledge, information or directions to the staff at Poligas Ltd. for the purpose of performing work. These will prescribe the activities to be performed by a person carrying out a specific task and as such will define how the task is to be carried out. Instructions may contain diagrams and tables or refer to other documents as necessary. The Quality System Manual and the Standard Operating Procedures contain MANDATORY requirements on all the staff. They are *living* documents, and will be continually amended and updated as required.

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The Standard Operating Procedures in particular are **strictly confidential**. No unauthorized copying of the procedures is allowed, and all copies of procedures are issued solely by the Quality Assurance Manager. All procedures are accompanied by the relevant forms as indicated in the procedure itself.

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## 5.0 Contract Review

### 5.1 Contract Review Procedures

Initial enquiries may be received in writing by formal letter or fax or through personal contract with the Chief Executive Officer. The initial enquiry is logged in the “Enquiry and Contract Register” and reviewed according to the documented procedures to determine whether the item is a standard Company product that is regularly supplied.


A formal review is carried out before signing any contract to ensure that:

- There are no unresolved discrepancies between any customer requirements and the proposed contract.
- Poligas Ltd. has the capability to meet its clients’ demand in an efficient and timely fashion.
- Any additional requirements are addressed with regards to customer supplied material.
- Any amendments necessary to the Quality System Manual are formally addressed and controlled.
- All reviews of orders/contracts are recorded in the “Enquiry and Contract Register” and are duly signed and dated.

Amendments to contracts are formally recorded in the “Enquiry and Contract Register”. These will be reviewed and should be acknowledged and signed by both parties.

The policy within this clause is implemented via Contract Review and Amendments (SOPGE/10/06/00).



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## **6.0 Document and Data Control Procedures**

### **6.1 Main Documentation for Quality Management System**

This Quality System Manual and associated Standard Operating Procedures form the main part of the documentation for the Quality Management System in order to meet both the requirements of the Maltese Medicines Authority and ISO 9001:2000 standards.

### **6.2 Quality System Manual Review & Authorisation**

This Quality System Manual has been reviewed and authorized by the Chief Executive Officer and only he can authorize alterations or additions. The issue and control of the manual and procedures are described below:

#### **6.2.1 Issue of Controlled Copies of the Quality System Manual.**


Copies of the Quality System Manual are issued either as “controlled” or “uncontrolled” documents. Controlled documents are issued only to the listed recipients who may be employees of Poligas Ltd. or to other bodies with which the Company has a formal contractual agreement. Holders of controlled copies are listed in Annex C of the manual. Each holder is responsible for its maintenance and safe keeping and also to ensure that the staff fully understands the procedures appropriate to their duties. The master reference copy is retained by the Quality Assurance Manager.

#### **6.2.2 Issue of Uncontrolled Copies of the Quality System Manual.**

Uncontrolled copies of the manual may occasionally be issued for information, contract or public relations reasons. These copies will not be maintained, updated or subject to any document control system. Such copies will be clearly marked or stamped “uncontrolled” on the front page.

#### **6.2.3 Authority for Issue**

Both controlled and uncontrolled copies, as well as extracts of the Quality System Manual are issued only with the knowledge and written consent of the Chief Executive Officer.

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#### 6.2.4 Amendments and Issue Control

When a change is required or made, the revised page or pages are given an issue number that is incremental by one. A revised issue amendment control sheet is issued with the new pages, and the master list and issue status is also updated.

For simplicity, when a change is made to a page/s of the Quality System Manual or the individual Standard Operating Procedures, the whole of the respective document will be re-issued and changed. The issue of the Quality System Manual and the Standard Operating Procedures is controlled by Document and Data Control (SOPGE/02/06/00).

#### 6.2.5 Record of Changes

All changes are recorded and carried out as per SOPGE/02/06/00.

#### 6.2.6 Issue of Standard Operating Procedures


The Standard Operating Procedures are controlled by the - Document and Data Control (SOPGE/02/06/00). Standard Operating Procedures and check lists are to be considered as **STRICTLY CONFIDENTIAL**. They will not be made available outside the company.

