	Title:	**UNDP TECHNICAL & REGULATORY REQUIREMENTS FOR OXYGEN PLANTS**		
	Number:	REQ-OXY-001	Version:	V01
	Effective date:	01 January 2025	Pages:	30
	Review date:	01 January 2028		

Contents

List of Abbreviations ii
Glossary ii
1. Background 1
2. Target Audience 1
3. Scope 1
4. General References 2
5. Regulatory Requirements for Components of PSA Oxygen Plant 2
5.1 Product Standard Requirements of Eligible Products 2
5.2 Regulatory Requirements for Eligible Products 3
5.2.1 Product Market Clearance 4
5.2.2 Declaration of Conformity 5
5.2.3 Third-party Laboratory Test Reports on Performance Standards 5
5.3 Requirements for Manufacturing Sites 6
5.4 Requirements for Bidders 6
5.5 Packaging and Labeling 7
5.5.1 Labeling of Medical Devices 7
5.5.2 Labeling of Pressure Equipment 7
5.5.3 Labeling of Transportable Pressure Equipment 9
5.5.4 Product Changes 10
5.5.5 Vigilance and Quality Issue 10
6. Technical Requirements for Components of Oxygen Plant 11
6.1 Product Description and Documentation 11
6.2 General Technical Requirements 12
6.3 Infrastructure Requirements 12
6.4 Electrical Requirements 12
6.5 Maintenance Services Requirements 13
6.6 Human Resources Requirements 13
6.7 Installation, Training, and Commissioning Requirements 14
7. Key Steps for Establishing a PSA Oxygen Plant in a Healthcare Facility 14
7.1 Planning and Assessment 14
7.2 Documentation and Specifications 14
7.3 Technical Work in the Procurement Process 15
7.4 Installation and Commissioning 15
7.5 Operationalization and Monitoring 16
7.6 Sustainability of PSA Oxygen Plants 16
8. Process Flow for Establishment of PSA Oxygen Plant in Health Facility 17
9. Documents to be Submitted by Bidder 19
Annex II–Site Evaluation for Oxygen Plant 22
Annex III–Commissioning Report for Oxygen Generator Plants 25

List of Figures

Figure 1: Typical configuration of PSA oxygen plant 11
Figure 2: Key Steps and processes for establishing PSA oxygen plants in healthcare facility 17

List of Tables

Table 1: Classification of significant components of PSA oxygen plant and standards requirements 2
Table 2: Standards and guidance documents on labeling requirements 7
Table 3: Process Flow for Establishment of PSA Oxygen Plant in Health Facility 18

List of Abbreviations

ASME	American Society of Mechanical Engineers
CAB	Conformity Assessment Bodies
DOC	Declaration of Conformity
ERP	World Health Organization Expert Review Panel
EU	European Union
GDPMD	Good Distribution Practices for Medical Devices
GHTF	Global Harmonization Task Force
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
LTA	Long Term Agreement
MD	Medical Device
MDD	Medical Device Directive
MDR	Medical Device Regulation
MGPS	Medical Gas Piping System
NB	Notified Body
NRA	National Regulatory Agency
PED	Pressure Equipment Directive
PSA	Pressure Swing Adsorption
QA	Quality Assurance
QMS	Quality Management Systems
TPED	Transportable Pressure Equipment Directive
UDI	Unique Device Identifier
US FDA	United States Food and Drug Administration
WHO	World Health Organization
WLA	World Health Organization Listed Authority

Glossary

Bidder: A bidder is an entity that submits an offer in response to a solicitation such as an EOI, RFI, ITB, RFQ, or RFP. Once selected and awarded the contract, the bidder becomes the supplier and is responsible for fulfilling the terms of the agreement, including delivering the required goods, services, or works.

Manufacturer: Any natural or legal person with responsibility for the design and/or manufacture of health products with the intention of making them available for use, under the Manufacturer's name; whether such a health product is designed and/or manufactured by the Manufacturer itself or on its behalf by another person(s).

Supplier (Suppliers): An entity that potentially provides goods or other products (including intellectual property), services, and/or works to the organization. Suppliers may be agents, distributors, importers, manufacturers, traders, etc., who may also bid for UNDP tenders.

Transportable Pressure Equipment: "Transportable pressure equipment" refers to all pressure receptacles, tanks, battery vehicles/wagons, multiple-element gas containers (MEGCs), valves, and accessories used to transport Class 2 gases. It encompasses gas cartridges but excludes aerosols, open cryogenic receptacles, gas cylinders for breathing apparatus, fire extinguishers, and equipment exempt from specific construction and testing rules.

Pressure Equipment: "Pressure equipment" means vessels, piping, safety accessories, and pressure accessories, including attached elements like flanges and couplings. A "vessel" contains fluids under pressure, while "piping" includes components for transporting fluids, such as pipes, tubing, fittings, and heat exchangers. "Safety accessories" protect pressure equipment from exceeding limits, including safety valves and pressure switches, and "pressure accessories" have operational functions with pressure-bearing housings.

1. Background

UNDP supports countries implementing large-scale health programs to increase access to Universal Health Coverage (UHC) within national policies and priorities.

Medical oxygen is a life-saving essential medicine with no substitution, required at all healthcare system levels to treat many pathologies involving the patient's respiratory distress and ensure safe surgical, emergency, and critical care services. Despite being an essential medicine, oxygen is a complex product. Medical oxygen is produced in an industrial process by applying good manufacturing practices or generated on-site through medical-grade concentrators, regulated as medical devices in many legislations. Medical oxygen also requires a whole system to reach patients safely. Only high-quality, medical-grade oxygen should be administered to patients.

Medical oxygen is obtained from the ambient air through a concentration process that varies based on the production source, process, and method. Medical oxygen is always delivered to patients in gaseous form, regardless of the production method, whether derived from gaseous or liquid oxygen (LOX) sources. The appropriate choice of oxygen source is based on several factors, which include oxygen demand, infrastructure, cost, technical capacity, supply chain of local production, reliability of power supply, and access to maintenance services and spare parts.

The effective establishment and operation of Pressure Swing Adsorpti5on (PSA) oxygen plants, a vital source of onsite medical-grade oxygen for healthcare facilities, require substantial initial investment, ongoing maintenance, technical expertise, reliable power sources, and robust sustainability planning to ensure access to quality-assured oxygen. However, the absence of a comprehensive guide for planning, preparing technical documentation, forming multidisciplinary teams, and addressing technical and regulatory requirements often leads to inefficient implementation, ultimately affecting oxygen availability in healthcare settings. This guide has been developed to address these challenges and provide clear and practical guidelines on the technical, quality assurance, and regulatory aspects of procuring and establishing PSA oxygen plants.

2. Target Audience

This document provides technical guidance to multiple entities engaged in procuring oxygen systems. The intended audience includes Bidders, Suppliers, the Procurement Team, the Technical Specialists Team in Country Offices, the QA Team, the Global Procurement Services Division (GPSD), and others in the procurement process. The UNDP’s procurement entity must share this document with suppliers and/or bidders as part of the solicitation process to ensure compliance with UNDP’s expectations regarding the safety and quality of the Oxygen Plant's components.

3. Scope

This document intends to provide standard regulatory and technical considerations for procuring oxygen generator plants.

PSA oxygen plants are prioritized in this document because of their broader market availability, well-established supply chains, and extensive service networks. However, most technical requirements also apply to VSA and VPSA systems. VSA and VPSA technologies offer advantages such as lower power consumption, particularly for larger production capacities, and reduced condensate risk. However, they face significant challenges, including the need for oil-free booster compressors, specialized maintenance tools, and limited spare parts and maintenance support in many regions. Additionally, these technologies are less accessible in the market due to the few manufacturers and suppliers marketing them for medical applications.

Procuring and setting up PSA oxygen plants requires multidisciplinary teams to design and implement solutions tailored to healthcare facilities' specific needs. This process involves close communication with end users and stakeholders to assess oxygen demand, evaluate site suitability, plan for human resources and infrastructure,

and determine long-term service, sustainability and financial viability. This document outlines key regulatory and technical considerations for procuring PSA oxygen plants.

4. General References

This document has been prepared based on a collection of well-established sources and adapted to offer comprehensive guidance for implementing PSA oxygen plant projects. It aligns with the International Medical Device Regulators Forum (IMDRF) classification of medical devices. It incorporates classifications and requirements based on technical documents from the Global Harmonization Task Force (GHTF) Study Group 1 - Pre-market Evaluation. The references include key international standards and technical documents designed to ensure compliance with global best practices for medical device safety, performance, and regulatory standards:

a) UNDP Quality Assurance Policy for Health Products 2024
b) GHTF/SG1/N78:2012: Principles of Conformity Assessment for Medical Devices
c) IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
d) IMDRF/GRRP WG/N52 FINAL, Principles of Labelling for Medical Devices and IVD Medical Devices: 2019
e) GHTF/SG1/N065:2010: Registration of Manufacturers and Listing of Medical Devices
f) Technical specifications for Pressure Swing Adsorption (PSA) Oxygen Plants, WHO 2020: WHO/2019-nCoV/PSA_Specifications/2020.1
g) WHO, Foundations of medical oxygen systems: web annex A: technical considerations for the procurement of oxygen generator plants, 17 February 2023
h) The Global Fund and Build Health International. Briefing Note: Pressure Swing Adsorption, Vacuum Pressure Swing Adsorption, and Vacuum Swing Adsorption, 30 Aug. 2023.

5. Regulatory Requirements for Components of PSA Oxygen Plant

5.1 Product Standard Requirements of Eligible Products

Eligible products should meet relevant safety requirements and the harmonized standards in Table 1.

Table 1: Classification of significant components of PSA oxygen plant and standards requirements.

