



Guideline to Medical Bulk Oxygen Supply System For Healthcare Facilities

AIGA 049/08

Asia Industrial Gases Association

298 Tiong Bahru Road, #20-01 Central Plaza, Singapore 168730
Tel : +65 6276 0160 • Fax : +65 6274 9379
Internet : <http://www.asiaiga.org>



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1 Introduction

Medical oxygen is used by patients in healthcare facilities for life support and for medical treatment. It is vital to ensure that the medical oxygen supply system provides a safe and reliable supply of oxygen to healthcare facilities and patients as end user. Past experience indicated that the consequence of system failure could be very serious. It is therefore important that both gas supplier and healthcare facilities management understand the requirements on the design and installation of medical oxygen supply and pipeline distribution system. This is particularly common in Asia where the gas supplier is responsible for the design and installation of medical bulk supply but may or may not be involved in the pipeline distribution system.

2 Scope and purpose

This publication provides a guideline of the most important points of the medical oxygen supply system but does not include the pipeline distribution system in the healthcare facilities.

This publication covers medical oxygen supply but does not include other gas supply systems.

3 Definitions

Manifold : device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas

Portable liquid cylinder : vacuum insulated cryogenic container used for the storage of liquefied gases having a maximum allowable working pressure of greater than 0.5 bar and the capacity normally not exceeding 500 litres.

Primary source of supply : that portion of the supply system which supplies the pipeline distribution system

Reserve source of supply : that portion of the supply system which supplies the complete, or a portion(s), of the pipeline distribution system in the event of failure or exhaustion of both the primary and secondary sources of supply

Secondary source of supply : that portion of the supply system which supplies the pipeline distribution system in the event of exhaustion or failure of the primary supply

Shall : The use of the word 'shall' implies a very strong concern or instruction.

Should : The use of the word 'should' indicates a recommendation.

4 Sources of supply

The Medical Bulk supply system shall comprise of:

- Primary supply
- Secondary supply
- Reserve supply

Each supply system can be a combination of the following:

- a) gas in cylinders or cylinder bundles;
- b) cylinders connected to a manifold;
- c) portable liquid cylinder;
- d) cryogenic liquid in stationary vessels;

Remarks:

- Only cylinders dedicated to medical grade oxygen are to be used.
- The connection of portable liquid cylinder should follow the requirements of AIGA 019/05 'Connections for portable liquid cylinders', and AIGA 016/05 'Safety Features of Portable Cryogenic Liquid Containers for Industrial and Medical Gases'.
- The connection of cryogenic liquid in stationary vessel should follow the requirements of AIGA 024/05 'Connections for Transportable and Static Bulk Storage Tanks'.
- Pressure relief valve must be installed in liquid oxygen supply system where liquid can be trapped between two closed valves. Refer to Training Package AIGA TP 05/05 'Prevention of over-pressurization'.

Figure 1 (see page 3) show how the above can be combined as acceptable sources of supply. It also shows the different sources of supply and key system components including alarms. This schematic is not a design drawing. A competent person should design the supply system after selecting a suitable source of supply.