#### 6.2.7 Master Lists of Documents and Data

A master list of all Quality System Manual documents and data including documents and data of outside origin are listed and controlled by Master SOP (SOPGE/01/06/00).

#### 6.2.8 Obsolete Documents

All obsolete documents will be removed from the system. However all copies retained, either for reference, or legal reasons, will be clearly identified as such to prevent unintentional use.

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## 7.0 Purchasing Procedures

All materials that have a direct effect on quality are treated with particular attention. All goods and services are purchased from approved and reliable suppliers in conformance to the company's pre-set specifications.

The procedures controlling the selection of suppliers and the purchasing of all products or services that affect the quality of the product or service are documented in SOPGE/08/06/00 and SOPGE/13/06/00 respectively. Most other items will be purchased via the same system.

### 7.1 The Evaluation and Control of Suppliers and Sub-Contractors

Materials and services affecting the quality of the products or services provided by Poligas Ltd., are purchased through the use of a formally controlled "Approved Suppliers List" (SOPGE/08/06/00/A-01).

The Approved Suppliers List has been developed using one of the following documented evaluations:


- The supplier holds ISO 9001:2000 certification from an accredited body for the scope of manufacture / supply of products / services that the Company wishes to purchase.
- Historical evidence and records of good supply.
- Evaluation by questionnaire, audit visit and / or controlled trial purchases.

### 7.2 Raising Purchase Orders

All purchase orders are written out on a specific Purchase Order Form (SOPGE/13/06/00/A-03), which is sequentially numbered. The Purchase Order will also define the material or service required in the form of its description, specification, or other identification. Every purchase order is reviewed, verified and authorized according to procedure before release to a supplier.

### 7.3 Independent Verification at Source by Poligas Ltd. or by our Customers


Poligas Ltd. retains the right to examine goods at the suppliers' premises prior to dispatch. In the event that customers of Poligas Ltd. also want to inspect the goods at

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source an agreement will be reached with the supplier, and documented separately in writing or on the purchase order.

Independent verification by customers at Poligas Ltd. is possible. Prior notice must however be given in order to ensure that

- An appropriate member of staff is available.
- Work at the store is not disturbed.
- Confidentiality with other customers is maintained.


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## 8.0 Procedures for Product Identification and Traceability

Traceability of materials and processing is not normally requested by customers. However ever conscious that the end product is intended for human medicinal use, whenever possible, strict audit trails of items purchased will be performed. Furthermore, for every individual oxygen cylinder purchased and sold, the batch and serial numbers will be identifiable through a carefully instituted and maintained labelling system. General Company and office materials and consumable items that have no bearing on the quality of the product or service to meet contracts also need to be identified.

Items that are unique and cannot possibly be mistaken for anything else need not be identified. All other items will be identified as required, either by a label, with appropriate details attached to the item, or, as in the case of individual cylinders, the identity will be marked onto the product.

Traceability of products, especially in case of product recall, is considered essential, and is carefully controlled and recorded via appropriate documented procedures SOPGE/19/06/00.


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## 9.0 Process Control Procedures

All the processes at Poligas Ltd. that affect the product or services that the Company provides to meet its contractual obligations, (or the implied contractual needs or requirements) of its customers are carried out under management controls which include:

- Formally documented, controlled and authorized operating procedures. Also, where appropriate, checklists, log books etc.
- Where found to be appropriate or necessary, SOPs, the quality plan, and other controlled documents. All such documents will be formally documented, identifiable to the process, be signed for authorization, and dated.
- Specifying where necessary experienced or trained staff, appropriate tools, instruments, equipment, and also the materials and components required.
- Definition of the acceptable standards and specification for processing throughout, in accordance with customer and partner specifications. Such documents are controlled, authorized, and dated.
- Inspection or Quality Assurance checks during the manufacturing process that affects directly the quality.

In general, all processes and controls are continually reviewed. The expectation is that over a period of time these will be modified, either to improve the standard of workmanship, to meet new or additional customer requirements, to maintain competitiveness, and also to meet new legislative requirements.