Designation	Classification	Standard Requirements
Medical air compressor, including air dryer	Pressure Equipment Cat II Generally, Not a Medical Device but may be classified as a Medical Device Class C	ISO 7396-1: Medical gas pipeline systems – Compressed gas and vacuum systems ISO 12500-4: Filters for compressed air ISO 8573-1: Compressed air quality – Contaminants and purity classes (Class 1.4.1)
Air and oxygen storage tanks and oxygen cylinder	Oxygen Cylinder: Transportable Pressure Equipment Small oxygen Storage tanks: Pressure Equipment cat II Large hospital oxygen cylinder: Pressure Equipment Cat III	Standards Compliance – Meets ISO, NFPA, CGA standards, and/or UL or CSA approval. ISO 11114: Gas cylinder and valve material compatibility ISO 10524: Pressure regulators for medical gases ISO 15002: Flow meters for medical gas systems ISO 15245: Valve threads for gas cylinders ISO 10297, 17871, 17879: Cylinder valve specifications & testing ISO 407: Pin-index valves for medical cylinders ISO 5145: Valve outlets for gases and mixtures ISO 11117: Valve protection caps and guards ISO 11363: Taper threads for valve connections ISO 12209: Outlet connections for breathable air ISO 14246, 22435: Valve manufacturing tests ISO 7866, 20701, 9809: Refillable gas cylinder design & testing ISO 13341: Valve fitting to gas cylinders ISO 32: Medical gas cylinder marking ISO 7225: Gas cylinder precautionary labels ISO 10461: Aluminum cylinder inspection and testing ISO 11623: Composite cylinder inspection and testing

		ISO 15996: Residual pressure valves testing ISO 11119: Refillable composite gas cylinders ISO 15001: Oxygen compatibility for anaesthetic/respiratory equipment
Oxygen generator	Medical device Class C **AND** Pressure Equipment	ISO 7396-1: Medical gas pipeline systems – Compressed gases and vacuum ISO 8573-1: Compressed air quality – Contaminants and purity classes ISO 8573-2: Compressed air – Oil aerosol content measurement ISO 8573-4: Compressed air – Particle content measurement ISO 5011: Inlet air cleaning equipment – Performance testing for engines and compressors ISO 21969: High-pressure flexible connections for medical gas systems
ACO - Pneumatic changeover system / Manifold	Medical device Class C And/or Pressure Equipment	ISO 7396-1: Medical gas pipeline systems – Compressed gases and vacuum ISO 10524-2: Pressure regulators – Manifold and line regulators ISO 15001: Anaesthetic and respiratory equipment – Oxygen compatibility ISO 18082: NIST low-pressure connectors for medical gases ISO 21969: High-pressure flexible connections for medical gas systems ISO 407: Pin-index valve connections for small medical cylinders ISO 5359: Color coding for anaesthetic and respiratory equipment If US: CGA V-7.1:2011: Cylinder valve outlet connections ASTM G175-13: Oxygen regulator ignition sensitivity CGA V-1:2013: Compressed gas cylinder valve connections
Cylinder filling station (booster pump, filling ramp, and vacuum pump)	Medical device Class C Pressure Equipment cat II/III *if applicable*	ISO 8573-1: Compressed air quality – Contaminants and purity classes ISO 15001: Anaesthetic and respiratory equipment – Oxygen compatibility ISO 7396-1: Medical gas pipeline systems – Compressed gas and vacuum systems
Pressure Regulator with Flowmeter for Oxygen Cylinders	Medical device Class C	ISO 10524: Pressure regulators for medical gases – Part 1: Pressure regulators and flow-metering devices ISO 15001: Anaesthetic and respiratory equipment – Oxygen compatibility ISO 7396-1: Medical gas pipeline systems – Compressed gas and vacuum systems
Oxygen regulator	Medical device Class C	ISO 10524-1:2018: Pressure regulators for medical gases – Pressure regulators and flow-metering devices ISO 10524-2:2018: Pressure regulators for medical gases – Manifold and line pressure regulators ISO 15001: Anaesthetic and respiratory equipment – Oxygen compatibility ISO 7396-1: Medical gas pipeline systems – Pipeline systems for compressed medical gases and vacuum
Medical-grade copper pipe	Medical device Class C	ISO 7396-1: Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum. EN 13348 Copper and copper alloys. Seamless, round copper tubes for medical gases or vacuum Safety
Safety/Isolation valve (main, area valve service units (AVSU)/ zonal)	Medical device Class C	ISO 4126-1:2013: Safety devices for protection against excessive pressure ISO 11197:2016- Medical supply unit
Alarm (master and zonal)	Medical device Class C	ISO 7396-1- Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum. ISO 60601-1 – medical Electrical equipment
Terminal Units (Wall Outlets)	Medical device Class C	ISO 9170-1-Terminal units for medical gas pipeline systems - Part 1: terminal units for use with compressed medical gases and vacuum ISO 11197:2016- Medical supply unit ISO 7396-2 -Medical gas pipeline systems Part 2- Anaesthetic gas scavenging disposal systems if scavenging

Apart from the piping system, all components of the PSA plant must comply with ISO 15001: Anaesthetic and Respiratory Equipment and be cleaned in accordance with ASTM G93 to ensure oxygen compatibility.

5.2 Regulatory Requirements for Eligible Products

Devices offered to UNDP must have a market clearance following the applicable classifications. Depending on the type of device, several product regulations may be applicable. If the device is covered by and falls within the scope of several legislations, e.g., medical devices and pressure equipment, the supplier shall provide evidence of compliance with both registrations. An item's classification and compliance with its corresponding legislation depend on how the manufacturer has placed the item in the market and its intended purpose.

Examples: PSA Plant must comply with medical devices and pressure equipment regulations

5.2.1 Product Market Clearance

5.2.1.1 Medical Devices

Class B, C, and D medical devices

Medical devices offered to UNDP must comply with one or more regulatory requirements listed in a, b, c, and d.

a. Prequalified by the WHO Prequalification Programme or
b. The medical devices shall have market clearance from at least one of the regulatory agencies mentioned below:

- Australia: Therapeutic Goods Administration (TGA) Device Licence
- Canada: Device Licence, Medical Devices Regulations (SOR/98-282)
- European Union: MDD 93/42/EEC or MDR 2017/745. These will apply according to the enforcement dates published by the European Commission.
- Japan: Device Licence from Pharmaceuticals and Medical Devices Agency (PMDA)
- USA: FDA 510(k) premarket Notification Clearance or Premarket Approval (PMA), Human Device Exception Approval (HDE). For Class I 510(k) exempt medical devices, the medical device manufacturers shall be registered with the FDA, and medical devices shall be listed with the FDA.

c. Authorized for use by the World Health Organization Listed Authority **(**WLA) for the relevant product stream[1] and all relevant regulatory functions; or
d. Recommended for use by the World Health Organization Expert Review Panel (ERP) for medical devices.

The pressure regulator, vacuum regulator, central gas supply system, terminal unit, oxygen generator, and cylinder valve are major components of an oxygen plant classified as MD class C.

5.2.1.2 Pressure Equipment

For devices falling within the scope of the Pressure Equipment regulations, e.g., PSA Oxygen Plants, the supplier must provide all required documentation for each respective market, ensuring compliance with the following regulatory requirements:

Australia

- TGA Device License: Approval for medical use by the Therapeutic Goods Administration (TGA) and
- AS 4343 Compliance: Documentation proving compliance with AS 4343 pressure equipment safety standards.

Canada

- CRN Approval: Canadian Registration Number for pressure safety design and
- Health Canada License: License for medical device use.

European Union

Under the Pressure Equipment Directive (PED) 2014/68/EU
- Category II : Module A2 and Module D1/E1
- Category III : Module B EU-Type Examination Certificate and Module C2, D, E or F

Japan

- PMDA Device License: Approval by the Pharmaceuticals and Medical Devices Agency (PMDA) and
- High Pressure Gas Safety Act Compliance: Compliance with Japanese gas safety regulations.

USA

[1] List of WHO Listed Authorities WLAs https://www.who.int/initiatives/who-listed-authority-reg-authorities

- ASME BPVC Section VIII Certification: For pressure vessel safety and
- FDA Approval: Certification for medical use.

5.2.1.3 Transportable Pressure Equipment

For devices falling in the scope of Transportable Pressure Equipment regulation, such as oxygen cylinders, the supplier must provide all required documentation for each respective market, ensuring compliance with the following regulatory requirements:

Australia

Compliance with Australian Dangerous Goods Code ADG for the safe transport of medical oxygen:
- Dangerous Goods Declaration (DGD) including UN number
- Certificate of Conformity (CoC)
- Compliance labels
- Cylinder Test reports confirming compliance to Australian standard AS 2030.5 and AS 2337.1

Canada

- CSA B341 requirements for the manufacture of UN pressure receptacles and MEGCs under the authority of the competent authority of Canada (Transport Canada).
- TDG Act: Transportation of Dangerous Goods (TDG) Act and regulations and
- MDEL: Health Canada Medical Device Establishment License

European Union: European Union

Under TPED 2010/35/EU for the transport of gases in accordance with ADR, RID.
- EC Type Examination Certificate (module B)
- EC Type Approval Certificate (modules C1, F or G)
- Certificate of Conformity related to the Type Approval Certificate including technical drawings and specifying the cylinder's CE and π-marking (final inspection)

Japan

- HPGSA: Compliance with the High-Pressure Gas Safety Act

USA

- DOT Compliance: Compliance with U.S. Department of Transportation hazardous materials regulations.
- FDA Approval: Medical oxygen regulated as a prescription drug by the FDA.

