Standard Operating Procedure (SOP) Template for Oxygen Plant Operators

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*This document was developed by Build Health International for the Global Fund’s Project BOXER.*

## 

## *0. Template Instructions*

*This Standard Operating Procedure (SOP) is intended to serve as a template for the operation of Pressure Swing Adsorption (PSA) and Vacuum Pressure Swing Adsorption (VPSA) oxygen generation systems that can be adapted to each facility. The procedures, parameters, and recommendations outlined herein may not be suitable for all plant models or operational contexts. All users of this document are advised to verify the applicability and accuracy of the content against the specific recommendations provided by the plant manufacturer and to ensure compliance with all relevant national regulations, codes, and standards in force. The information and examples in this document does not supersede manufacturer instructions or legally mandated requirements such as included in the warranty and maintenance contracts.*

*This document is intended to be adapted for use at a specific facility. It includes sections and phrases that must be reviewed and updated to reflect the applicable national, regional, or facility-level context. These sections are commonly indicated by* ***yellow highlighting****, which serves as a visual prompt for required customization. Once the appropriate information has been inserted and verified, the yellow highlight may be removed.*

*In addition, the document may contain* ***italicized blue text****, which provides instructions or additional guidance for tailoring the template. This text is not intended to be part of the final SOP and should be deleted (Along with this Section 0) once the relevant content has been incorporated.*

*It is the responsibility of the user to ensure that all context-specific modifications are completed accurately and that the finalized SOP reflects current manufacturer recommendations, applicable national standards, and facility protocols.*

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## 

## 1. Purpose

This SOP outlines the procedures for the safe, efficient, and continuous operation of Pressure Swing Adsorption (PSA) and Vacuum Pressure Swing Adsorption (VPSA) oxygen plants. All activities described below are meant to ensure the continuous production and distribution of medical-grade oxygen with purity levels of 93% ± 3% or higher as required for hospital usage.

## 

## 2. Scope

This SOP applies to plant operators, maintenance personnel, and quality control teams responsible for the operation and maintenance of oxygen plants. It includes safety guidance, procedures for start up and shutdown, maintenance and repair procedures, and documentation practices. This SOP can be used to guide future refresher trainings or new technical staff trainings

*The scope of this document does not include clinical facing medical equipment and accessories (bedside concentrators, ventilators, nose cannulas, etc.) which are part of the oxygen ecosystem. An independent SOP on medical equipment and consumables management should be developed by the relevant authority.*

## 3. Facility Operating Plan

Hospital Name is a Hospital Description in Hospital Location. The facility has ### beds making up —--------- wards. The hospital treats # inpatients and # outpatients annually.

The Hospital’s oxygen sources consist of the following:

* Liquid oxygen (LOX) tank with a ### L Capacity equivalent to ### L of gaseous oxygen. The LOX tank is connected to an evaporator system which supplies oxygen directly to the hospital medical gas pipeline system OR which is then used to fill cylinders.
* [PSA / VSA / VPSA] [simplex OR duplex] oxygen plant with a production capacity of ## m3/hr ( ## LPM) The oxygen plant is connected directly to a Medical Gas Piping System (MGPS) and/or a ## m3/hr cylinder filling booster compressor which should be filling ## cylinders of size ## L per 24 hours.
* ## Oxygen concentrators with a capacity of ## LPM which are used in the wards to treat individual low flow patients
* ## oxygen cylinders of size ## L and ## oxygen cylinders of size ## L

The Hospital MGPS system is connected to the OXYGEN SOURCE as the primary source and OXYGEN SOURCE as the secondary oxygen source. The oxygen plant is designed to operate [Insert number of hours] per day, [Insert number of days] per week.

During this time, the hospital plans to fill [insert number and size of cylinders], ## of which will be consumed onsite, and ## of which will be distributed to surrounding facilities. These cylinders are distributed by [Insert Job Title] and are delivered on [Insert time/date schedule of cylinder delivery].

The supported peripheral facilities include the following:

* Insert Facility Name
* Insert Facility Name
* Insert Facility Name
* Insert Facility Name
* Insert Facility Name

The Hospital Name has the following cylinder manifolds:

* [Insert Size] Filling Manifold. Based on the booster filling rate, ##L cylinders will need to be changed out every ## hours
* [Insert Size] Back up Manifold. Based on the pipeline demand, ##L cylinders will need to be changed out every ## hours when the manifold is in use
* [Insert Size] Supply Manifold. Based on the pipeline demand, ##L cylinders will need to be changed out every ## hours

The piping system supplies a total of ## bedside outlets as shown in the table below:

| **Ward Type** | **Bed Count** | **Outlet Count** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

INSERT HOSPITAL LAYOUT AND/OR PIPING DIAGRAM HERE

The oxygen plant is located in a [Plant House / Container / Plant Room within the hospital]. Its main power supply is [Utility Power / Solar Power / Diesel Generator]. Its back up power supply is [Utility Power / Solar Power / Diesel Generator]. The plant is cooled via [air conditioning / exhaust fans / passive air flow].