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## 10.0 Inspection and Testing Procedures

All inspection procedures are carried out as documented in the Self Inspection SOPQA/08/06/00, by appropriately trained staff.


### 10.1 Incoming Inspection

After a batch of compressed medical oxygen cylinders is manufactured, all cylinders forming part of that batch will be verified as conforming to European Pharmacopoeia requirements and Marketing Authorisation. They will also be individually visually inspected before released for sale.

All items must be signed off as “Quality Satisfactory” on the Medicinal Gas Production Sheet (SOPPR/19/06/00/A-01), by the Quality Control Manager and the Qualified Person.

### 10.2 Final Inspection

If specified in the contract, a final inspection can be held jointly with the customer or his representative prior to cylinder dispatch.


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## **11.0 Procedures for Control of Inspection, Measuring and Test Equipment**

All inspection and measuring equipment used to inspect or verify the quality of the processes carried out at Poligas Ltd. and that have a direct impact on product quality is listed on the Calibration Register.

Each instrument that is controlled is given an individual registered number, and may not be used to monitor processes unless listed in the calibration register. The calibration status of each instrument is also noted on the equipment.




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## 12.0 Procedures for Control of Non-Conforming Products

All manufactured compressed medical oxygen cylinders found to be non-conforming to specifications are carefully identified, labelled and documented. These products are carefully controlled to prevent inadvertent or accidental use. Non conforming products are identified using the non-conformance document system as described in procedure SOPQA/05/06/00.

Non conforming cylinders will immediately be segregated from conforming ones. Corrective actions can then be taken by authorized persons as dictated in the operating procedure SOPQA/05/06/00.

All non conformances leading to corrective actions or any longer term preventive actions are reviewed by the Quality Assurance Manager, Qualified Person and the Engineer and discussed at the management reviews as per procedure SOPGE/02/06/00.


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### **13.0 Procedures for Handling, Storage, Packing, Preservation and Delivery**

Storage areas are identified and set aside on the premises of Poligas Ltd. for the safe storage of filled cylinders (SOPGE/15/06/00). Similarly, final dispatch storage areas are used to ensure that goods do not sustain damage prior to dispatch.


All medical oxygen cylinders conform to TPED, EN 1964-2 (Refer to file: Engineering European Standard). All storage areas are visited and inspected regularly during the working week.

Oxygen cylinders intended for use by the local market will be distributed by Poligas Ltd., and delivery staff will be given appropriate training in the handling, and the correct methodology for the placement of oxygen cylinders in the distributing trucks (SOPGE/18/06/00).

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#### **14.0 Procedures for Control of Quality Records**

Records of inspection, tests, and quality related activities are maintained to show effective operation of the Quality Management System and to provide records of the product standards being maintained (SOPGE/03/06/00).


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## 15.0 Procedures for Internal Quality Audits

All aspects of the operations of Poligas Ltd. are subjected to a programme of scheduled internal quality audits on a biannual basis at a minimum, in order to determine whether the Quality Management System is being effective, and to verify that the customers' requirements are being met.

Internal Quality Audits are carried out according to a formal procedure (SOPQA/08/06/00), with the results recorded and reported to the Chief Executive Officer by the Quality Assurance Manager at the Management Review Meeting, so that any necessary corrective and/or preventive action may be delegated.

Audits are carried out by personnel who have undergone basic training in internal auditing, and who are also totally independent of the processes being checked.


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## 16.0 Training Procedures

New employees selected according to qualifications based on documented requirements as described in the Recruiting and Training procedure (SOPGE/05/06/00) are given an initial in-house induction training programme carried out by an authorized and appropriate member of staff at Poligas Ltd., which is common to all grades of employment.

There is a biannual formal appraisal of experience and training achievement against that required for each job function or individual to enable any eventual training needs to be identified. As these needs are established, they will be immediately addressed- either in-house, or by the use of an external body.

Appropriate records of training, qualifications and experience are maintained.

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## 17.0 Servicing Procedures

The products supplied by Poligas Ltd., are supplied without any need to provide maintenance. This includes cases in which cylinder recall may be required, which procedure is regulated by SOPGE/19/06/00.