5.2.2 Declaration of Conformity

The product(s) shall conform to applicable standards as per the International Organization for Standardization (ISO) or equivalent standards published by similar organizations recognized by the founding members of the GHTF/IMDRF, designated as Applicable Harmonized International Standards

The bidder shall draw up the Declaration of Conformity (DoC) to the defined applicable regulation(s) and/or standard(s) applied.

This DoC must comply with the format outlined in ISO/IEC 17050 or relevant applicable regulations. The declaration of Conformity shall include details such as a statement from the manufacturer, device classification and conformity route, applicable standards, conformity to other regulations, the date and signature by the manufacturer. It should also include the device identifier, list of accessories or components, and details of the authorized representative for manufacturers outside the region (e.g., EU Authorized Representative for Europe).

If several regulations are applicable, the manufacturer shall submit a Declaration of Conformity confirming compliance with all relevant regulations.

5.2.3 Third-party Laboratory Test Reports on Performance Standards

Official performance test reports for key parameters of oxygen generators including purity, flow and pressure (all pages, in English) must either originate from accredited test labs, whereby the accreditation authority is a member of the International Laboratory Accreditation Cooperation (ILAC), or from an EU-notified body. Accredited facilities must be ISO 17025 certified, and test reports should indicate the accredited laboratory name, address, and accreditation. Test standards must be within the scope of the laboratory's accreditation. Instructions for authentication of test report(s) and certificates should be provided.

5.3 Requirements for Manufacturing Sites

Bidders, suppliers, manufacturers, and private label manufacturers (also known as own-brand labellers or virtual manufacturers) shall conform to the following quality management system standards (as per the current revision), as applicable:

a. For products classified as medical devices

All sites involved in manufacturing medical devices must be authorized by the Regulatory Authorities or be declared to the Regulatory Authorities of the country of manufacture according to the national regulation.

The manufacturing sites of medical devices must comply with the requirements of the current ISO 13485 or an equivalent QMS (i.e., US FDA 21 CFR 820 QSR) or appropriate QMS based on the device's risk classification.

The Conformity to standards of Manufacturing sites of medical devices Class B, C or D should be established by a Conformity Assessment Body:

- authorized/registered/licensed by an NRA in one of the GHTF founding members; or
- authorized/registered/licensed by an NRA in one of the WLA for the relevant product stream and all the relevant regulatory functions; or
- accredited to carry out conformity assessment according to international, national, or regional standards by a national regulatory/competent authority of one of the GHTF founding members.[2]

The bidder shall submit a Risk Management Report in compliance with ISO 14971:2019 for all medical device products.

b. The manufacturer shall submit a copy of the valid registration certificates for the manufacturing facility of medical devices or Establishment Registration Certificates

- Australia: TGA Manufacturing Site License
- Canada: Medical Device Establishment License (MDEL)
- European Union: Manufacturing Site Registration Certificate (MDR 2017/745)
- Japan: PMDA Manufacturing Site Registration Certificate
- USA: FDA Establishment Registration Certificate

b. For products not classified as medical devices

All sites involved in the production, storage and/or transportation of medical gases must be authorized by the Regulatory Authorities of the country of manufacture.

Manufacturers shall submit evidence that all the manufacturing sites involved in the manufacturing shall comply with the current ISO 9001 or an equivalent Quality Management System (QMS) standard.

Conformity to the QMS standards will be established by a Conformity Assessment Body (CAB) accredited to conduct conformity assessment according to international, national, or regional standards by an accreditation body recognized by the International Accreditation Forum (IAF) or one of the GHTF Founding members.

5.4 Requirements for Bidders

Bidders that are not manufacturers are expected to comply with all the requirements of ISO 13485 for medical device products and ISO 9001 certificates for non-medical device products. Good Distribution Practices for

[2] UNDP Quality Assurance Policy for Health Products (2.0) July 2024

Medical Devices (GDPMD) or equivalent should also be in place for all bidders dealing with medical devices. The bidder must ensure that the product complies with the manufacturer's specifications, including temperature, humidity, or other relevant requirements.

5.5 Packaging and Labeling

5.5.1 Labeling of Medical Devices

As applicable, the product labels and graphic symbols of primary and secondary packaging should meet the requirements described in the Global Harmonization Task Force (GHTF) document Principles of Labeling for Medical Devices and IVD Medical Devices. [3], including but not limited to:

- Name and/or trademark and address of the manufacturer and Authorized Representative as applicable
- Product name, model, and reference.
- Unique device identification (UDI), type of product and main characteristics,
- Performance testing information against the mentioned standards,
- Lot number prefixed by the word “LOT” (or equivalent harmonized symbol),
- Expiry date by year and month, prefixed by the word “EXP” (or equivalent harmonized symbol),
- Information for storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol), if applicable,
- Information for handling, if applicable (or equivalent harmonized symbol),
- Product labels and graphic symbols of the primary and secondary packaging meet international norms.

If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating its position in the packaging, including a gross weight and cubic measurement.[4] The recipient Labeling, instructions for use, or a user manual must be provided in English, as requested by the recipient country. The bidders shall provide photographs of labels and primary, secondary, and tertiary packaging (as applicable) for the products under the offer. If the photographs of the labels cannot be provided at the time of offer, UNDP will consider signed and approved packaging and labeling artwork issued by the manufacturer’s QA. If artwork is presented during the RFQ stage, the bidder shall submit a picture of the primary package labeling at the purchase order stage, which the UNDP QA Team will review.

Table 2: Standards and guidance documents on labeling requirements

ISO 15223-1:2021	Symbols to be used with information to be supplied by the manufacturer
IMDRF/GRRP WG/N52 FINAL	Principles of Labelling for Medical Devices
GHTF/SG1/N70:2011	Label and Instructions for Use for Medical Devices

5.5.2 Labeling of Pressure Equipment

Europe

For pressure equipment in the European Union, compliance with PED 2014/68/EU is mandatory. The markings should include:

- CE marking followed by the Notified Body’s number.
- Serial number or unique identifier.
- Manufacturer’s name or trademark.
- Design pressure (PS) in bar.
- Test pressure (PT) in bar.
- Nominal volume in liters.

[3] International Medical Device Regulators Forum. (2019, March 21). Principles of labeling for medical devices and IVD medical devices. IMDRF Good Regulatory Review Practices.

[4] WHO Foundations of medical oxygen systems: web annex A: technical considerations for the procurement of oxygen generator plants, 17 February 2023

- Date of manufacture (year).
- Material of the equipment.
- Tare weight in kilograms.

USA

For pressure equipment in the USA, compliance with the ASME Boiler and Pressure Vessel Code (BPVC) is mandatory. The markings should include:

- ASME stamp followed by the certification mark.
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Design pressure in psi.
- Test pressure in psi.
- Date of manufacture (year).
- Material of the equipment.
- Volume in liters (if applicable).
- Tare weight in pounds or kilograms.

Canada

For pressure equipment in Canada, compliance with the Canadian Registration Number (CRN) system and Boiler and Pressure Vessel Code is required. The markings should include:

- CRN number for pressure vessel approval.
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Design pressure in psi or bar.
- Test pressure in psi or bar.
- Date of manufacture (year).
- Material of the equipment.
- Volume in liters (if applicable).
- Tare weight in kilograms.

Australia

For pressure equipment in Australia, compliance with the Australian Standard AS 4343 for pressure systems is required. The markings should include:

- AS 4343 classifications (hazard level).
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Design pressure in bar.
- Test pressure in bar.
- Date of manufacture (year).
- Material of the equipment.
- Volume in liters (if applicable).
- Tare weight in kilograms.

Japan

For pressure equipment in Japan, compliance with the High Pressure Gas Safety Act (HPGSA) is required. The markings should include:

- HPGSA marking.

- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Design pressure in bar.
- Test pressure in bar.
- Date of manufacture (year).
- Material of the equipment.
- Volume in liters (if applicable).
- Tare weight in kilograms.

5.5.3 Labeling of Transportable Pressure Equipment

The labeling and the markings of transportable pressure equipment must comply with the relevant legislation.

Europe

Under TPED, the bidder is required to submit the artwork of the visible markings on the cylinder and the technical drawing, ensuring that the following mandatory information is engraved on the oxygen cylinder:

- Pi marking followed by the Notified Body's number
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Service pressure (PS) in bar.
- Test pressure (PT) in bar.
- Nominal volume in liters.
- Date of manufacture (year).
- Next periodic inspection date.
- Material of the cylinder (e.g., steel or aluminum).
- Empty weight in kilograms.
- Optional: Design temperature (if applicable), CE marking (if applicable under other directives).

USA

For oxygen cylinders in the USA, the markings must comply with DOT regulations for hazardous materials and FDA standards for medical use. The bidder is required to submit the artwork of visible markings on the cylinder and the technical drawing, ensuring the following mandatory information is engraved on the oxygen cylinder:

- DOT marking followed by the applicable specification (e.g., DOT-3AA or DOT-3AL).
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Service pressure (PS) in psi.
- Test pressure (PT) in psi.
- Nominal volume in liters.
- Date of manufacture (month/year).
- Requalification date (for periodic testing/inspection).
- Material of the cylinder (e.g., steel or aluminum).
- Tare weight in pounds or kilograms.
- Optional:
    - Temperature range (if applicable).
    - USP oxygen label (for medical-grade oxygen).
    - FDA label (for medical device compliance, if applicable).

Canada

The markings must comply with CSA B341 and the Transportation of Dangerous Goods (TDG) Act. The following information should be engraved:

- CSA marking (e.g., TC-3AAM).
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Service pressure (PS) in psi or bar.
- Test pressure (PT) in psi or bar.
- Nominal volume in liters.
- Date of manufacture (year).
- Requalification date (for periodic testing/inspection).
- Material (e.g., steel or aluminum).
- Tare weight in kilograms or pounds.