## 4. Responsibilities

Effective operation of an oxygen plant requires coordination among multiple personnel, each with distinct responsibilities to ensure safety, reliability, and compliance. While staffing may vary by facility size and context, typical roles include: plant operators, supervisors or facility managers, biomedical or technical officers, external service providers, and regulatory bodies. The roles and responsibilities of managing and operating the plant at Hospital Name are divided as follows:

**Plant Operators**:

* Monitor system parameters
* Perform daily checklists
* Perform daily security check
* Report issues to management
* Identify when service is due
* Ensure startup and shut down procedures are followed
* Monitor supply manifolds and replace empty cylinders if necessary
* Fill cylinders and manage empty and full cylinder inventory

**Biomedical Engineers/Technicians:**

* Perform scheduled maintenance or if there is a service contract in place, monitor the maintenance and verify completion.
* Schedule preventative service with supplier OR conduct preventative service
* Troubleshoot faults and replace faulty components
* Routinely inventory tools
* Review daily checklists for issues and keep maintenance logs updated.
* Routinely check fire safety equipment and update plan as needed

**Supervisors**:

* Ensure adherence to SOPs,
* Coordinate maintenance schedules,
* Provide training to plant operators
* Audit maintenance records for completion
* Ensure adherence to regulatory requirements
* Budget for operational costs
* Ensure plant is appropriately staffed
* Order spare parts
* Procure appropriate tools and PPE
* Routinely update security list of authorized personnel

*The division of roles and responsibilities described in this section is intended as a general example. Each hospital or facility should review and adapt these roles to reflect its specific organizational structure, staffing norms, and operational protocols. Additional roles not listed here such as inventory managers, pharmacists, or other technical and administrative personnel may have responsibilities related to oxygen plant operation, maintenance, or supply chain management. It is the responsibility of each facility to clearly define, assign, and document all relevant duties to ensure safe and efficient plant operation.*

## 

## 5. Safety Precautions

Oxygen is a key element of fires and due to the high pressure at which it is stored and distributed, oxygen handling can create significant safety risks if the proper safety interventions are not taken.

*Please note, this section does not include an electrical safety section. This should be developed as a separate document in accordance with any national standards and referenced here as an Appendix.*

#### 

#### **5.1 Fire Safety**

As oxygen concentration increases within a space, fires will burn faster, hotter, and more violently. For a fire to occur, there must be oxygen, heat, and fuel present. The following actions should be taken to limit the risk of fire:

* Ensure adequate ventilation to limit oxygen accumulation
  + Routinely verify that all active ventilation systems are working properly
  + Open doors before starting the plant
  + Routinely Inspect for and address leakages
* Do not allow fuel sources to accumulate in or near the oxygen plant. This includes
  + Birds nests, grasses and other fibrous materials
  + Stacks of paper
  + Gasoline, diesel, propane, oil, solvents
  + Clothes, rags, fabrics
  + Wood (including furniture
* Do not allow heat sources near the oxygen equipment. This includes:
  + Stoves, cooktops, grills
  + Heaters of any kind
  + Matches, lighters, etc
  + Grinding, welding, soldering, hot work. Such facility repairs that generate heat should be done with the plant shut down and the room properly ventilated beforehand.
  + Smoking
  + Idling cars, trucks, or motorcycles
  + Overloaded power strip,
* Follow the fire safety plan
  + Ensure there are fire suppression systems within the plant
  + If there are smoke detectors and alarms, routinely inspect that they are properly installed and working
  + If there are fire extinguishers, they should be placed in an easily accessible location along an escape route. Fire extinguishers should be routinely inspected against the expiration date
  + Ensure there is a secondary escape route accessible in the plant room

#### 

#### **5.2 Personal Protective Equipment (PPE)**

To ensure safe working conditions for technical staff, the following PPE is required:

* Safety goggles: Eye injuries are the most common injury while working with pressurized systems. Eye protection should be properly rated (ex. ANSI Z87 or EN 166)
* Hearing protection: Earplugs or earbuds can help reduce noise levels to safe levels for long term exposure
* Work clothes and shoes: To avoid mechanical injuries to limbs, close-toed shoes or boots should always be worn and loose clothing or jewelry should be avoided so it is not caught and pulled into equipment.
* Electrical PPE: During electrical work, technical staff must wear insulated boots, insulated electrical gloves, and insulated tools that are rated for the level of electrical voltage that technicians will be working with. In addition, no metal jewelry should be worn.