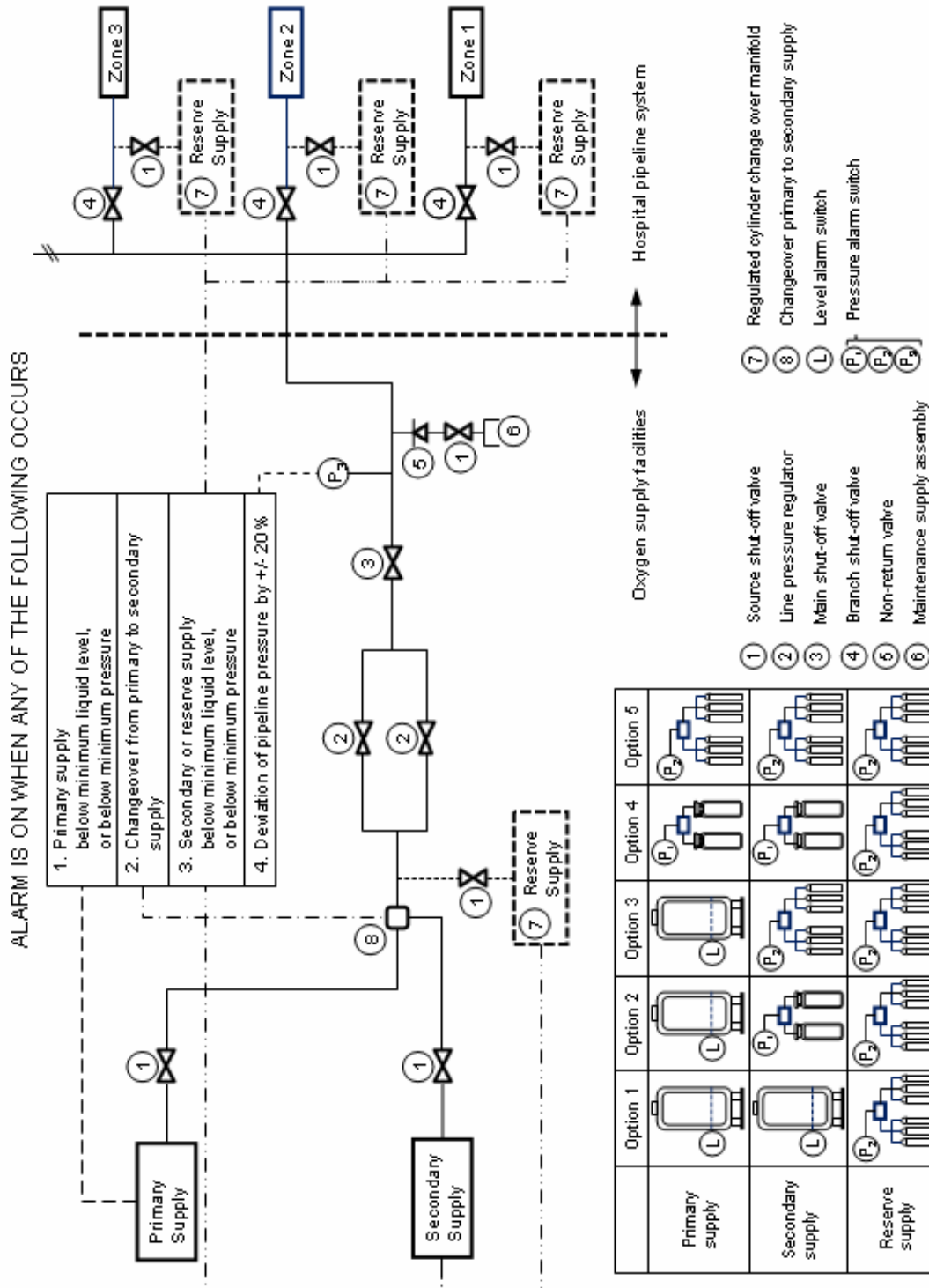


Figure 1

4.1 Primary supply

The primary source of supply shall be permanently connected and shall be the main source of supply to the medical oxygen supply system.

As a minimum, the primary supply should have usable quantity of product to meet expected usage between scheduled product deliveries.

4.2 Secondary supply

The secondary source of supply shall be permanently connected, automatically supply the pipeline, and capable of providing the total oxygen flow requirement in the event of a primary supply failure.

As a minimum, the secondary supply should have usable quantity of product to meet expected usage between a request for product delivery and the delivery of the product.

4.3 Reserve supply

The reserve supply is the final source of supply to specific sections of the pipeline, capable of meeting the required demand in the event of failure of the primary and secondary supplies, or failure of the upstream distribution pipe work.

As a minimum, the reserve supply should have usable quantity of product to meet critical patient care between a request for product delivery and the delivery of the product.

Under most conditions, compressed gas cylinders are the most appropriate method of providing a reserve source of supply. The reserve supply system should include the need for installation of independent reserve supplies to zones on the medical gas pipeline supplying critical care areas or wards or departments that are remote or vulnerable to interruption. The positioning of these manifolds is very important to ensure that the critical supply and high-dependency areas defined in the risk management process have adequate stocks of medical oxygen available in the event of a medical oxygen supply system failure.