Australia

The markings must comply with the Australian Dangerous Goods (ADG) Code. The required markings are:

- ADG Code marking.
- ARTG number if the cylinder is listed as a medical device.
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Service pressure (PS) in bar.
- Test pressure (PT) in bar.
- Nominal volume in liters.
- Date of manufacture (year).
- Requalification date or date of last inspection
- Material (e.g., steel or aluminum).
- Tare weight in kilograms.
- The label must clearly state the contents of the cylinder, typically as "Medical Oxygen" or its chemical symbol "O_2."

Japan

For oxygen cylinders in Japan, the markings must comply with the High-Pressure Gas Safety Act (HPGSA). The following information must be engraved:

- HPGSA marking.
- Serial number or unique identifier.
- Manufacturer's name or trademark.
- Service pressure (PS) in bar.
- Test pressure (PT) in bar.
- Nominal volume in liters.
- Date of manufacture (year).
- Requalification date.
- Material (e.g., steel or aluminum).
- Tare weight in kilograms.

5.5.4 Product Changes

After awarding the long-term agreement or issuance of a purchase order (PO) for specific products, if any changes or modifications are made to the product(s), the LTA/PO awardee shall notify UNDP QA immediately. UNDP QA reserves the right to reconsider the approval based on the supporting documents provided.

5.5.5 Vigilance and Quality Issue

During the long-term agreement, the LTA/PO awardee shall notify UNDP QA, without undue delay, of any alert or quality issue related to the qualified product. Any adverse event (complaint, internal nonconformity alert, or quality issue related to the qualified product) leading to one of the following outcomes:

- Death of a patient, user, or other person
- Serious injury of a patient, user, or other person
- No death or serious injury occurred, but the Event that Might Lead to Death or serious injury of a Patient, User, or Other Person if it Recurs must be investigated. Corrective actions such as field safety notices and/or product recalls must be defined and implemented, if necessary, in compliance with the regulation.

6. Technical Requirements for Components of Oxygen Plant

6.1 Product Description and Documentation

The oxygen generation plant solution is tailored to facility, subnational, or national oxygen needs, factoring in energy availability, technical capacity, operational hours, proximity to other oxygen sources, and backup supply. Oxygen generator plants use pressure swing adsorption (PSA), vacuum swing adsorption (VSA), or hybrid vacuum pressure swing adsorption (VPSA) technologies to produce medical oxygen, typically with 93% ±3% purity. All systems compress ambient air, filter it, and pass it through molecular sieves to achieve the pressure and purity required. PSA relies on an air compressor, while VSA uses a blower and vacuum pump, offering benefits like longer sieve life and better efficiency in humid conditions. However, a booster compressor is required for output pressure. VPSA combines both technologies, ideal for large-scale production but with higher complexity and cost. Although VSA plants cost around 15% more than PSA, the cost gap narrows for capacities over 100 Nm3/hr. PSA remains the primary focus of this document due to wider market availability, though most technical requirements also apply to VSA and VPSA systems. The following diagram illustrates the main components of a PSA oxygen generator.

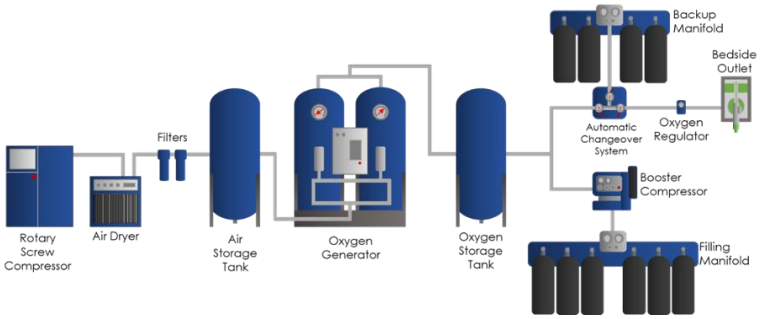

Figure 1: Typical configuration of PSA oxygen plant

Source: Pressure Swing Adsorption, Vacuum Pressure Swing Adsorption, and Vacuum Swing Adsorption - Briefing Note The Global Fund[5]

Bidders must provide detailed descriptions of goods and services and technical documentation proving compliance with safety and performance standards (IMDRF/GRRP WG/N47). The solicitation should include:

- PSA plant configuration (primary/secondary/backup/ skid mounted/ containerized/ built on site) to meet oxygen demand estimates per healthcare facility.
- Functional components that include interconnections with a cylinder filling ramp, pipeline network, automatic changeover (manifolds), and others (e.g., connectors, tubing, filters, electrical panels, alarms).
- Certificates of analysis, technical tests, and other documents proving the quality, safety, and effectiveness of all components
- User and service manuals in English and the official language of the end user
- Piping and Instrumentation Diagram (P&ID)
- A 10-year lifespan guarantee and a 24-month warranty from the manufacturer.
- A 3-year spare parts kit, including detailed part descriptions and costs.

[5] https://www.theglobalfund.org/media/13269/c19rm_psa-vpsa-vsa_briefingnote_en.pdf

- Summary of Technical Documents (STED), technical datasheets, and commercial catalog explicitly identifying the model and product code of each component

6.2 General Technical Requirements

- PSA oxygen plant capacity should be designed based on the assessed oxygen demand and specific healthcare facility context[6,7,8].
- PSA oxygen plant configuration can be built on-site, skid-mounted, or containerized and supplied as turn-key packages with all necessary equipment.
- The PSA oxygen plant must meet the end user's technical specifications; minimum specifications are outlined in [9].
- Site-specific factors like elevation, temperature, humidity, and dust should be considered during design, along with system output and configuration.
- The suppliers of the PSA oxygen plant must provide site preparation details, including:
    - Power requirements: mains capacity, single line diagrams (SLDs) for electrical works, electrical connections, grid compatibility, and backup diesel generators.
    - Safety and structural requirements, including building dimensions/space requirements, door/window size, ventilation, air extractors, and copper piping. A final layout and drawings must be provided.
    - Pre-shipment inspection, performance tests (minimum three days continuous operation), alarm tests, and commissioning reports are required.

6.3 Infrastructure Requirements

- The PSA oxygen plant location should be carefully chosen, considering proximity to the medical gas piping system (MGPS) to prevent pressure drops, safety distances, and low-pollution areas.
- The oxygen production system must be housed in a structure that protects it from environmental factors such as precipitation, wind, and dust and reduces operational noise.
- Housing structures should consider local environmental conditions and insulation availability to manage heat and fire. If metallic roofing and corrugated sheets cause overheating, enhanced ventilation is needed.
- Entrance doors should have protective shutters accessible only to authorized personnel, with proper signage for medical gases and fire safety.
- Adequate ventilation is needed for rapid air exchange, with oxygen depletion sensors to monitor enriched atmospheres.
- Floors should be flat, durable, easy to clean, and vibration-reducing, while underground areas that risk oxygen accumulation should be avoided.
- Proper ducts for water discharge, exhaust ventilation, and pathways for cables and pipelines should be provided.
- To prevent contamination, the nitrogen discharge duct should be vented at least 3 meters from doors or windows and face downward.
- The housing dimensions must match manufacturer guidelines, allowing sufficient space for maintenance.
- Pipelines and fittings must comply with national or international standards.
- Full and empty high-pressure gas cylinders should be stored separately and provided with sufficient space for ease of maneuvering.

6.4 Electrical Requirements

- The PSA oxygen plant requires reliable, continuous primary a nd backup power supply sources connected

[6] WHO Foundations of Medical Oxygen Systems,17 February 2023
[7] UNICEF Oxygen System Planning Tool, 2021
[8] The Global Fund Review of Implementation of PSA oxygen generating plants, October 2024
[9] World Health Organization. *Technical specifications for Pressure Swing Adsorption (PSA) oxygen plants: Interim guidance, 8 June 2020*.

- Appropriately sized electrical cables must connect all components, including the air compressor, dryer, oxygen generator, and booster compressor. At the same time, a power cabinet with surge and earth protection and a built-in phase controller is needed for three-phase devices.
- The supplier must provide an electrical requirements chart detailing the starting current, minimum protection current, and load curves, essential for determining total power needs for the complete components of the plant.
- The unit must be powered from an armored grounded outlet, ensuring electrical components match the power source's frequency, voltage, and plug type.
- If diesel generators are used, they must come with spare part kits and maintenance services, with features like shunt excitation and integrated automatic voltage regulators if they serve as primary power sources.
- Generators should be weatherproofed, sound-attenuated, and located safely away from the PSA plant and oxygen sources. Exhaust should be directed away from walkways, and unobstructed air intake should be provided for easy refueling while restricting access to authorized personnel.

6.5 Maintenance Services Requirements

- Implementing regular preventive maintenance programs (PMP) is essential to prevent malfunctions and optimize utilization, as the manufacturer recommends.
- Spare part kits must be available throughout the plant's lifespan and include a detailed list with part numbers, descriptions, quantities, brand/model specifics, and expiration dates where applicable.
- Operators should have a maintenance toolkit containing an oxygen analyzer, testing, mechanical tools, and PPE such as gloves, protective glasses, and hearing protection.
- If a service level agreement (SLA) exists with the supplier, it should outline corrective maintenance terms, including estimated response times, lead times for spare parts, stockpile locations, remote support capabilities, and availability of local agents.
- The maintenance services must include a warranty covering a minimum of two years, encompassing preventative and corrective maintenance services, refresher training for users and technicians, and the supply of spare parts throughout the warranty period.