## 

## 6. Plant Start-up

The following is the procedure that plant operators should follow to ensure safety of technical staff and avoid damage to plant equipment.

*Below is a general PSA plant startup procedure. Most manufacturers give specific start up instructions which should be closely followed. Update the procedure below with the manufacturer's specific recommendations. If your plant is a VSA or VPSA plant, these start up steps may need to be changed to accurately reflect the type of equipment being used (e.g. blower and vacuum equipment instead of an air compressor).*

1. Open plant room doors to ensure the room has safe levels of oxygen and nitrogen for 3-5 minutes
2. **Slowly** open all other valves between each piece of plant equipment **except** the valve connecting the plant to the piping system or cylinder filling station which should remain closed.
3. Confirm the equipment is receiving power
4. Start up plant equipment as recommended by the manufacturer. Typically this involves starting up the air compressor and air dryer first and then starting up the PSA generator. If the air dryer is a stand-alone unit, the air dryer should be turned on first and run until the dew point temperature reaches the manufacturer recommended level. Then the air compressor can be turned on.
5. Wait for the plant to build up oxygen purity. Depending on the plant and how long it has been off, this may take anywhere from a few minutes to a few hours. If target purity is not reached, begin troubleshooting and if necessary contact the plant manager.
6. Check that other parameters for the gas being produced such as carbon monoxide and water vapour are within acceptable limits.
7. Once oxygen purity has stabilized, **slowly** open the oxygen outlet valve to supply oxygen to the hospital distribution system or the cylinder filling system
8. If this is the first time of the day that the plant has is starting up, the plant operator should fill out the daily checklist

## 7. Plant Shut-Down

Proper shutdown of the oxygen plant protects equipment, maintains safety, and ensures continuity of patient oxygen supply through backup systems. Shutdowns may be scheduled (e.g., for maintenance) or unscheduled (e.g., faults or emergencies).

#### 

#### **7.1 Emergency Shutdown**

In case of fire, oxygen leaks, critical alarms, or equipment failures:

1. If there is a safety hazard (e.g., smoke, fire, strong oxygen leak), evacuate the area immediately!
2. If it is possible to briefly stay in the plant room, first press the emergency stop button located on the control panel.
3. Inform relevant personnel and ensure the backup oxygen supply is actively serving the hospital.
4. If it is safe to do so, shut off power to the plant.
5. Do not attempt to restart the system until the cause has been fully investigated and resolved.

#### 

#### **7.2 Scheduled Shutdown**

*Below is a general plant shutdown procedure. Most manufacturers give specific shutdown instructions which should be closely followed. Update the procedure below with these recommendations. If your plant is a VSA or VPSA plant, these start up steps may need to be changed to accurately reflect the type of equipment being used (e.g. blower and vacuum equipment instead of an air compressor).*

1. Confirm that an alternative oxygen source is connected and supplying the facility. Notify clinical and facility personnel of the expected shutdown and duration.
2. Slowly close the main product oxygen valve to isolate the PSA plant from the hospital distribution or cylinder filling system.
3. Shut down plant equipment as **recommended by the manufacturer.** Typically this involves hitting the shutdown button on the central PLC screen which will shutdown all equipment accordingly. Some plants require shutting down individual equipment which should be done in the following order: booster compressor, oxygen generator, air compressor then air dryer
4. **DO NOT** shutdown equipment by pressing the emergency stop button. This could damage the equipment if left in this state.
5. If required, use the main disconnect switch or circuit breaker to isolate electrical power, if required for maintenance.

#### 

#### **7.3 Low-Utilized Plants**

If a plant is not run frequently (less than once a week) it is important to carry out the following actions during shutdown:

* Close all valves in between each piece of equipment to prevent humidity from ambient air from damaging the equipment.
* Check and empty the coalescing filters, condensation drains, and air tank.
* Check the air compressor for oil leaks (leak could expose the screw element to humid air causing rust damage).

After being idle, the PSA plant needs to be run for several full cycles before purity is built back to 93 +/- 3%. This may take anywhere from a few minutes to a few hours. As the purity is building, it may be necessary to manually open a blow off valve to dump the low purity oxygen product from the system.

## 

## 8. Maintenance and Documentation

When operating an oxygen plant there are three types of maintenance activities to plan for and track. It is important to ensure logs are accurate and up-to-date. Store all documents in a centralized location accessible to authorized personnel.