4.4 Storage requirements

- The selection of location should comply with national regulations.
- Avoid installing liquid storage vessel in indoor environment or near drains or pits.
- The control equipment should be protected from the weather and the area fenced.
- Oxygen cylinder storage should be separated from vacuum and medical air compressor plant to avoid possible oil contamination.
- Appropriate undercover storage facilities for cylinders should be provided to ensure that the cylinders are maintained in a safe, secure and clean condition.

4.5 Capacity requirements

The capacity of any supply system shall be based on the estimated usage and frequency of delivery. The location and the capacity of the primary, secondary and reserve sources of supply, of all supply systems and the number of full cylinders held in storage, as defined by the management of the health care facility in consultation with the gas supplier, using risk management principles, shall be taken into account by the system manufacturer.

Refer to ISO 7396 -1 for the recommended risk management procedure and typical risk assessment checklist used to identify the associated risks with the medical oxygen supply system.

4.6 Review of demand

A system should be in place to regularly review healthcare facility demand patterns and for ensuring that the bulk medical supply can reliably meet this demand. This review should involve the gas supplier and healthcare facility management.

5 The alarm system

Alarm requirements

The following alarm signals should be fitted:

- Liquid level in any cryogenic vessel below the minimum specified by the management of the healthcare facility in consultation with the gas supplier
- Changeover from primary to secondary supplies
- Secondary or reserve supply below minimum pressure
- Deviation of pipeline pressure by more than $\pm 20\%$ from the nominal distribution pressure

5.1 Further requirements

- Both visual signal and auditory signal are required for the alarm.
- If an auditory signal can be silenced by the operator, the silencing shall not prevent the auditory signal from being activated by a new alarm condition.
- Alarm system should be tested periodically as recommended by equipment manufacturer.
- Master alarm should be located in an area where 24 hours attendance is provided.

6 System components

6.1 Pressure reducing station

- The healthcare facility supply pipeline reducing station which reduces supply pressure to the healthcare facility pipeline pressure must consist of a dual parallel regulator system.
- Both regulators must be online and ALL isolation valves and regulators must be in the open position.
- The design based on a single pressure regulator with a by-pass is not accepted.
- The nominal distribution pressure should be within the range of 400 kPa to 500 kPa.

6.2 Pressure relief valve

Medical oxygen pipeline system should be provided with a pressure relief device downstream of the line pressure regulator connected by means of a three-way valve so that the safety device can be exchanged for a "certificated" replacement in accordance with the frequency required by the Regulations.

6.3 Material selection

- The system supplier should ensure oxygen compatible material is used for oxygen supply system which comes into contact with the medical oxygen gas under operating conditions.

- The specific hazards of toxic products of combustion or decomposition from non-metallic materials (including lubricants, if used) and potential contaminants should be addressed. Refer to EIGA IGC 73/08/E 'Design considerations to mitigate the potential risks of toxicity when using non-metallic materials in high pressure oxygen breathing systems' for details.

7 Testing and commissioning

The objective of testing and commissioning is to ensure that all the necessary safety and performance requirements of the medical oxygen supply system will be met. Testing and commissioning procedures will be required for new installations, additions to existing installations and modifications to existing installations.

8 Operational management system

Operational management system should be in place to include statutory requirements, functional responsibilities, operational procedures, training and communications, cylinder and sources of supply management, preventive maintenance and repair and risk assessment, giving definitions and working practices throughout.

9 References

ISO 7396-1 Medical gas pipeline systems - Part 1: Pipelines for compressed medical gases and vacuum.

HTM 02-01 Medical gas pipeline system – Part A: Design, installation, validation and verification. [Health Technical Memorandum, United Kingdom]

HTM 02-01 Medical gas pipeline system – Part B: Operational management. [Health Technical Memorandum, United Kingdom]

NFPA 99C – Standard on gas and vacuum systems, 2005. [National Fire Protection Association]

AIGA 019 /05 – Connections for Portable Liquid Cylinders.

AIGA 024/05 – Connections for Transportable and Static Bulk Storage Tanks.

AIGA 016/05 – Safety Features of Portable Cryogenic Liquid Containers for Industrial and Medical gases.

AIGA TP 05/05 – Prevention of over-pressurization.

IGC 73/08/E - Design considerations to mitigate the potential risks of toxicity when using non-metallic materials in high pressure oxygen breathing systems. [European Industrial Gases Association (EIGA)]