6.6 Human Resources Requirements

The procurement, installation, commissioning, and management of PSA oxygen plants require key personnel, including:

- **Country Office Responsibilities:**
    - Project Manager: An engineer with medical oxygen systems experiences who manages the project’s execution, oversees its progress, and communicates with stakeholders.
    - Biomedical Engineer: Provides technical support and ensures quality during the oxygen plants' procurement, installation, and commissioning phases.
    - Civil/Architectural Engineer: Oversees the design and construction of the physical infrastructure required for the plant, ensuring it meets the necessary standards.
    - Trained Personnel at Facility: Hospitals must have trained staff to operate, maintain, and manage the medical oxygen system.
- **Supplier Responsibilities:**
    - Provide skilled and unskilled labor for PSA projects and an organizational structure outlining roles and responsibilities.
    - Project Manager: An engineer experienced in medical oxygen systems, overseeing the project, ensuring goals are met, and acting as the main point of contact with stakeholders.
    - Electrical Engineer: A specialist in electrical systems who designs and installs the plant’s electrical components to ensure safety and efficiency.
    - Mechanical/Biomedical Engineer: An expert in designing medical gas piping systems, ensuring oxygen is delivered safely throughout the facility.

- Biomedical Engineer: Focuses on installing and commissioning oxygen plants, ensuring they operate effectively and meet safety standards.
- Civil/Architectural Engineer: Designs and implements the building and infrastructure needed for the plant, ensuring it meets all regulatory and functional requirements.

6.7 Installation, Training, and Commissioning Requirements

- The PSA oxygen plant shall be installed and configured according to manufacturer instructions and international/local standards, with manufacturer-certified competent personnel.
- All components, including the proper interconnection of the oxygen plant with medical gas systems, shall ensure compliance with the required specifications.
- The PSA oxygen plant should be commissioned following the comprehensive test, calibration, and performance verification against specified standards, ensuring proper operation of flow rates, pressures, oxygen concentration, alarms, and backup system functionality.
- Comprehensive training should be provided on-site during commissioning, covering equipment operation, maintenance, troubleshooting, and safety procedures. This training should be conducted by certified trainers from the manufacturer and include all necessary training materials, manuals, and SOPs.
- The final handover should include all end-user acceptance reports, training reports, detailed built-in drawings, testing and calibration reports, warranties, manuals, and other relevant documentation.

7. Key Steps for Establishing a PSA Oxygen Plant in a Healthcare Facility

7.1 Planning and Assessment

- **Establish a multidisciplinary team:** At the initial stage of the PSA oxygen plant project, the UNDP Country Office (UNDP CO) and its Project management Units (PMU) should form a multidisciplinary team of biomedical engineers, civil engineers, project managers, procurement officers, and finance professionals to oversee procurement and implementation. Biomedical engineers manage the technical aspects, including equipment selection, installation, and commissioning. Civil engineers ensure infrastructure readiness, project managers coordinate activities, procurement officers handle tendering, and finance professionals manage budgeting. The team should develop a comprehensive work plan with clear timelines, roles, responsibilities, and milestones, guiding the project through all phases to ensure technical and logistical success. The UNDP CO should actively engage key stakeholders, including donors, the Ministry of Health, relevant hospital personnel, partners, and other involved parties during this phase and beyond.
- **Conduct an assessment**: The UNDP/PMU should perform a comprehensive assessment to identify oxygen demand at the facility or regional level, evaluate infrastructure for PSA plant installation, and assess space and electrical requirements. This includes considering power stability and operational hours and ensuring backup oxygen sources for a consistent supply. Biomedical engineers assess oxygen demand and evaluate existing oxygen systems, while civil engineers focus on assessing infrastructure requirements. Additionally, it is essential to conduct an environmental and social impact assessment (ESIA) to evaluate potential risks and ensure the project complies with environmental and social safeguards. The ESIA should address waste management, noise pollution, energy consumption, and the impact on nearby communities.

7.2 Documentation and Specifications

- **Develop technical specifications**: The UNDP/PMU should develop detailed technical specifications using this template[10]. Specifications should cover all PSA plant components, including oxygen generation units, compressors, filters, dryers, manifolds, pipeline connections, infrastructure, civil works, and electrical requirements. These specifications must address critical parameters such as flow

[10] TEMPLATE FOR TECHNICAL SPECIFICATIONS OF HEALTH PRODUCTS v01 release.xlsx

rate, purity, pressure, energy efficiency, and compatibility with existing systems. The Global Fund Partnership and Health Systems Team (GFPHST) Quality Assurance (QA) team should review these technical specifications to ensure they meet quality standards.

- **Develop Bills of Quantities (BOQs)**: The UNDP/PMU should prepare detailed BOQs for all required materials, equipment, services, piping, civil works, infrastructure upgrades, and electrical requirements, ensuring that they align with the technical specifications developed. The GFPHST QA team should review these BOQs to ensure compliance with technical and quality standards.

- **Develop Terms of Reference (TOR)**: The UNDP/PMU should clearly define the scope of work, encompassing the supply, installation, testing, commissioning, warranties, maintenance, training, quality assurance, safety protocols, and minimum qualifications for vendors and personnel. This comprehensive definition ensures that all project requirements are met and sets clear expectations for performance and accountability. The GFPHST QA team should review the scope of work to ensure that it aligns with technical and quality standards.

7.3 Technical Work in the Procurement Process

- **Prepare technical documents for solicitation**: The UNDP/PMU should prepare and consolidate all necessary documents, including technical specifications, Bills of Quantities (BOQs), and Terms of Reference (TORs).
- **Evaluation of Bids**: The GFPHST QA team, in collaboration with the UNDP/PMU where necessary, should conduct technical and regulatory evaluations to ensure compliance with end-user requirements and UNDP QA Policy.

7.4 Installation and Commissioning

- **Prepare the site**: The UNDP/PMU should collaborate with the vendor to complete civil works infrastructure modifications and electrical upgrades[11]. They should conduct site readiness checks to verify that electrical capacity, ventilation, and structural requirements meet the specifications, as detailed in the site preparation checklist provided in Annex II.

- **Install**: The UNDP/PMU should inspect all components upon product delivery to verify compliance with the required specifications. The supplier is responsible for the installation work, while the UNDP/PMU should provide technical oversight to ensure the proper installation of all components, including oxygen pipelines, cylinder filling ramps, manifold systems, and control panels, while ensuring compliance with technical specifications.

- **Verification and acceptance tests**: The supplier is responsible for conducting comprehensive testing of the complete PSA oxygen plant, including assessments of oxygen purity, flow rate, pressure, functionality, and safety checks for alarms, emergency systems, and operational parameters. The UNDP/PMU should provide technical oversight during this process, ensuring acceptance tests are performed and results are documented to verify compliance with technical specifications and TORs. To enhance this process, UNDP/PMU is encouraged to engage certified third-party organizations, where available, to provide independent verification and certification, ensure adherence to relevant standards, and validate the plant's quality, safety, and readiness for operation. A sample commissioning report is provided in Annex III.

- **Training**: The supplier should provide training in collaboration with the UNDP/PMU to equip facility staff, including operators, maintenance personnel, and technical support teams, with knowledge of operational theory, safety protocols, maintenance, troubleshooting, and system monitoring of the PSA oxygen plant.

- **Inventory and documentation**: The supplier should submit all required documentation, including test results, training reports, manuals, warranties, and standard operating procedures, ensuring all

[11] The Global Fund, Project BOXER Info Session PSA Plant Site Readiness, February 2023

relevant materials are provided. The UNDP/PMU, in collaboration with the end user, should oversee the quality of the commissioning process and ensure that the equipment is registered in the inventory system. Once functionality is verified, the PSA oxygen plant should be officially commissioned, confirming it is fully operational and ready for use in patient care. A sample commissioning report is provided in Annex III.

7.5 Operationalization and Monitoring

- **Optimize performance**: The end user should establish a continuous monitoring plan for critical parameters such as purity, flow rate, and pressure to optimize the PSA oxygen plant's performance. This should include real-time monitoring if the capability is available.
- **Scheduled maintenance and repair**: The end user, in collaboration with the supplier, should implement a preventive maintenance schedule according to the manufacturer's recommendations, including routine inspections, filter cleaning, part replacement, and control system calibration. Repairs should be conducted promptly to prevent system failures. The end user should also coordinate with the supplier for post-warranty services, such as spare parts and technical support, while maintaining a log of all maintenance activities to track system health and performance over time. To formalize these responsibilities, any supplier obligations related to maintenance, repair, or post-warranty services should be explicitly detailed and incorporated into a comprehensive Service Level Agreement (SLA) between the end user and the supplier/local service provider. The SLA must specify response times for emergency repairs, scheduled maintenance intervals, spare parts availability, and technical support responsibilities, including remote diagnostics, on-site troubleshooting, and staff training.
- **Incident reporting and response**: The end user should establish reporting protocols for malfunctions, deviations, or incidents and develop a response plan with emergency repair services and backup strategies.
- **Data reporting**: The end user should generate regular production, maintenance, and repair performance reports. These reports inform facility management and vendors of necessary system improvements or adjustments. Incorporate feedback into future operational planning and optimization efforts.

7.6 Sustainability of PSA Oxygen Plants

Ensuring the long-term sustainability of PSA oxygen plants is vital for continuous access to medical oxygen in healthcare settings, encompassing the following key aspects:

Long-term operational planning: Country Offices, in collaboration with end users, should develop a sustainability roadmap for PSA oxygen plants to ensure continuous and reliable operation, minimize system failures, and guarantee uninterrupted access to medical oxygen. This roadmap should prioritize preventive maintenance, operational efficiency, and backup systems to address fluctuations in oxygen demand and environmental conditions, aligning with hospital goals to maintain a resilient oxygen supply.