#### 

#### 8.1 Daily Checks

Daily (and weekly) checks let operators track plant status and can prompt actions to keep the plant functioning optimally. This is the primary responsibility of a plant operator. It is the health record of the plant. The required daily checklist activities can be found in [Appendix A](#_heading=h.iyeo67p6stq). The form only needs to be completed on days the plant is on. If the plant is not turned on, the operator should mark “OFF” for the day so it is clear the checklist was not skipped. If the plant is a duplex configuration, two checklists should be completed daily with an indication of which production line is being checked. The daily checklist activities can be separated into two categories below:

Visual Inspection: Check marks, Yes/No answers, N/A where not relevant

Daily Data Collection: Numbers, data from display, measurements, readings from gauges, operating hours

It is critical that the data collected in these checklists is carefully monitored so routine preventative maintenance can be scheduled and issues can be flagged before they cascade into critical damage to the plant. The plant operator or biomedical engineering manager should routinely check the daily checklists against an expected set of parameters specified in the manufacturer’s manual. An example table of expected values which can be customized is in [Appendix B](#_heading=h.376nnwo5a8y5). If an issue is found it should be escalated to MANAGER TITLE. If the plant is under a service contract the local service provider should be contacted using the contact details in Section 10.2.

*Sometimes oxygen plant suppliers provide a specific daily checklist. That is required to comply with service contract or warranty terms. If this is the case, then use the required daily checklist. An example daily checklist is attached to this document as* [Appendix A](#_heading=h.iyeo67p6stq)*. If the supplier does not provide a daily checklist or the provided checklist is less thorough, then adapt and use the example checklist provided.*

#### 8.2 Preventative Maintenance:

Preventative maintenance is planned maintenance activities (see [Appendix I](#_heading=h.u42p9vaix9hk)) that occur at set intervals to keep the oxygen plant functioning optimally. The schedule of these activities is determined by the manufacturer's recommendations for each piece of equipment. This information can typically be found in the equipment manuals or service contract details. The preventative maintenance log can be found in [Appendix C](#_heading=h.uv6rygz0qjf3). The following should be completed no matter if hospital staff or a contracted service provider carries out these activities:

* Enter equipment information (manufacturer, model serial number) at the top fields of the log
* Populate the frequency of each activity based on the manufacturer recommended schedules
* When maintenance is performed, the operating hours and initials of the supervising hospital technical staff should be logged

*The template preventative maintenance log in* [*Appendix C*](#_heading=h.uv6rygz0qjf3) *has fields for common preventative activities for each piece of equipment. However each make and model of equipment may have slightly different and specific activities. The template should be adjusted to include the preventative maintenance activities of the specific plant equipment onsite.*

#### 8.3 Corrective Maintenance (Repairs)

Corrective maintenance is unplanned maintenance that is needed when the plant unexpectedly breaks down and requires a repair. A repair log template can be found in [Appendix D](#_heading=h.zhk4vm1w9jkg). Each time corrective maintenance is required, the plant operator or managing biomedical engineer must record the date, identified issue, and corrective actions taken. This log must be completed even if the repair is done by a contracted service provider. If an external provider conducts the corrective maintenance, the hospital technical staff should be onsite observing the activities and require a follow up report of the works completed.

#### 8.4 Reporting

It is the PLANT OPERATOR’s responsibility to share completed Daily checklists, and updated maintenance logs with the BIOMEDICAL ENGINEER at least [INSERT FREQUENCY]. The BIOMEDICAL ENGINEER is responsible for synthesizing the data and reporting relevant updates to the FACILITY SUPERVISOR on a [INSERT FREQUENCY] basis.

## 9. Warranty and Service Contract

Proper understanding of warranties and service contracts is essential to ensure that oxygen plant equipment is maintained, repaired, or replaced in a timely and cost-effective manner. These documents are kept in hard copy at [INSERT LOCATION] as well as digital format [INSERT DIGITAL LOCATION].

* A **warranty** is a manufacturer’s guarantee that equipment will function as intended for a specified period, typically covering defects in materials or workmanship and unexpected breakdowns under normal operating conditions. A warranty is usually purchased at the time of the plant purchase.
* A **service contract** is a separate agreement often with the manufacturer or a local service provider that covers routine preventative maintenance. A service contract can be included in the plant purchase or can be negotiated separately after the plant is already operational. Critical details of these contracts can be found below:

*This section should only be included if the plant has an active service contract (*[*Appendix F*](#_heading=h.gww5bvd0xt9y)*) or warranty (*[*Appendix E*](#_heading=h.z5owgw28ck9u)*). The subsections below should be customized based on the details of the documents. If these details are not clear, reach out to the supplier or service provider for clarification.*

#### 

#### 9.1 Warranty

| Supplier Contact Info |  |
| --- | --- |
| Start of warranty | *Some warranties have start dates and some warranties start at installation and are active for a specific number of operating hours. Enter whichever metric applies for your warranty.* |
| End of warranty | *Some warranties have end dates and some warranties are active for a specific number of operating hours. Enter whichever metric applies for your warranty. Note here if different equipment has different warranty durations.* |
| Included Costs | e.g., labor, diagnostics, travel, accommodations, incidental expenses, replacement parts, part shipping, etc. |
| Excluded Costs | e.g., labor, diagnostics, travel, accommodations, technician incidental expenses, replacement parts, part shipping, etc. |
| Personnel authorized to operate and maintain the plant under the warranty |  |
| Activities authorized personnel are allowed to perform under the warranty | Operate the plant, perform daily maintenance checks |
| Are authorized hospital staff allowed to train other hospital staff to operate and maintain the plant? | Yes / no |
| Supplier response time *(How long after the facility requests the support does the supplier guarantee they will respond by?)* |  |
| Remote support available | Yes / no |
| Acceptable nominal voltage range |  |
| Acceptable voltage difference between phases |  |
| Acceptable frequency range |  |
| Backup power requirements |  |
| Maximum downtime allowed during a power outage |  |
| Conditions that will void the warranty | * Unauthorized Maintenance: The warranty is void if maintenance is conducted by hospital staff or others not trained by the manufacturer * Lack of Maintenance: Failure to perform maintenance per the manufacturer’s minimum requirements can void the warranty * Lack of documentation of maintenance activities * Tampering and Unauthorized Repairs: Modifications, alterations, or repairs by unapproved personnel void the warranty * Lack of active supplier maintenance contract |

Steps to make a Warranty Claim:

1. Collect photos/videos and any error messages of issue
2. Share collected data and equipment nameplate info by calling/emailing the local service provider
3. XXX
4. XXX

SUPPLIER NAME HERE must respond to warranty claims within \_\_\_\_\_\_ Hours/Days

If the supplier fails to respond within the specified time, the hospital should do the following: contact the parent company of the local service provider/file a legal complaint.

#### 9.1 Service Contract

| Service Provider Contact Info |  |
| --- | --- |
| Service Provider hours of Operation |  |
| Start Date |  |
| End Date |  |
| Included Costs | e.g., labor, travel, accommodations, service parts, part shipping, preventive vs corrective maintenance |
| Service Frequency/Schedule | See [Appendix I](#_heading=h.u42p9vaix9hk) |
| Who is responsible for scheduling visits? | service provider/Hospital |
| How is service completion verified? | Plant operators/technicians being invited to observe service being conducted/detailed service reports with photographs within \_\_\_\_ weeks of service |
| Who is responsible for storage and inventory of consumables and spare parts? |  |

SUPPLIER NAME HERE must respond to support requests within \_\_\_\_\_\_ Hours/Days

If the supplier fails to respond within the specified time, the hospital should do the following: contact the parent company of the local service provider/ file a legal complaint.

## 10. Oxygen Cylinders

Oxygen cylinders must be handled with extreme care due to the serious risks they pose in healthcare settings. Improper management can result in fire, injury, or even death. Oxygen supports combustion, making even minor ignition sources dangerous in its presence. Additionally, cylinders contain high-pressure gas that can cause severe injury if released uncontrollably, especially if the valve is damaged. Their weight and size also pose physical hazards if not properly secured. Awareness and adherence to proper handling protocols are essential to maintaining a safe healthcare environment.

#### 

#### 10.1 Oxygen Cylinder Handling

* Always secure cylinders and containers with a chain, strap, rack or other suitable device. Do not use extension cords, clothing belts, etc. Use non-abrasive strapping to secure composite cylinders.
* Never force connections that do not fit. Use of adaptors or incorrect valve outlets can result in dangerous connections leading to injury/death, equipment damage, or uncontrolled product release.
  + The national standard of valve type is British Standard (Bullnose BS341)
* When connecting equipment, point the valve outlet away from personnel, and open the valve slowly.
* Personal protective equipment, such as eye and hand protection, should be worn when handling oxygen cylinders.
* All tools, accessories, and gloves used in conjunction with oxygen cylinders must be clean and oil-free.
* If a cylinder is potentially damaged. It should be removed from circulation and inspected and tested per national guidelines (See section 14)

#### 10.2 Changing Cylinders in Manifolds

1. Close valve to manifold.
2. Close the connected cylinders valves.
3. Slowly disconnect pigtails from cylinder valve outlets. Use clean nitrile gloves and a clean oil free wrench to do so. Use an appropriately sized wrench, not an adjustable wrench to prevent damage to the pigtail.
4. Place protective caps over the cylinders valves and move the disconnected cylinders aside, remove the new cylinders protective caps and inspect for dust, grease, and oil.
   1. If needed follow the valve cleaning procedure outlined in the section below.
5. Connect the pigtails to the new cylinders.
6. Slowly open the cylinder valves one at a time.
7. Open valve to manifold.

#### 

#### 10.3 Cleaning Cylinder Valves

1. If available use oil-free compressed air or another inert gas to blow out dust and debris
2. A lint free cloth or soft bristle brush can also be used to gently wipe out the valve openings and dislodge visible particles, taking care to prevent debris from scratching or embedding into the valve
3. It is common practice to briefly open the cylinder valve, and allow the compressed oxygen to clear away any potential debris before closing the valve again and connecting it to the manifold or regulator. If this activity is done, the following must be considered:
   1. Open the valve very slowly and very slightly
   2. Stand to the side of the opening valve
   3. Point the valve away from all people
   4. The surrounding area must be well ventilated
4. After cleaning, reinspect the valve. If there is still debris remaining in the valve after the above activities have been performed, the cylinder should be removed from service to allow for the valve to undergo a more comprehensive deep cleaning. This deep cleaning must be performed by a qualified professional and typically entails removing the valve from the cylinder, cleaning it in an oxygen safe solution according to industry standards, and reattaching the valve to the cylinder body.

#### 10.4 Oxygen Cylinder Storage

* Cylinders must be secured in an upright position,
* Oxygen cylinders should be stored separately from all other gases and separated based on if they are full or empty
* Safety caps should remain on cylinders at all times when not in use.
* When multiple cylinders are grouped together, it is recommended that cylinders be secured by racks and chains or nesting so that they have three points of contact. Nested cylinders will still require chains or straps to secure them.
* Cylinders should be placed only on flat floors or platforms.
* Ensure the storage area is well ventilated and not exposed to any temperature or humidity extremes. Any ignition sources should be kept at least 5 meters away from storage areas.

#### 10.5 Oxygen Cylinder Ground Transportation

* When moving cylinders, ensure valves are closed, valve protection is in place, the cylinder is properly secured, and moved in the upright, valve-up position.
* Cylinder dollies or other mechanical lifting devices should be used to move the cylinders.
* Secure cylinders in a cylinder cart with a chain and move to a new location.
* Use platforms or cradles that keep cylinders upright and secured when lifting with mechanical equipment.
* Only one cylinder should be handled at a time except on carts designed to transport more than one cylinder.
* Avoid dropping, rolling, or dragging cylinders.
* Do not let the cylinders fall or bang into anything.
* Do not lift cylinders by valve protection cap.
* Secure cylinders in an upright, valve-up position at all times to prevent movement as they should not be allowed to shift relative to each other or the supporting structure.

#### 10.6 Oxygen Cylinder Vehicle Transportation

* For vehicle transport, all cylinders must be stored in an upright position in a separate enclosure from the driver
* Secure the cylinders in the vehicle or trailer to prevent movement during transit. Cylinders should not be allowed to shift relative to each other or the supporting structure.
* Vehicles should include appropriate signage with hazard statements, signal words, and pictograms in accordance with local regulations for the transport of flammable compressed gas.

## 11. Tools

Operating and maintaining an oxygen plant requires the use of proper tools to ensure safety, efficiency, and equipment longevity. Using the correct tools helps prevent damage to sensitive components such as valves, sensors, and fittings, and reduces the risk of oxygen leaks or contamination. Only clean, oil-free, and non-sparking tools should be used when working on the oxygen side of the plant to avoid fire hazards. Plant operators must ensure that all tools are well-maintained, readily accessible, and used strictly according to manufacturer guidelines. Plant operators must keep tools safely stored in Location and inventory the tools every time interval. A list of oxygen plant tools that are provided for exclusive use on the oxygen plant can be found in [Appendix G](#_heading=h.7gxny6banqfh) and a list of oxygen clean tools that are provided exclusively for the cylinder filling booster compressor can be found in [Appendix H](#_heading=h.b64m5bkogmae).

*The tool lists attached are BHI’s recommended tools for PSA plants. Please adjust these lists based on your plant type and specific manufacturer recommendations and what has actually been provided to the plant operators*

#### 

#### 11.1 Oxygen Analyzers

It is critical to use at least one hand held oxygen analyzer. This handheld analyzer should be used to verify the oxygen plant’s onboard analyzer and to perform spot checks throughout any piping systems or filled cylinders. There are multiple different types of analyzers

* Galvanic Chemical Cell: Measures purity with a chemical reaction creating electrical current. Needs to be replaced yearly and needs to be calibrated
* Zirconia Chemical Cell: Needs to be replaced about every five years. Typically also found as onboard analyzer in oxygen generators
* Ultrasound analyzer: Measures using purity with changes in speed of sound. Does not have a chemical cell that needs to be replaced.

If operators are using a chemical handheld analyzer, accurate calibration is essential to ensure reliable purity readings. Calibration should be performed daily before use, after extended storage, or if readings appear inconsistent. The following steps should be taken to calibrate the analyzer:

1. Power on the analyzer and allow it to stabilize according to the manufacturer’s instructions.
2. Connect the analyzer to a calibration gas and set the reference value to the calibration gas value.
3. If calibration gas is unavailable, expose the sensor to ambient air in a clean, well-ventilated area free from contaminants. Verify or set the reference value to 20.9% oxygen, which is the typical concentration of oxygen in ambient air.
4. Use the calibration knob or digital interface (depending on the model) to adjust the reading until it matches the reference value.
5. Wait for the reading to stabilize and ensure no significant drift occurs.If the analyzer fails to stabilize or cannot be calibrated, it must be taken out of service and inspected or replaced.

It is important to ensure the analyzer is taking accurate readings by ensuring the measurements are taken within the analyzer's specified flow rate (typically 1-10 lpm).

#### 11.2 Clamp Meter

A clamp meter is a valuable tool for safely measuring electrical current (amperage) and voltage without directly contacting live conductors. It is commonly used for troubleshooting and verifying power supply to equipment such as air compressors, booster compressors, dryers, and backup generators. Basic Use

* To measure current, place the clamp around a single live conductor (one wire only).
* The clamp meter will display the amperage, allowing you to determine If a circuit is connected, whether equipment is on or off, and how much current is flowing through the wire

Some clamp meters can also be used as phase rotation meters. Most medical oxygen plants use three phase power, with three AC lines (phases) powering the air compressor and possibly the booster compressor. Motor rotation direction in this equipment is determined by the connection to the phases and switching the phase order can cause the motors to run in reverse which can cause catastrophic damage to the equipment. To verify motor rotation conduct the following steps:

* + Connect the three leads to each phase (L1, L2, L3)
  + Use the “bump” test: briefly connect power for ~1 second and observe motor spin-down direction.
  + If the phase orientation does not match the equipment requirements, then phase order should be switched before running the plant.

Always confirm phase orientation for both main and backup power supplies before commissioning equipment, or after electrical work has been completed.

## 

## 12. Spare Parts

It is critical to keep spare parts readily available to ensure timely repairs and preventative maintenance. This will limit equipment downtime and ensure reliable oxygen supply to the hospital. If spare part handling is not being managed by a service provider, it is critical that ## operating hours (about XX years) of spare parts is kept in inventory by HOSPITAL OR MINISTRY OF HEALTH (MoH) ENTITY at Location. This list of spare parts is derived from the equipment manuals preventative service recommendations and can be found in [Appendix J](#_heading=h.z1qk1t9qodz). Spare part storage must be in line with manufacturer recommendations within ## - ## degC and ##-##% humidity. Some parts and consumables have a limited shelf life and should be tracked in inventory documentation. It is HOSPITAL OR MoH ENTITY’s responsibility to keep the inventory continuously updated and to place a new order for spare parts before they run out. The facility minimum mandatory spare parts inventory can be found in [Appendix J.](#_heading=h.z1qk1t9qodz)

*A list of minimum mandatory spare parts should be developed for at least two years. Based on the oxygen plant operating plan, the equivalent number of operating hours that the equipment will reach in two years needs to be calculated. Then based on the service schedules in the equipment manuals. The required parts and consumables to complete all of the services within the planned operating hours can be developed and attached as an appendix. additional parts that may be prone to breakdowns can be added to this list to further minimize repair downtime.*

## 

## **13. Plant Security**

Maintaining the physical security of the oxygen plant is essential to ensure safe, continuous, and reliable operation. Unauthorized access or tampering can lead to equipment damage, oxygen supply disruption, or safety hazards.

#### 

#### **1**3**.1 Restricted Access**

* The oxygen plant must be kept locked at all times when not actively attended.
* Access should be restricted to authorized personnel only. This includes plant operators, maintenance technicians, and designated supervisory staff.
* A current list of authorized personnel must be maintained and updated regularly by the facility management.
* Any visitor requiring access to the oxygen plant (e.g., contractors, inspectors) must be **escorted** by authorized personnel. Consider requiring visitors to sign in on a log that includes the date, visit purpose and signature. A safety briefing before entering the plant area is highly recommended.

#### 

#### **1**3**.2 Perimeter Security**

* The plant area should be enclosed by a secure perimeter, such as a fence or walled enclosure, with a lockable gate.
* The perimeter should be inspected daily for signs of damage, unauthorized entry, or obstruction.
* Where feasible, install security cameras and lighting to monitor the plant entrance and surrounding area.
* Any security breach, attempted unauthorized access, or suspicious activity must be reported immediately to facility management and documented in the plant operations log. Corrective actions should be taken promptly to prevent recurrence.

## 

## 14. Regulatory Requirements

To ensure the consistent safety, quality, and performance of oxygen produced by the oxygen plant, quality assurance activities must be carried out in alignment with national standards and the local regulatory body. The purpose of QA is to ensure that medicinal oxygen meets the required specifications for identity, purity, and quality, and is produced under controlled and verifiable conditions.

#### 

#### 14.1 Routine QA Activities

The following activities must be carried out on a regular basis as part of operational QA:

* Oxygen Purity Testing (Included in Daily Checklist)
  + Measure and document oxygen purity using a calibrated oxygen analyzer.
  + Frequency: At minimum, daily before use, and after any shutdown or maintenance event.
  + Acceptable purity threshold: *[Adjust based on national pharmacopeia or regulatory authority]* (typically ≥90% for medical oxygen USP/Ph. Int.).

*If purity drops below the acceptable purity threshold on both the oxygen generator analyzer and handheld analyzer, then the plant operators and biomedical engineers should start troubleshooting. Operators and administrators should align on what the shut off threshold is (e.g. shut off threshold could be 85% even though the purity requirement is 90% or above).*

* CO₂ and Moisture Testing
  + If available, periodically verify carbon dioxide (CO₂) and dew point/moisture content to ensure impurities are within acceptable limits
  + Frequency: *[Adjust based on national guidance]*
* Cylinders
  + Cylinders must be tested every ## years according to ISO standards *(typically hydrostatic testing every 5 years)*
  + Cylinders must be visibly marked and painted White / Blue / Black to indicate they are for oxygen use
* Calibration of Instruments
  + Verify that oxygen analyzers, pressure gauges, and flow meters meet AFNOR/British/DIN standards, are calibrated and functioning correctly.
  + Maintain a calibration log and ensure recalibration is done at time interval
* Alarm and Safety Device Checks
  + Confirm all alarm systems (pressure, power failure, purity) are functional and test emergency shutoff switches and interlocks.
  + Frequency: *[Adjust based on national guidance]*

#### 

#### 14.2 Documentation and Record-Keeping

* Maintain QA logs for:
  + Purity tests
  + Instrument calibration
  + Preventive maintenance
  + Batch or cylinder filling (if applicable)

All QA records must be stored securely and retained for a minimum period defined by local regulatory standards (*[insert required retention period]*).

#### 

#### 14.3 Review and Oversight

* QA records must be reviewed regularly by a supervisor or designated quality officer to ensure compliance and detect trends or recurring issues.
* Any out-of-specification results (e.g., purity below acceptable threshold) must be investigated, documented, and resolved before the oxygen is used.

*This SOP section provides general QA expectations based on WHO GMP guidelines. Specific QA testing frequencies, acceptable limits, documentation protocols, and review procedures must be adapted in accordance with applicable national pharmacopeia, Ministry of Health guidelines, or regulatory body requirements.*

**APPENDICES**

#### [Daily Checklist](https://resources.theglobalfund.org/media/xbanfgrc/cr_c19rm-psa-plant-daily-maintenance_checklist_en.pdf)

#### [Expected Daily Checklist Values](https://resources.theglobalfund.org/media/zkgo145k/cr_c19rm-oxygen-plant-daily-maintenance-checklist-values_table_en.pdf)

#### [Preventative Maintenance Log](https://resources.theglobalfund.org/media/vqejr02v/cr_c19rm-psa-plant-preventative-maintenance-log_form_en.pdf)

#### [Repair Log](https://resources.theglobalfund.org/media/cgmpwgii/cr_c19rm-psa-plant-repair-log_form_en.pdf)

#### **Plant Warranty** *(if applicable)*

#### **Service Contract / Service Level Agreement** *(if applicable)*

#### [General PSA Plant Tool List](https://resources.theglobalfund.org/media/qjhhstb5/cr_c19rm-psa-plant-maintenance-toolkit-inventory_list_en.pdf)

#### [Booster Compressor PSA Plant Tool List](https://resources.theglobalfund.org/media/b23hang3/cr_c19rm-psa-plant-maintenance-toolkit-inventory-booster-compressors_list_en.pdf)

#### Preventative Service Schedule

#### Spare Parts Inventory List

*Oxygen plant managers are responsible for populating these appendices with hospital specific documentation. Currently attached are tools, guides, and examples to assist the managers in developing customized documentation for their facilities.*