Capacity building for sustainability: Country Offices should facilitate ongoing training for end users, ensuring they can operate and maintain PSA oxygen plants effectively. Training should focus on preventive maintenance, troubleshooting, energy optimization, and resource efficiency to reduce failures and maintain uninterrupted oxygen supply.

Spare parts and resource optimization: Country Offices should work with end users to establish a reliable supply chain for spare parts and consumables, ensuring the continuous availability of critical components. Emphasis should be placed on maintaining optimal inventory levels to balance resource needs with waste reduction while collaborating with suppliers to source sustainable, high-quality components.

Adequate budgeting for operation and maintenance: End users should plan and allocate a budget sufficient to cover the ongoing operation, maintenance, and repair of PSA oxygen plants using available planning tools such as UNICEF Oxygen System Planning Tool[7]. This includes ensuring funds for routine maintenance, spare parts, energy consumption, and upgrades to maintain optimal performance. Proper budgeting helps minimize downtime, provides a continuous supply of medical oxygen, and allows for timely responses to unexpected issues or equipment failures.

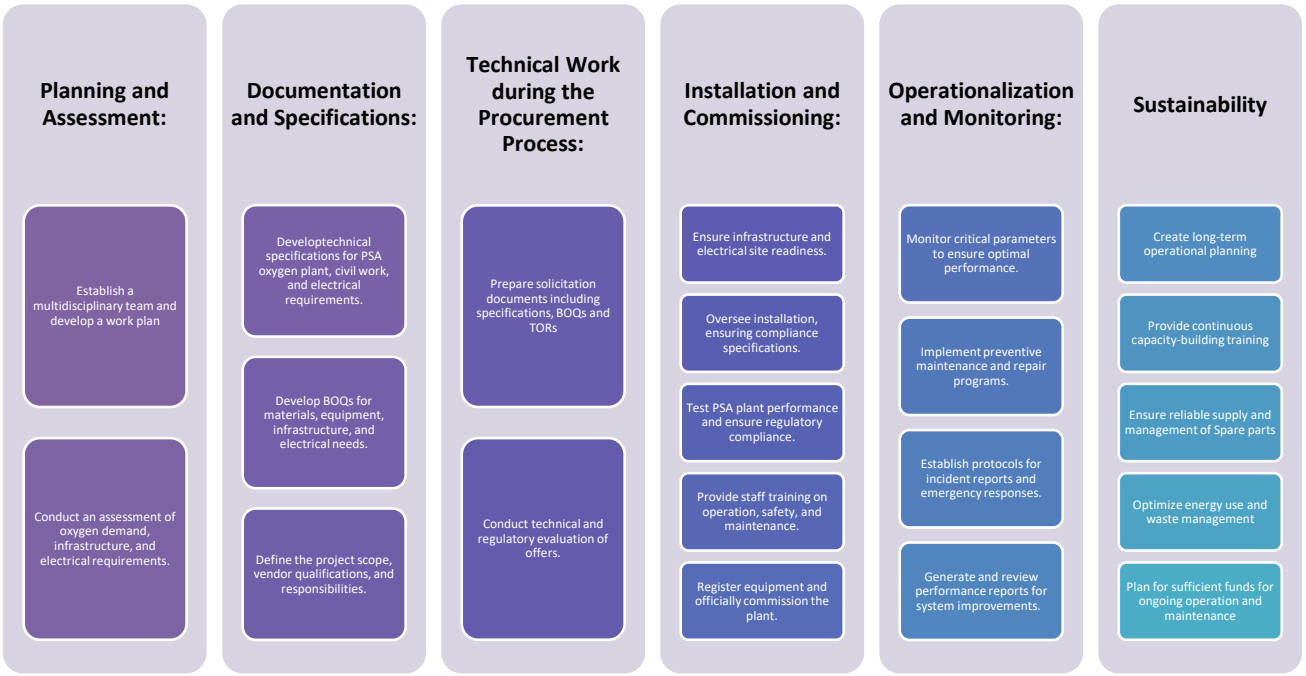

Figure 2: Key Steps for Establishing a PSA Oxygen Plant in a Healthcare Facility

8. Process Flow for Establishment of PSA Oxygen Plant in Health Facility

This process flow provides a structured framework to ensure the successful implementation of PSA oxygen plant projects in healthcare facilities. The process ensures that each phase is thoroughly planned and executed by addressing key steps such as assessment, site preparation, specification development, procurement, installation, and commissioning, reducing the risk of errors or delays. It facilitates coordination among stakeholders, including UNDP/PMU, Quality Assurance and Procurement teams, and suppliers. This process, summarized in Table 3, enhances efficiency, resource allocation, and plant functionality, ensuring healthcare facilities can meet critical oxygen demands and improve patient care. The timeline provided is illustrative and should be adapted to the specific context, considering factors such as the number of plants and sites, infrastructure requirements (new housing for skid mounted/ built onsite vs containerized plants), and the procurement modality (request for quotation vs invitation to bid).

Table 3: Process Flow for Establishment of PSA Oxygen Plant in Health Facility

Process	Key Activities and Responsibilities	Responsible Office/Team	Indicative Timeline
Initiation and Planning	1. Conduct stakeholder meetings to outline project goals, timelines, and expected outcomes.	UNDP CO/PMU and PSM Specialist	Four months
	2. Form a multidisciplinary team of biomedical engineers, civil engineers, project managers, procurement officers, and finance professionals to oversee procurement and implementation	UNDP CO/PMU	
	3. Develop a project budget and work plan by defining milestones, responsibilities, timelines, and outcomes.	UNDP CO/PMU	
Assessment	1. Conduct facility audits and assess gaps in existing infrastructure, oxygen systems (if any), power supply, and backup systems to ensure proper installation and reliable electricity supply.	UNDP CO/PMU	Two months
	2. Assess projected oxygen demand and gaps by analyzing inpatient admissions, bed counts, terminal outlets per bed, occupancy rates, historical consumption, average flow rates, hypoxemia rates, and future expansion plans.	UNDP CO/PMU	
	3. Assess the staffing and additional plant operation and maintenance training requirements.	UNDP CO/PMU	
	4. Compile and document the assessment's findings, including identified gaps and recommended actions for addressing them.	UNDP CO/PMU	
Specification Development	1. Develop technical specifications for the PSA oxygen plant and components (e.g., medical gas piping, filling stations, humidifiers, flowmeters, pressure regulators, manifolds, cylinders, and monitoring systems) considering local climate and operational conditions.	UNDP CO/PMU	Two months
	2. Identify essential safety and quality standards and regulatory requirements in alignment with UNDP QA Policy.	UNDP CO/PMU	
	3. Identify requirements for spare parts, maintenance tools, and availability of local technical support to ensure sustainability.	UNDP CO/PMU	
	4. Develop specifications for civil works, including site preparation, structural modifications, and infrastructure requirements for PSA oxygen plant installation.	UNDP CO/PMU	
	5. Specify electrical requirements, including backup power supply, wiring standards, and integration with existing systems.	UNDP CO/PMU	
	6. Develop BOQs that align with the technical specifications for the PSA oxygen plant, civil works, and electrical requirements.	UNDP CO/PMU	
	7. Develop TORs that define the scope of work for guiding the procurement process.	UNDP CO/PMU	
Review of Specifications	1. Conduct a review to ensure the specifications, BOQs, and TORs are accurate and complete and comply with end-user technical requirements and the UDP QA Policy.	GFPHST QA	One month
	2. Refine and finalize the technical specifications, BOQs, and TORs, ensuring they meet end-user technical requirements and the UNDP QA Policy.	UNDP CO/PMU	
	3. Confirm that the final specifications, BOQs, and TORs comply with the end-user technical requirements and UNDP QA Policy.	UNDP CO/PMU and GFPHST QA	
Bidding	As per the UNDP Procurement procedures, including tender document development, clarifications, and launch a tender in Quantum.	GPSD Health	Three months
Technical Evaluation	1. Form a technical evaluation committee comprising biomedical engineers, civil engineers, and QA specialists.	UNDP CO/PMU and QA GFPHST	Two months
	2. Develop or review an evaluation matrix to evaluate and rank each bid based on technical and QA criteria.	GFPHST QA	
	3. Conduct technical and regulatory compliance evaluations of the submitted bids to ensure the offers meet all required specifications and standards.	QA GFPHST	
	4. Select the supplier based on evaluation for technical and compliance with QA requirements.	GFPHST QA	
	5. Prepare an evaluation report summarizing the assessment process, results, and recommended supplier(s).	GFPHST QA	

Contracting	1. As per the UNDP procedures	GPSD Health and UNDP CO/PMU	One month
Site Preparation	1. Assess the infrastructure and reliable power supply and design detailed technical drawings that comply with relevant regulations for installation readiness.	UNDP CO/PMU and Supplier	Six months
	2. Implement infrastructure upgrades, including construction, renovation, and electrical work.	UNDP CO/PMU and Supplier	
	3. Verify site readiness through inspections and certifications, ensuring all infrastructure and electrical requirements are prepared for the PSA oxygen plant installation.	UNDP CO/PMU and Supplier	
Inspection and Reception	1. Inspect the equipment upon delivery to ensure all components are in good condition and comply with specifications per UNDP SOP for Inspection and Receipt of Health Products[12].	UNDP CO	One month
Installation	1. Evaluate the installation site to ensure it meets all technical requirements, including space, structural integrity, and electrical connections.	UNDP CO/PMU and Supplier	One month
	2. Install the PSA oxygen plant according to the design plan, assemble components, and follow manufacturer guidelines.	Supplier	
	3. Connect the PSA oxygen plant to the electrical supply, filling, and oxygen distribution pipelines, ensuring compliance with relevant standards for efficient oxygen delivery.	Supplier	
Testing, Training, and Commissioning	1. Conduct comprehensive PSA oxygen plant and components testing to ensure oxygen purity, flow rate, and pressure compliance technical specifications.	UNDP CO/PMU and Supplier	Two months
	2. Conduct hands-on training sessions for technical staff and healthcare workers on using, operating, and maintaining the PSA oxygen plant.	Supplier	
	3. Submit testing results, training reports, manuals, as-built drawings, and SOPs to obtain formal sign-off.	Supplier	
	4. Complete commissioning by certifying the system, securing end-user approval, and handing over the PSA oxygen plant for clinical use.	UNDP CO/PMU and Supplier	
	5. Engage certified third-party organizations to independently verify the commissioning of PSA oxygen plants, ensuring compliance with international standards, risk mitigation, and reliable operation for sustainable oxygen supply	UNDP CO/ PMU and Third Party	
Operationalization and Maintenance	1. Develop regular maintenance and capacity-building plans to ensure efficient operation and reduce system failures.	UNDP CO/PMU and End User	One month
	2. Establish a system to track repairs, performance metrics, and operational issues and ensure long-term system sustainability.	UNDP CO/PMU and End User	Two months
	3. Oversee warranty management and spare parts inventory to ensure timely servicing and optimize resource use and sustainability.	UNDP CO/PMU and End User	Ongoing
	4. Monitor oxygen output levels, purity, flow rates, and system pressures to ensure the PSA oxygen plant meets operational requirements.	UNDP CO/PMU and End User	Ongoing

9. Documents to be Submitted by Bidder

Bidders and manufacturers must submit valid and current copies of certificates of compliance with the technical and regulatory requirements mentioned in Annex l. The supplier is responsible for checking the expiry of the certificates before submitting them to UNDP.

All submissions must be in English and in a language as stated in the bidding documents. See Annex l for the checklist for document submission. The bidder shall provide clarifications in the event of non-availability of proof/certificates that are mandatory at the time of submission. Depending on the foreseeable use of a product, the QA team may request additional documents, as applicable.

[12] SOP for Inspection and Receipt of Health Products

Annex I–Document Submission Checklist for Bidders

Serial No.	Type of information required from the bidder
1.	**Specifications and quality standards specific to Oxygen Systems**
2.	Detailed Configuration and distribution system
3.	List of components of PSA(s) and distribution systems
4.	List of accessories and spare, mandatory spares parts and consumables
5.	Other technical requirements (infrastructure, electrical needs, and documentation)
6.	A minimum life span of 10 years is guaranteed by a letter from the manufacturer.
7.	The warranty period is a minimum of 24 months (2 years) starting from the date of commissioning, confirmed by a signed letter from the manufacturer—a list of activities within the Warranty Period.
8.	Detailed project team composition, including CVs of key personnel for the supplier and local agent.
9.	Evidence of previous experience in executing similar projects for at least three years
10.	Site assessment report, including architectural and technical drawings (applies to the awarded bidder)
11.	A site assessment report on the existing infrastructure's medical gases/electrical installation and actual compliance with applicable national and international norms, including an electrical load test report (applies to the awarded bidder).
12.	Photo documentation of the electrical and oxygen sources, storage, and distribution systems.
13.	Technical drawings necessary for the execution of the contract, including medical gas piping systems, civil works, integration, pneumatic interconnections, electrical and alarm connections, HVAC, electrical for the plant cabinet, cable and connection to the hospital main board or power grid, lighting systems, painting, and finishing, fire systems according to regulations, and security systems.
	Technical documentation
1.	Product/Device description (Name, manufacturer's product reference/code aligned with labelling, trade name/brand, intended use, brochure, etc.)
2.	Product specification or Technical Data Sheet (STED)
3.	Certificate of Conformity or Test Report of compliance to harmonized standards, issued by Accredited Laboratory in accordance with ISO 17025.
4.	Certificate of analysis (CoA) conforming compliance with International Pharmacopoeia (Ph. Int.), US Pharmacopoeia (USP), and European Pharmacopoeia (Ph. Eur.) for oxygen purity level.
5.	Picture of the label/identification plate for electrical and/or battery-operated equipment and instruments. Electrical power input requirements (voltage, frequency, and socket type)
6.	Pictures of packaging with complete labelling clearly visible (all sides). Labelling shall include name and trademark of the manufacturer, model, or product's reference; information for storage conditions (e.g., temperature, pressure, light, humidity). Product labels and graphic symbols of the primary and secondary packaging to meet international norms. If several legislations are applicable, all mandatory labels must be submitted.
7.	Instruction for use, transportation, storage, and disposal
8.	User manual, as applicable, detailing: a) specific protocols for operation. b) list of equipment and procedures required for cleaning, disinfection, troubleshooting, calibration, and routine maintenance.
9.	Service manual detailing: a) specific protocols for technical maintenance. b) list of equipment and procedures required for preventive and corrective maintenance.
10.	MSDS for dangerous goods or parts
	Regulatory documents
1.	**Quality Management System certificate** of the manufacturing site, as applicable: - Medical Devices: ISO 13485 certificate or equivalent issued by a CAB recognized by the NRAs in the GHTF founding member countries. - Non-Medical Devices: ISO 9001 certificate or equivalent issued by a CAB recognized by the NRAs in the GHTF founding member countries.
2.	**Marketing authorization** of the device in a founding members of GHTF as per classification applicable. For the Medical Device class B/C/D in a GHTF founding member country: - EC Certificate according to MDD/MDR issued by a Notified Body and

	- Declaration of conformity to MDD/MDR - Or Equivalent Regulatory compliance from another GHTF founding member country For the oxygen generator/PSA oxygen plant, provide market authorization for both Medical Devices and Pressure Equipment regulation: - Market clearance certificate as a pressure equipment in accordance with the regulations of a GHTF founding member country. - EC Certificates PED 2014/68/EU issued by a NB, all modules applicable listed in 5.2.1.2 Pressure Equipment and - Declaration of conformity to Pressure Equipment Directive (PED) 2014/68/EU - Or equivalent Regulatory compliance from another GHTF founding member country - Market clearance certificate as a Medical Device class in a GHTF founding member country: - EC Certificate according to MDD/MDR issued by a Notified Body and - Declaration of conformity to MDD/45 MDR - Or Equivalent Regulatory compliance from another GHTF founding member country For Transportable pressure equipment (i.e. oxygen cylinders), provide market authorization in accordance with the Transportable Pressure Equipment regulations of a GHTF founding member country. - Europe: under TPED 2010/35/EU for the transport of gases in accordance with ADR, RID. • EC Type Examination Certificate (module B) and • EC Type Approval Certificate (modules C1, D, E, F or G) and • Certificate of Conformity related to the Type Approval Certificate including technical drawings and specifying the cylinder's CE and π-marking (final inspection) • Declaration of Conformity related to TPED - Or equivalent Regulatory compliance from another GHTF founding member country
3.	For medical devices offered under EU regulation 2023/607, supplier to submit (1) A self-declaration from manufacturers to continue to place devices on the EU market after expiration of the MDD CE certificate under 2023/607 regulation (2) A confirmation letter from notified body confirming extension of EC Certificate valid under MDD/AIMDD
4.	Declaration of conformity (DoC) as per ISO 17050 drawn up according to all applicable legislation (medical devices, electrical equipment, pressure equipment, etc.). listing all applied international standards
5.	Manufacturing Authorization or Manufacturing license of the Legal manufacturer.
	Requirements for Supplier
1.	Name and address
2.	Quality management system certificate and Good Distribution and Storage practice certificate or equivalent
3.	Letter or Certificate of Authorization from the manufacturer confirming that the bidder is authorized for provisions, as applicable

*Proof or copy shall be provided for each of the requirements either separately or as a part of the technical documents. Copies of all documents shall be current and valid at the time of submission.

Annex II–Site Evaluation for Oxygen Plant

Adapted from WHO Foundations of Medical Oxygen Systems: Web Annex B – Site Evaluation for Oxygen Generator Plants, 2023.

Preliminary activities at the new oxygen generator plant site should include site evaluation and preparation, covering human resources, electrical supply, and infrastructure readiness. Long-term service agreements, financial needs, and security measures must also be addressed. The site assessment should be completed two weeks before the equipment arrives, ensuring alignment with manufacturer recommendations, national regulations, and service contracts.
Site Information
Ambient conditions
Highest monthly average temperature: .....°C
Altitude (meters above sea level): .....[m]
Highest monthly average humidity ..... %
General information
Indicate the configuration of the new system that will be installed on the site: • Single, duplex, multiplex, booster + filling manifold, piping, distribution manifold, cylinders • Skid-mounted, containerized, built onsite
Security and environment
Has the security been assessed (for example, UNDSS cleared if applicable)?
Have considerations from the delivery port up to the destination of the oxygen generator plant been cleared?
Facility/housing of plant
Space dedicated to the installation of the system (indicated in meters [m]): • Skid Mounted.....[m] (W x L x H) • Containerized.....[m] (W x L x H) • Built onsite.....[m] (W x L x H)
Mechanical guide provided by the vendor (drawings, plans, and engineering specifications for equipment to operate correctly and safely):
Does the facility have permission to renovate/modify or construct if applicable?
Is the housing located in a floodable or seismic area?
Is the air intake far enough from known air contaminants? • Specify the distance from the air intake to the nearest contaminant source: ..... [m] (approx.)
Is the air intake protected from insect entry and precipitation?
Is the air intake free from “blockage” (e.g., debris)?
Is the housing well-ventilated, considering environmental conditions (temperature and humidity)? • Natural ventilation, Forced ventilation: Air extractors: Qty…, Air conditioner: Qty: …
Is the wall reinforced where the ducting (for extracting heat from the air compressor system) will be installed?
Are the minimum safety distance requirements respected to (m): • Wooden structures, mall stocks of combustible materials, liquefied petroleum gas storage vessels • Pits, ducts, surface water drains, vehicle parking areas (other than authorized), property boundaries • Public roads, places of public assembly, openings, windows, and escape routes from buildings • Medium voltage and high voltage substations, process equipment and machinery • Fuel gas vent pipes, compressor, ventilator, and air conditioning intakes • Offices, canteens, and areas of occupancy
Is there enough distance from the housing to the nearest ward to avoid noise?..... [m] (approx.)
Is the access controlled only to authorized personnel?
Do the doors have the following minimum dimensions:2 x 2.5 [m] (W x H)?
Is there an entrance wide enough to allow the passage of different plant elements?
Is the walls’ finish made of washable material (i.e. water-resistant paint or tiles)?

Is there proper signage to mitigate fire risk (e.g. “Medical Gases - NO Smoking or Open Flame”)?
Is there enough space for cylinder storage (full and empty segregation)?
Floor preparation
Concrete slab load resistance calculated for a minimum of 1000 kg/m²?
Is the floor leveled?
Is there a sloped entry (access ramp) for cylinder movement (if needed)? • Dimensions of sloped entry (L x H) • The slope of the sloped entry
Is the floor finish made of washable material (i.e., paint or coating quartz)?
Is there a way to facilitate flow for evacuation of condensed water network (i.e. floor siphon)?
Cylinder storage station
Concrete slab load resistance calculated for a minimum of 1000 kg/m2?
Is there a sloped entry (access ramp) for cylinder movement (if needed)?
Is the housing well-ventilated to avoid concentration of gas?
Is the housing with a roof top to protect from direct sunlight and rain?
Is there a clear separation between the filled vs empty cylinders storage zones?
Is there a zone to park trolleys and keep the PPE neat and accessible?
Electrical supply
Electrical requirements provided by vendor/distributor/supplier?
Power supply
Primary
¨ Electrical grid ¨ Diesel generator ¨ Solar power station ¨ Hybrid. Specify characteristics:
Secondary
¨ Electrical grid ¨ Diesel generator ¨ Solar power station ¨ Hybrid. Specify characteristics:
Diesel generator power capacity (attach the sizing calculation), if applicable: kVA/KW
Diesel consumption projection: L/month/ US$/L
Power cabinet inside the room with electrical protection by resettable circuit breakers or replaceable fuses, fitted with both neutral and live lines, and grounding requirements included?
Is there a system to protect against lightning?
Are minimum requirements for electrical installations respected? Wire cross-sectional dimensions based on power, current, and distance. • Appropriate electrical connections/adaptors, as well as the presence of junction boxes. • The presence of an enclosed electrical board, including various circuit breakers (MCB, RCCB, etc.), appropriately dimensioned to ensure the safety of the installation. • The plant's power consumption was calculated (including light installation), and the diesel generator was sized based on the result. • Sufficient electrical sockets have been installed, including one close to the air compressor and another one close to the booster, for cleaning/air blower/maintenance purposes
The customer is responsible for the equipment's power supply unless otherwise agreed. • Power connection requires single- or 3-phase grounded outlets with a 3-prong plug. • Electrical filters are recommended to protect the PLC, and improper voltage may void the warranty. • A dedicated circuit and a UPS are suggested to prevent accidental shutdowns and maintain production during power failures.
Existing or already installed MGPS *(if applicable, work to be done before the arrival of the oxygen source)*
Did you receive an MGPS sizing analysis?
Did you receive a layout of the network distribution?
Is there a purging system using a shielding gas (e.g., nitrogen)?

Are all system components installed (e.g., pressure alarm devices, pressure indicators, pressure relief valves, outlets)? • Dual-line regulators assembly, pressure relief valves, wall outlets, pressure indicators • Main isolation valve, master alarm, one isolation valve, zone alarms
Is the pipeline network labeling in place (at intervals not more than 6.1 m and with flow direction)?
If applicable, are requirements met to perform the interconnection between the incoming medical oxygen plant and current installations?
Is the pipeline network labeling in place (at intervals not more than 6.1 m and with flow direction)?
If applicable, are requirements met to perform the interconnection between the incoming medical oxygen plant and current installations?
Risk mitigations
Is there an ambient room oxygen sensor installed in the plant's housing?
Is a heat and smoke detector installed in the plant's housing?
Is there a fire safety plan in place? Did the National Fire Organization assess it?
Are adequate fire extinguishers accessible in high-fire-risk areas?
Other safety and structural requirements needed to ensure that the building and placement of equipment is to standard and ready to receive the equipment:
Other requirements
Are trained human resources available (minimum two operators per shift of 8 hours)? Qty…
Operators should participate in the commissioning and training activities.
Are there enough ancillary devices to cover the current use of cylinders? ¨ Pressure regulators Qty: .... ¨ Flowmeters Qty: .....¨ Trolleys Qty:….
Are there enough trolleys to safely transfer cylinders inside the healthcare facility? Qty:….
Are dedicated trucks transporting cylinders offsite (e.g., to other healthcare facilities)? Qty:…Truck's payload:…
If applicable to the project.
Are there drivers for the trucks to transport cylinders offsite (e.g., other health care facilities)?
Other requirements Remarks Notes
A focal point should be identified to facilitate communications with the vendor. It is recommended that periodic updates on the work progress of pre-installations be sent to the vendor to allow them to provide inputs before commissioning the system.

Annex III–Commissioning Report for Oxygen Generator Plants

Adapted from WHO Foundations of Medical Oxygen Systems: Web Annex D – Commissioning Report for Oxygen Generator Plants, 2023.

This section reports on the technical audit and acceptance of the oxygen generator system installation per the vendor contract. The commissioning report, completed post-installation and before oxygen distribution, should be prepared by knowledgeable personnel and include critical documents like the user manual, test reports, and training records.
Evaluator information Name: Organization: Job title: E-mail: Phone number (optional):
Health facility information Name of facility: Responsible person name: Job title: E-mail: Phone number:
Oxygen generator plant information
• Manufacturer • Model • Serial Number
Verification list
Area: system must be placed in a spacious, levelled area and protected against rain and lightning.
Place: each part of the system must be placed according to installation layout; consider space around each item necessary for servicing.
Security: minimum safety distances are respected from identified risk area (risk mitigation for fire prevention and polluted air). Area clearly identified and security signalling clear and legible.
Civil engineering: slab and infrastructure respecting manufacturer requirements, safe access for cylinders movement, floor condition and finishing respect standards.
Architectural and structural conditions: material used and design/flows of the structure respect the master plan.
Storage area: respect the place security, civil engineering, architectural and structural conditions, as required by the manufacturer and the master plan, including clear separation between full and empty cylinders
Safety: all promises have been visited by a third-party to evaluate and report compliance with fire safety and other safety risk requirements. Safety posters are present.
Electrical connection: always refer to manufacturer's manual for power supply requirements of each equipment.
Electrical installation: connections from power source to the plant elements respect safety recommendations; is reliable and continuous using proper protection equipment (e.g. voltage stabilizers, UPS in the electrical panel, etc.). Power supply considers main and stand by source.
Heating, ventilation, air conditioning, as applicable: well-ventilated area, temperature must be maintained between 5-40°C; monitoring device for temperature and hygrometry included.
Drainage: if applicable and water/oil separator is not part of the order, then at least two 20-L storage barrels are necessary for the drain condensate.
Ducting: consider ducting for air compressor (for proper cooling) following manufacturer's recommendations.
Nitrogen – exhaust: vent systems made of proper materials; exhaust to the outside secured.
Test run the equipment: running to reach nominal performance/ check the oxygen generator/check oxygen purity/check oxygen pressure/check flow rate/check for leakage/check for alarms or error messages
Air compressor/ Air dryer/ Water/ Oil Separator/Cola tower/Air tank/ Oxygen concentrator (PSA)/Oxygen analyzer/ Control panel with UPS/ Oxygen tank/Booster compressor/ Cylinder filling ramp, adapters, pigtails and valves are compatible with applicable standards/ Pneumatic changeover system (manifold)/ Additional portable oxygen / medical gas analyser(s)/ Supervision/remote control system/

• Manufacturer • Model • Serial Number
MGPS is tested according to applicable standards and includes all the items in the approved design (e.g., zone and master valves, and alarms).
Oxygen copper pipe network, i.e. certified material; proper color coding; as less as possible bends; appropriated braising and fitting elements; enough safety valves
Spare parts kit and toolkit in accordance with preventive maintenance programme.
Monitoring calibration sensor: make sure the report of calibration of the oxygen sensor before commissioning is available
Monitoring oxygen purity: filled in after 3 days of continued evaluation period and before commissioning, specifying oxygen concentration, temperature and pressure gauge control, room aeration check
In hard and/or soft copies and in the agreed language. • User manual • Service manual • Purchase contract • Service level agreement • Training material • Installation report from the supplier • Equipment card available and technical data completed
Preventive maintenance programme: clearly describing tasks and frequency of activities.
Personnel from the health facility: clearly describing tasks and frequency of activities.
Operation and maintenance: training is provided by certified personnel.
Safety training: awareness training on the dangers of mismanagement of medical gases and risk mitigation measures.
Oxygen cylinders management: storage, transport, manoeuvring, setting-up and connections training.
Continuous training plan: training content and schedule to teach new local staff and refresher trainings for current staff
Signature and stamps: Date Signature and name of evaluator: Signature and name of vendor: