OXYGEN

POLICIES

AND

PROCEDURES
Table of Contents

Concentrator Guidelines 1-3
Oxygen Concentrator Procedure 4-5
Oxygen Conserving Device Procedure 6-9
Oxygen Cylinder Inventory 10
Oxygen Definitions 11-12
Oxygen: Equipment Standards 13-14
Oxygen: Labeling 15-17
Oxygen: Product Rejection 18
Oxygen: Tank Procedure 19-21
Liquid Oxygen Procedure 22-24
Review of Oxygen Policies and Procedures 25
Quality Control Unit (QCU) 26
Responsible Persons List 27
Education: Oxygen Services/ Support Staff Members 28-29
Filling Lox Units from PG 45 Lox Unit 30-31
Filling Lox Units from MDX 119 Lox Unit 32-33
Record Keeping: Compressed Medical Gases 34
Record Keeping: Cryogenic Home Vessels 35-37
Record Keeping: Lot Numbers 38-39
Record Keeping: Manifests 40
Record Keeping: Retention 41
Storage and Handling: Compressed Gases 42-43
Testing: After Repair 44-45
Verification of Supplier’s Analysis 46
Prescription Tracking and Rotation 47
Calibration: Diagnosis Equipment 48
Certificate of Analysis 49
CONCENTRATOR CHECK GUIDELINES

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

Step 1: Unit must be running at least 20 minutes prior to conducting the check

Step 2: Check all filters (cabinet and internal)

Step 3: Remove humidifier bottle and place tree connector on concentrator

Step 4: Purity Check

   a) The purity check should run between 90% to 94%. (May vary between concentrator models).

   b) If the concentrator is below 92% replace the unit and bring to the office for Repair.

   c) After the unit filters have been changed and you have documented the unit serial number and hours of operation, log this information on the concentrator check form. (Serial #’s are located on the back of the concentrator on most models).

   d) Connect the handheld 02 analyzer to the concentrator via the tree connector at the patient supply port or DSS. (Analyzers should be calibrated every day before the tech leaves the office. This must be logged in the calibration log).

   e) Allow the 02 analyzer to remain on the concentrator for 30 sec. to 1 minute. Allow the reading to balance out. If the reading is between 90% to 94.6% this is acceptable. (If the purity of the concentrator does not meet this standard then remove and replace concentrator.).

Step 5: Checking liter flow

   a) Take a 0-8 LPM liter pin and a 4-7 ft 02 tubing from tech bag.
b) Connect the tubing to patient supply port or DSS. Check the position of the liter flow indicator on the machine and compare it to the liter pin. The liter flow should match. If the unit liter flow does not match the concentrator bring to the office for repair.

Step 6: Checking the Patient Alarm

a) With the liter pin hooked to the patient supply port and the O2 tubing, plug the end of the flow pin with the tip of your finger. You will notice the liter flow indicator on the concentrator drop to zero.

b) The concentrator will sound an alarm in 1-2 minutes. This is telling you the concentrator is not putting out any O2 and purity is low.

c) After the unit alarm has sounded remove your finger and the concentrator will return to normal within a few seconds.

d) If the concentrator fails this test you should remove and replace concentrator. (Some models have an alarm and a yellow caution light).

Step 7: Checking Power Interruption

a) With the concentrator in the ON mode, verify that power light in the front of the concentrator is green.

b) Place the concentrator in the OFF mode. Locate the power cord and unplug from wall outlet.

c) Place the concentrator in the ON mode. The concentrator should alarm with a steady ring. The tech should ask the patient if they can hear the alarm.

d) If the concentrator fails to alarm or the patient can not hear the alarm you may need to replace the 9V battery.

e) Make sure the unit is clean and has no defects in the cabinet or power cord.
STEPS 1-7 MUST BE DONE ON ALL CONCENTRATORS THAT ARE PICKED UP AND RETURNED TO THE OFFICE. THIS MUST BE DOCUMENTED BEFORE CONCENTRATOR GOES BACK OUT TO A PATIENT.

Step 8: Final Procedure to be done in Patient's Home

a. Remove all trash and debris from patient's home that you may have carried in.

b. Replace all tubing, cannulas and humidifier bottles.

c. Return the concentrator to normal operating mode.

d. Because the unit has been in the test or check mode always double check the liter flow of the patient concentrator and ask the patient if there have been any changes to the current order for 02.

e. Have patient sign the concentrator check form and ask if they have concerns or questions.

f. Make sure you (tech) sign the form. Forms without signatures are not acceptable.

Special note: All concentrator checks are done on 5 LPM and the tech should make note of the current 02 setting before starting the concentrator check. Return 02 setting to current setting (If liter flow is not known contact office for the current Doctor's order)
OXYGEN CONCENTRATOR PROCEDURE

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

An oxygen concentrator is an electrically operated device that compresses room air and directs the gas to a molecular sieve bed where the sieve material holds the nitrogen molecule and allows other gases to pass. The resulting mixture contains 87% to 95% oxygen, depending on the liter flow to the client/patient and the brand of equipment.

Admission Criteria

1) Determination by a physician of the need for supplemental oxygen.

2) Insurance criteria for payment has been met, unless client/patient is private pay.

3) Residence adaptable for placement and use of an oxygen concentrator.

4) Client/patient or caregiver(s) trainable in the basic use, maintenance, cleaning, and troubleshooting of the device.

Physician Responsibilities

1) Provide diagnosis of the physiologic need for supplemental oxygen.

2) Inform the client/patient or caregiver(s) of the necessity for such a device in the home.

3) Provide a written, signed physician's prescription and any other necessary documents.

Company Responsibilities

1) Equipment delivery and set-up per policy, unless otherwise specified.

© 2005 Affordable Health Care Consultants
2) Equipment delivered will be clean, properly maintained, and safely operating within manufacturer's specifications. Accessories will be provided as per physician's prescription.

3) Provide written documentation of the delivery, set-up, and proper function of the device to referral source.

4) Provide written documentation that the client/patient or caregiver(s) has been instructed about basic safety procedures associated with the device. The client/patient or caregiver(s) will sign the Equipment Management Admission Assessment and Plan of Service, indicating that they have been instructed and understand the proper use, maintenance, cleaning, and troubleshooting of the equipment, and also basic home safety and the Plan of Care.

**Client/Patient Responsibilities**

1. Client/patient or caregiver(s) must demonstrate the use, maintenance, cleaning, and troubleshooting of the equipment, and also basic safety procedures associated with the device.

2. Client/patient or caregiver(s) must sign all necessary Oxygen Plus, Inc. paperwork.

3. Client/patient must have acceptable reimbursement source.

**Equipment Needed**

1. Oxygen concentrator
2. Humidifier, if ordered
3. Oxygen tubing
4. Oxygen cannula(s)
5. "No Smoking" signs
OXYGEN CONSERVING DEVICE PROCEDURE

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

An oxygen-conserving device is a device that regulates the delivery of oxygen to conserve the oxygen in a tank so it will last longer. It is used to deliver oxygen to clients/patients when the client/patient is very ambulatory and would require being away from their oxygen concentrator more than 4 hours per day, and would require more than 3 oxygen tanks per week if the conserver were not available.

Admission Criteria

1) Determination by a physician of the need for supplemental oxygen.

2) Insurance criteria for payment has been met, unless patient/client is private pay.

3) Residence adaptable for placement and use of oxygen tank.

4) Client/patient or caregiver(s) trainable in the basic use, maintenance, cleaning, and troubleshooting of the device.

Physician Responsibilities

1) Provide diagnosis of the physiologic need for supplemental oxygen.

2) Inform the client/patient or caregiver(s) of the necessity for such a device in the home.

3) Provide a written, signed physician's prescription and any other necessary documents. The prescription must document the oxygen-conserving device order.

Company Responsibilities

1) Equipment delivery and set-up per policy, unless otherwise specified.
2) Equipment delivered will be clean, properly maintained, and safely operating within manufacturer's specifications. Accessories will be provided as per physician's prescription.

3) Provide written documentation of the delivery, set-up, and proper function of the device to referral source.

4) Provide written documentation that the client/patient or caregiver(s) has been instructed about basic safety procedure associated with the device. The client/patient or caregiver(s) will sign the Equipment Management Admission Assessment and Plan of Service, that they have been instructed and understand the proper use, maintenance, cleaning, and troubleshooting of the equipment, and also basic home safety and the Plan of Care

**Client/Patient Responsibilities**

1) Client/patient or caregiver(s) must demonstrate the use, maintenance, cleaning, and troubleshooting of the equipment, and also basic safety procedures associated with the device.

2) Client/patient or caregiver(s) must sign all necessary Company paperwork.

3) Client/patient must have acceptable reimbursement source.

**Equipment Needed**

1) Oxygen tank with conserving device
2) Humidifier, if ordered
3) Oxygen tubing and oxygen cannula(s)
4) Tank wrench and "No Smoking" signs

**NOTE:** DELIVERY PERSONNEL MAY NOT APPLY ANY APPARATUS TO A CLIENT/PATIENT. DELIVERY PERSONNEL MAY NOT PRACTICE RESPIRATORY CARE (SEE STATE LAWS AND RULES).
Set-up Requirements

1) Instruct per manufacturer's guidelines

2) Complete all necessary paperwork

Return Procedure

Oxygen concentrator equipment may only be returned (picked up) if:

a. The client/patient's physician discontinues the equipment.

b. The client/patient signs an AMA form (Against Medical Advice) if the physician wants the client/patient to keep using the equipment.

c. The client/patient moves outside Oxygen Plus, Inc.'s service area. We will refer the client/patient to another company serving the area to which the client/patient moved.

d. The client/patient wishes to use another home care dealer.

e. The client/patient expires.

Set-up Requirements

1) Instruct per manufacturer's guidelines.

2) Complete all necessary paperwork.

NOTE: DELIVERY PERSONNEL MAY NOT APPLY ANY APPARATUS TO A CLIENT/PATIENT. DELIVERY PERSONNEL MAY NOT PRACTICE RESPIRATORY CARE (SEE STATE LAWS AND RULES).

Return Procedure

Oxygen conserving equipment may only be returned (picked up) if:

1) The client/patient's physician discontinues the equipment.
2) The client/patient signs an AMA Form (Against Medical Advice) if the physician wants the client/patient to keep using the equipment.

3) The client/patient moves outside Oxygen Plus, Inc.'s service area. We will refer the client/patient to another company serving the area to which the client/patient moved.

4) The client/patient wishes to use another home care dealer.

5) The client/patient expires.
OXYGEN CYLINDER INVENTORY

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

The number and type of all full cylinders shall be recorded on the Oxygen Cylinder Inventory Log at the end of each working day and reviewed each morning for discrepancies. The Oxygen Cylinder Inventory Log shall be checked for routine removals. Any discrepancies shall be reported to the Compliance Officer for verification and documentation. All losses shall be reported to the supervisor for investigation and documentation. The Compliance Officer shall notify the police of any thefts.
Location personnel must become familiar with the following terms or phrases that are related to FDA compliance with regard to medical gases.

**Certificate of Analysis (COA):** Document that is supplied by your oxygen distributor that confirms, among other information, lot number/strength of gas that is provided. Refer to FDA Policy 4-02, "Valid Certificate of Analysis".

**Compressed Gas Association (CGA):** Industry Association

**Compressed Medical Gas Guidelines:** Guidelines developed by the CGA that specifically relate to medical gases. These were first dated in June of 1981 with a subsequent revision in 1983. We are currently operating under the 1983 interpretation of these standards.

**Cryogenic Home Vessels:** Vessels designed to hold liquid oxygen in a client/patient's home.

**FDA Form 2656:** The document that is utilized by the FDA to register firms that manufacture medical gases.

**Good Manufacturing Practices (GMP's):** Federal document, published by the FDA, which outlines the procedures for drug manufacturing and distribution.

**Handheld oxygen analyzers:** Analyzers that are made to be portable and operate on the fuel, electrochemical, galvanic, or polargraphic cell principle. When properly calibrated, these analyzers will provide a specific oxygen identification test result only, since they fail to possess the required USP accuracy.

**Home Care Company/Home Respiratory Care Company:** An entity that rents and/or sells durable medical equipment and supplies oxygen to clients/patients in their home.

**Large Cryogenic Vessels or Dewars:** Containers used to hold a low pressure, liquid product which is at a very low temperature, and are similar in design to that of an insulated thermos bottle with a vacuum between the inner and outer
container. These vessels contain the incoming drug product, and may be either permanently mounted in a vehicle, such as HLI 19s, MDX 60's, 80's, 119's, etc., or may be portable such as VGL's (Vertical Gas Liquid), GPs (Gas Pack), or PLCs (Portable Liquid Container). This definition does not pertain to tankers, etc.

Lot Number: A unique number that is assigned to each new batch of incoming oxygen delivered to your location or a batch of oxygen manufactured at your Location for distribution.

Manufacturing: Filling I transfilling of liquid to liquid, liquid to gas, and gas to gas (i.e., cascading). The filling of a medical gas is a manufacturing operation, not a repackaging operation, and requires registration. If you provide liquid oxygen services, you are a considered a manufacturer and must list with the FDA as a "Registrant".

Oxygen Distributor: A firm that receives labeled, finished drug product (either liquid oxygen of gas) and does not manipulate the product or the labeling in anyway. This classification applies to Oxygen Plus, Inc. Locations that receive and distribute ONLY compressed gas cylinders (e.g., E tanks). If you provide ONLY tanks, you are not required to register with the FDA.

Oxygen for Environmental Use: Oxygen that meets the USP specifications and is used to support life artificially in environments that are normally deficient. This includes, but is not limited to, space and space simulation capsules, deep submersibles, scuba, etc. It specifically excludes oxygen used in chambers or devices for the medical therapeutic treatment of man or animals.

Oxygen for Industrial Use: Oxygen that is not intended for inhalation or therapeutic treatment of man or animals.

Reference Standard Gases: Specialty gas that is purchased from a distributor and must be accompanied by its own COA. Refer to FDA Policy 4-08, "Calibration: Oxygen Analyzer".

Storage (Stand) Tank: Large cryogenic stationary holding tank with a storage capacity of several hundred or thousand gallons/liters of a liquid product.

© 2005 Affordable Health Care Consultants
OXYGEN: EQUIPMENT STANDARDS

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

The purpose of this procedure is to ensure that compressed-gas cylinders at each Location are in safe condition and meet the applicable standards set forth by the Department of Transportation (DOT), the Compressed Gas Association (CGA) and the FDA. The extent of compliance will be evaluated and determined by visual and other inspections required by these regulations.

All cylinders received will be inspected to verify that the following standards are met:

1) The oxygen cylinders will be seamless, welded insulated vessels that are made in accordance with the DOT specifications.

2) The regulator inlet connections and cylinder valve outlets will conform to CGA Valve Outlet and Connection Standards. (Note: All compressed-gas publications can be purchased from the CGA at 1235 Jefferson Davis Highway, Arlington, VA 22202).

3) Oxygen cylinders must be equipped with pressure-relief devices. These devices consist of a disc designed to burst under excessive pressure, a core of fusible metal with a low melting point designed to melt and release the gas in case of fire, or a combination of these types of devices.

4) The oxygen cylinder will be the proper color. The Compressed Medical Gas Association has set the following standards for the various gas cylinders.

   a. Nitrogen - black
   b. Oxygen - green or silver with green top
   c. Carbon dioxide - gray
   d. Air-yellow
   e. Oxygen-nitrogen - green and black

© 2005 Affordable Health Care Consultants
f. Nitrous oxide – blue  
g. Carbon - green with gray top  

5) The oxygen cylinder will be labeled in accordance with FDA regulations.  
The label should not be outdated, damaged, or illegible. (Refer to the  
labeling procedure)  

6) Cylinders will be marked on the shoulder, top, head, or neck with the  
following:  
   a) The specification number  
   b) The service pressure  
   c) A serial number  
   d) The inspector's official mark  
   e) Date of the test to which the cylinder was subjected in manufacture  
   f) All retest dates  

7) The cylinder will contain a four-inch diamond-shaped yellow label  
designating the contents as a oxidizing compressed gas in addition to the  
required labeling and cylinder marking previously described.  
8) The cylinder will be equipped with only standardized valve outlet  
connections.  
9) Oxygen equipment will contain only approved replacement parts supplied by  
the manufacturer. Substitution of unauthorized parts is prohibited. All parts  
that will come in contact with oxygen will be "cleaned for oxygen service".  
Thread sealant and lubricants used on oxygen equipment must be approved  
for such use. No petroleum products will be used on the cylinders.  
10) If the above criteria are not met, the cylinder(s) will not be accepted  
for distribution.
OXYGEN: LABELING

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

The purpose of this procedure is to ensure that oxygen containers are labeled in a correct manner. The oxygen supplier is responsible for labeling the cylinders. Oxygen Plus, Inc. verifies proper labeling upon delivery and will reject those cylinders not properly labeled. Oxygen Plus, Inc. will verify that all cryogenic vessels it distributes to clients/patients have the proper labeling.

Precautionary labeling must be applied to oxygen containers to identify the container contents and to warn of hazards associated with the container and content. The word "label" refers to decals, tags, stenciling, labels, and similar methods of presenting precautionary information. The handlers and users of medical gases have a direct responsibility to read the precautionary information on the label, and to label the containers which are filled in accordance with the applicable regulations.

1) Precautionary labels containing the following information will be affixed to cylinders and cryogenic vessels:

a) Product Name. The product name will be legibly marked. (Oxygen USP)

b) Signal Word. Indicate the relative degree of severity of a hazard (Danger, Warning, or Caution).

c) Statement of Hazard. This notice provides information regarding the hazards that may be present in connection with the customary or reasonable anticipated handling or use of the product.

d) Precautionary Measure. These statements are intended to supplement, if necessary, the statement of hazard by briefly setting forth measures to be taken to avoid injury or damage from the hazards.

e) First Aid.
f) Instructions in case of a fire or leak and instructions for container handling and storage.

g) CAUTION: Federal law prohibits dispensing without prescription.

2) The label will also contain the lot number and date of expiration. When space permits, the label shall be located on the shoulder of the cylinder but not covering any permanent markings, or on the side of the cylinder at a point approximately two-thirds of the distance from the cylinder bottom to the top of the valve or cap.

3) There should only be one drug label on a high-pressure cylinder or cryogenic vessel. When a label becomes worn or illegible, it must be replaced.

4) Cryogenic home vessels come from the manufacturer with a DEVICE label, which should not be confused with the required drug label. This device label must not be removed.

5) The FDA further requires that the cylinder be marked with the name and address of the supplier (the party who filled the cylinder), the lot number, and expiration date. If the tank is owned by CMS, the words "the property of" must be present on the Location labels.

6) In accordance with FDA policy, a copy of the Oxygen Plus, Inc. LOX Label (FDA Form #127) and an identification label must be submitted along with FDA Form #2657 at the time of renewal.

7) The FDA requires that there are procedures governing the tracking/reconciliation of warning labels that are issued to staff members for replacement purposes. Acceptable procedures include recording (1) the number of labels issued, (2) the number of containers actually labeled, and (3) the number of labels destroyed and/or returned to inventory.

8) When labels are issued to employees, list the number issued and the date on the Oxygen Label Tracking Log. When labels are used or replaced, the serial number of the vessels should be listed on the Oxygen Label Vessel Tracking Log along with the date the change was made. If a label is destroyed, it must be documented on the Log to denote destruction.
9) Each employee that is issued labels (e.g., drivers, therapists, etc.) must maintain a separate Oxygen Label Vessel Tracking Log sheet, and each sheet must be reconciled monthly to ensure that the number of labels absent matches the amount distributed.

**NOTE:** See following example:

<table>
<thead>
<tr>
<th>LIQUID OXYGEN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CAUTION:</strong> Extremely cold oxidizing liquid. Vigorously accelerates combustion. May cause frostbite. May explode on ignition or impact. Do not drop. Keep away from oil, grease, or other combustibles. Assure adequate ventilation. Close valve after use and when empty. Avoid spills. Keep out of the reach of children.</td>
</tr>
<tr>
<td><strong>Dispensing:</strong> For emergency use by trained personnel for oxygen deficiency and resuscitation. Do not use high concentrations for more than 5 hours without a 1-hour interruption. For other medical uses, only by a licensed practitioner. Use only with pressure reducing equipment and apparatus designed for oxygen.</td>
</tr>
<tr>
<td><strong>CAUTION:</strong> Federal law prohibits dispensing without prescription.</td>
</tr>
<tr>
<td><strong>FIRST AID:</strong> In case of frostbite seek medical treatment immediately.</td>
</tr>
</tbody>
</table>

| PROPERTY OF OXYGEN PLUS, INC. DO NOT REMOVE |
OXYGEN: PRODUCT REJECTION

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

The following policy outlines the procedure to follow if an oxygen product fails to pass the 99.0% purity standard.

Products that fail to pass the 99.0% purity standards will be rejected.

The following procedure must be followed if a product is rejected:

• Record the information on the Quality Control Log, including the testing results and reason for rejection.

• Isolate the product (place in quarantine area) and prohibit further distribution or transfer.

• Notify immediate supervisor about the problem, and about all products that do not meet the specifications. The supervisor will contact the supplier regarding procedures for disposal and replacement.

• The FDA must be notified of any product rejection within 15 days of the occurrence.
OXYGEN TANK PROCEDURE

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

An oxygen tank is a device that contains oxygen under high pressure (up to 2500 psi). It is used to deliver oxygen to clients/patients when:

1) It is more cost-effective to use the tank instead of an oxygen concentrator.
2) The tank is used for a back-up to an O2 concentrator that has malfunctioned.

Admission Criteria

1) Determination by a physician of the need for supplemental oxygen.
2) Insurance criteria for payment has been met, unless client/patient is private pay. (No additional rental charge for back-up tanks)
3) Residence adaptable for placement and use of oxygen tank.
4) Client/patient or caregiver(s) trainable in the basic use, maintenance, cleaning, and troubleshooting of the device.

Physician Responsibilities

1) Provide diagnosis of the physiologic need for supplemental oxygen.
2) Inform the client/patient or caregiver(s) of the necessity for such a device in the home.
3) Provide a written, signed physician's prescription and any other necessary documents.

Company Responsibilities

1) Equipment delivery and set-up per policy, unless otherwise specified.
2) Equipment delivered will be clean, properly maintained, and safely operating within manufacturer's specifications. Accessories will be provided as per physician's prescription.

3) Provide written documentation of the delivery, set-up, and proper function of the device to referral source.

4) Provide written documentation that the client/patient or caregiver(s) has been instructed about basic safety procedure associated with the device. The client/patient or caregiver(s) will sign the Equipment Management Admission Assessment and Plan of Service, to indicate that they have been instructed and understand the proper use, maintenance, cleaning, and troubleshooting of the equipment, and also basic home safety and the Plan of Service.

**Client/Patient Responsibilities**

1) Client/patient or caregiver(s) must demonstrate the use, maintenance, cleaning, and troubleshooting of the equipment, and also basic safety procedures associated with the device.

2) Client/patient or caregiver(s) must sign all necessary Company paperwork.

3) Client/patient must have acceptable reimbursement source.

**Equipment Needed**

1. Oxygen tank and regulator
2. Humidifier, if ordered
3. Oxygen tubing and oxygen cannula(s)
4. Tank wrench and "No Smoking" signs

**Set-up Requirements**

1. Instruct per manufacturer's guidelines
2. Complete all necessary paperwork
NOTE: DELIVERY PERSONNEL MAY NOT APPLY ANY APPARATUS TO A CLIENT/PATIENT. DELIVERY PERSONNEL MAY NOT PRACTICE RESPIRATORY CARE (SEE STATE LAWS AND RULES).

Return Procedure

Oxygen equipment may only be returned (picked up) if:

a. The client/patient's physician discontinues the equipment.

b. The client/patient signs an AMA Form (Against Medical Advice) if the physician wants the client/patient to keep using the equipment.

c. The client/patient moves outside Oxygen Plus, Inc.'s service area. We will refer the client/patient to another company serving the area to which the client/patient moved.

d. The client/patient wishes to use another home care dealer.

e. The client/patient expires.
LIQUID OXYGEN PROCEDURE

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

A liquid oxygen (LOX) tank is a device that contains oxygen under low pressure (20-22 psi). Since the oxygen is in liquid state instead of a gaseous state, the tank can hold a greater volume of oxygen. A liter of liquid oxygen is equivalent to 860 liters of gaseous oxygen. A portable LOX vessel will hold a greater volume of oxygen than standard gaseous tanks and will weight much less. The equipment is used to deliver oxygen to clients/patients when:

- The client/patient is on continuous oxygen, and
- The client/patient is ambulatory more than 2 hours each day.

**Admission Criteria**

1. Determination by a physician of the need for supplemental oxygen.

2. Insurance criteria for payment has been met, unless client/patient is private pay.

3. Residence adaptable for placement and use of LOX system.

4. Client/patient or caregiver(s) trainable in the basic use, maintenance, cleaning, and troubleshooting of the device.

**Physician Responsibilities**

1. Provide diagnosis of the physiologic need for supplemental oxygen.

2. Inform the client/patient or caregiver(s) of the necessity for such a device in the home.

3. Provide a written, signed physician's prescription and any other necessary documents.

© 2005 Affordable Health Care Consultants
Company Responsibilities

1. Equipment delivery and set-up per policy, unless otherwise specified.

2. Equipment delivered will be clean, properly maintained, and safely operating within manufacturer's specifications. Accessories will be provided as per physician's prescription.

3. Provide written documentation of the delivery, set-up, and proper function of the device to referral source.

4. Provide written documentation that the client/patient or caregiver(s) has been instructed about basic safety procedure associated with the device. The client/patient or caregiver(s) will sign the Equipment Management Admission Assessment and Plan of Service to Indicate that they have been instructed and understand the proper use, maintenance, cleaning, and troubleshooting of the equipment, and also basic home safety and the Plan of Care.

Client/Patient Responsibilities

1. Client/patient or caregiver(s) must demonstrate the use, maintenance, cleaning, and troubleshooting of the equipment, and also basic safety procedures associated with the device

2. Client/patient or caregiver(s) must sign all necessary Company paperwork

3. Client/patient must have acceptable reimbursement source

Equipment Needed

1. LOX stationary vessel

2. LOX portable vessel

3. Humidifier, if ordered.

4. Oxygen tubing and oxygen cannula(s).

5. "No Smoking" signs
Set-up Requirements

1. Fill LOX stationary vessel outside the home per Oxygen Plus, Inc. policies and procedures.

2. Complete the required FDA fill record sheets.

3. Instruct client/patient or caregiver(s) per manufacturer’s guidelines.

4. Complete all necessary paperwork

NOTE: DELIVERY PERSONNEL MAY NOT APPLY ANY APPARATUS TO A CLIENT/PATIENT. DELIVERY PERSONNEL MAY NOT PRACTICE RESPIRATORY CARE (SEE STATE LAWS AND RULES).

Return Procedure

Liquid oxygen equipment may only be returned (picked up) if:

1. The client/patient's physician discontinues the equipment.

2. The client/patient signs an AMA Form (Against Medical Advice) if the physician wants the client/patient to keep using the equipment.

3. The client/patient moves outside Oxygen Plus, Inc.’s service area. We will refer the client/patient to another company serving the area to which the client/patient moved.

4. The client/patient wishes to use another home care dealer.

5. The client/patient expires.
REVIEW OF OXYGEN POLICIES AND PROCEDURES

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

Each employee involved in the transport, filling, review and documentation of Oxygen Services must annually read and review the policies and procedures associated with these services.

The following records associated with oxygen services will be placed in a separate file or notebook labeled OXYGEN SERVICES:

1. REVIEW OF OXYGEN POLICIES AND PROCEDURES
2. OXYGEN SERVICES IDENTIFICATION LIST
3. RESPONSIBLE PERSONS LIST
4. ANNUAL SUPPLIER AUDIT

This file/notebook will be audited annually for completeness. The file/notebook will be readily available for FDA inspectors and/or accrediting surveyors.
It is the policy of Oxygen Plus, Inc. to establish a Quality Control Unit (QCU) in accordance with FDA guidelines. It is the responsibility of the President to appoint an individual that has the authority to either approve or reject all drug product containers, closures, in-process materials, packaging material, and labeling. This individual shall also have the authority to review production records to ensure completeness and accuracy, and is responsible for the approval or rejection of all oxygen products. This individual shall meet in conjunction with the local Quality Improvement Committee and report findings through the established Company Ql process.

There is also a QCU established at the Company's office that will consist of all members of the Company's Quality Improvement Committee, with the capacity to enlist other individuals based on current needs. It is the responsibility of the Company's QI Committee to approve or reject policies and procedures when needed.

The QCU Supervisor for the Oxygen Plus, Inc. operation is: __________________
RESPONSIBLE PERSONS LIST

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/032007 – 2/09/2013

Joint Commission Standard:

The individuals listed below are trained in the proper handling, storage and
distribution of prescription drugs (oxygen) as they relate to Oxygen Plus, Inc.
activities. A description of job duties and qualifications may be found in the Job
Description section of this manual.

QCU

------------------------------
------------------------------
------------------------------
------------------------------
------------------------------
------------------------------
------------------------------

© 2005 Affordable Health Care Consultants
EDUCATION: OXYGEN SERVICES/SUPPORT

STAFF MEMBERS

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. that any staff member involved in the delivery, review, or instruction of oxygen care/services must be educated in keeping with the recommendations of the FDA, DOT, and state regulatory agencies.

Upon Hire

Upon hire, there will be adequate orientation on the equipment and services that are utilized by Oxygen Plus, Inc. to provide oxygen services to clients/patients. Orientation will be documented and placed in the employee's file.

Annually

Annual training will be provided specific to the analytical methodology that the local oxygen distributor utilizes in the production of liquid oxygen products. This is accomplished by completing a training session conducted at the distributor or Location. Upon completion, Training Documentation will be placed in the employee's file.

Oxygen Plus, Inc. requires that competencies be evaluated on an annual basis. A competency evaluation will be performed and documented. Upon completion, Training Documentation will be placed in the employee's file.

The decision to educate staff members on various topics is based on the scope of care/services provided.
Orientation and competencies include, but are not limited to, the following areas:

1. Record requirements for receipt of PG 45 Tanks to include receiving a Certificate of Analysis.

2. Filling of LOX vessels from the PG 45 Tank. Use and Calibration of Oxygen analyzer(s).

3. FDA policies and Procedures relating to LOX filling and record keeping.


5. Batch filing of LOX Fill records.
FILLING LOX UNITS FROM MDX 119 LOX UNIT

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

This procedure describes the steps and documentation necessary when filling a LOX vessel (C-41, C-31 and C-21) from a MVE model MDX 119 Liquid Delivery Tank (LOX Van Unit):

1) Log the MDX 119 fill lot number into the Liquid Oxygen Form. Document date, patient name, serial number of the LOX vessel, and purity analysis. The purity analysis is found on the COA for the MDX 119 fill.

2) Attach transfilling hose to LOX port on MDX 119.

3) Check pressure gauge on MDX 119 and vent if pressure is greater than 50 psi.

4) Use the pressure Builder Valve to maintain the pressure at 30 to 40 psi. Turn counter clockwise to increase and clockwise to decrease the pressure.

5) Perform a prefill inspection of the vessel (C41/31/21) to be filled. Visually inspect the vessel for any damage. Check the valves and gauges for any damage. Document on the Liquid Oxygen Form. Weigh vessel before filling.

6) Connect pressure gauge to LOX vessel 02 outlet and set flow at 2 LPM.

7) Remove cover from transfilling hose. Open vent on LOX vessel and connect transfilling hose to LOX vessel.

8) Open the liquid oxygen valve on the MDX 119 and begin filling process.


10) Close vent on LOX vessel when full. Remove transfilling hose and cover end.

© 2005 Affordable Health Care Consultants
11) Tag LOX vessel with LOT #, and patient's name. (See Record Keeping: Lot Numbers policy)

12) The post-fill inspection must include (1) Checking the flow rate with a flow meter attached to the LOX vessel outlet with flow set at 2 LW. The flow should read 2 LW + 7-1/4 LW. (2) Checking for any leaks. (3) Check the odor of the oxygen flowing out the LOX outlet, there should be no odor. (4) Check the identity of the oxygen with a calibrated oxygen analyzer (Unless you witnessed the suppliers purity check). (5) Clean the vessel with Madacide. Document on the Liquid Oxygen Form.

13) Weigh vessel, subtract previous weight, and document the pounds of liquid oxygen filled into the vessel under amount delivered (amt. del.) on the Liquid Oxygen Form.

14) Document date, patient name, serial number of the LOX vessel, Lot # assigned to the LOX unit fill, and filled by initials on the Liquid Oxygen Form.

15) Deliver vessel into patient's house and attach humidifier (if used) and O2 tubing. Set flow rate at prescribed oxygen flow rate. Attach a condensate bottle to port on side of vessel.

16) Each LOX Fill Form is to be reviewed and signed by another qualified LOX filler within 24 hours and then given the QCU director for review, billing and filling.
FILLING LOX UNITS FROM PG 45 LOX UNIT

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

This procedure describes the steps and documentation necessary when filling a LOX vessel (C-41, C-31, and C-21) from a PG 45 LOX Tank:

1) Log the PG 45 LOX Tank lot number into the Liquid Oxygen Form. Document date, client/patient name, serial number of the LOX vessel, and purity analysis. The purity analysis is found on the COA for the PG 45 LOX Tank.

2) Perform a pre-fill inspection of the vessel (C41/31/21) to be filled. Visually inspect the vessel for any damage. Check the valves and gauges for any damage. Document on Liquid Oxygen Form. Weigh vessel before filling.

3) Connect pressure gauge to LOX vessel 02 outlet and set flow at 2 LPM.

4) Remove cover from transfilling hose. Open vent on LOX vessel and connect transfilling hose from the PG 45 LOX Tank to LOX vessel's blue quick connect.

5) Open the liquid valve on the PG 45 LOX Tank to begin the filling process. Maintain 30-45 PSI on the PG 45 LOX Tank by use of the pressure-building valve.

6) Perform fill inspection. The fill inspection includes monitoring the pressure on the LOX vessel. Maintain 20 PSI. Do not exceed 21 PSI. Document on LOX form.

7) Close vent on LOX vessel when full. Turn off the PG 45 LOX Tank liquid valve and pressure-building valve. Remove transfilling hose and cover end.

8) Tag LOX vessel with LOT #, client/patient's name and serial number of vessel. (See Record Keeping: Lot Numbers policy)
9) The post-fill inspection must include: (1) Checking the flow rate with a flow meter attached to the LOX vessel outlet with flow set at 2 LPM. The flow should read 2 LW +1-1/4 LPM, (2) Checking for any leaks, (3) Check the odor of the oxygen flowing out the LOX outlet, there should be no odor, (4) Check the identity of the oxygen with a calibrated oxygen, and (5) Clean the vessel with germicide. Document on the Liquid Oxygen Form.

10) Weigh vessel, subtract previous weight, and document the pounds of liquid oxygen filled into the vessel under amount delivered (amt. del.) on the Liquid Oxygen Form.

11) Document date, client/patient name, serial number of the LOX vessel, Lot # assigned to the LOX unit fill, and filled by initials on the Liquid Oxygen Form.

12) Deliver vessel or arrange for delivery of the vessel. Attach humidifier (if used) and 02 tubing. Set flow rate at prescribed oxygen flow rate. Attach a condensate bottle to port on side of vessel. Pick up empty LOX vessel for return to office.

13) Each LOX Fill Form is to be reviewed and signed by another qualified LOX filler within 24 hours and then given the QCU for review, billing and filling.
RECORD KEEPING: COMPRESSED MEDICAL GASES

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. to ensure accurate documentation of compressed medical gases that meets the standards and intents of the Department of Transportation (DOT), the FDA, and applicable state laws and regulations.

Compressed medical gas cylinders will be tracked and cross-referenced by client/patient name and lot number. The Oxygen Tank Tracking Log is to be utilized for this purpose.

As tanks are delivered to a client/patient, the following will be documented on the Oxygen Tank Tracking Log:

1) Date of delivery
2) Client/patient the tanks are delivered to
3) The name of the tank supplier (company who filled the tank)
4) Type of tank (The size, e.g. C, D, H, and M)
5) Lot # of the tank (check affixed label for lot number and expiration date)
6) Expiration date
7) Initial form

The Lot Number for each individual tank will be listed one tank per line. For example, if 10 E tanks are received bearing lot number 12345, the tanks must be listed ten times on the Oxygen Tank Tracking Log.
RECORD KEEPING: CRYOGENIC HOME VESSELS

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. to ensure that accurate documentation is performed to meet the standards and intents of the Department of Transportation (DOT), FDA, and applicable state law and regulation.

Location personnel who perform(review transfilling procedures from source vessels to cryogenic home vessels will follow the procedures listed below and record the appropriate information on the LOX Fill Record.

**Daily Documentation**

- Log LOX scales calibration on LOX Scale Calibration Log in the warehouse.
- Document the date and the PG 45 Lot # on the LOX Fill Record.
- On the LOX Fill Record document the Lot #, the purity of the current PG 45 lot and the client/patient's name.
- List the serial number of the cryogenic vessel that you are filling. List the lot number assigned to that vessel fill.
- Perform the "Prefill Inspection" and check the corresponding boxes for completion.

**Visual Inspection**

- Check unit for damage (e.g., cracks, dents, etc.)
- Inspect unit for loose, bent, or missing components
- General Cleanliness

© 2005 Affordable Health Care Consultants
Value Inspection

- Inspect flow control knob and valves for cracks. Verify that knob on valve shaft is tight.

Gauge Inspection

- Confirm that gauge is patent and shows appropriate contents.
- List the pressure and flow at which the unit was filled.

Fill the Vessel per Company procedure and document the filling pressure in the Fill Inspection Pressure box.

Perform the "Post-fill Inspection" and check the corresponding boxes for completion:

Flow Test

- Check the flow of the vessel with a testing flow meter at 2 LPM. The flow should read 2 LPM plus or minus 4 LPM.

Leak Test

- Verify that there are no leaks in any vessel connections.

Odor Test

- Smell the oxygen going out of the vessel and verify it has no odor.

Purity Test.

- Analyze the oxygen output at 2 LPM with a calibrated Servomex oxygen analyzer. Document the reading on the LOX Fill Record.

Clean

- Clean external portions of equipment with Germicide.
Tag

- ✓ A label must be placed noting the client/patient's name, date of fill, and lot number of the LOX from the source vessel.
- ✓ Verify the presence and legibility of all warning labels. If not present, replace or return unit to Location for processing.
- ✓ Note the amount (pounds) delivered. The amount delivered is the post-fill weight minus the pre-fill weight.

Daily Review

All paperwork is to be turned in at the beginning of the next workday to the QCU supervisor for review, signature and billing and filing.
RECORD KEEPING: LOT NUMBERS

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

This policy describes the procedure to assign LOT numbers to C21, C31 and C41 LOX refills.

1. The Lot numbers assigned to client/patient stationary LOX vessels, (C21, C31 and C41) will be as follows:

The date filled followed by the fill number for the day, e.g.:

For the date 10/01/2022 (3 fills that day)

1001021
1001022
1001023

For the date 10/02/2022 (2 fills that day)

1002021
1002022

2) Each PG45 tank will have a lot number assigned by the supplier. The Lot number must appear on both the C OA and the P G45 tank. If the Lot number is not present, the P G45 tank must not be used for transfilling and must be returned to the supplier.

3) The lot numbers assigned to the PG45 tank will be written in the LOX Fill Record. The lot number for client/patient LOX vessels will be written on the LOX Fill Record and on a tag placed on the vessel itself. The Tag will also have the client/patient's name and the serial number of the vessel.
4) The Quality Control Unit supervisor is responsible for batch filing all LOX fill records in the following order:

a) The COA from oxygen supplier for the PG45.

b) All client/patient LOX Fill Records for that PG45 Lot Number. The records will be arranged in ascending date order.
RECORD KEEPING: MANIFESTS

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. that manifests be utilized at any time that hazardous materials of any amount are being transported in Company vehicles.

The following standards apply to the use of hazardous materials manifests.

The manifest will be:

- Clearly distinguished from other shipping papers or route sheets.
- Within the driver's immediate reach while restrained by the seat belt.
- Visible to persons entering the driver's compartment or in a holder inside the door of the driver's side of the vehicle.
- In a holder or side pocket of the driver's side of the vehicle while the vehicle is unattended.
- Marked with the number of the Chemical Transportation Emergency Center (1-800-424-9300). The Center is monitored 24 hours a day.
- Turned in daily to the Location QCU and kept in a file at the Location for no less than one year.
RECORD KEEPING: RETENTION

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. to ensure that accurate documentation that meets the standards and intents of the Department of Transportation (DOT), FDA, and applicable state law and regulation.

The following timetable should be adhered to with respect to retention of oxygen records:

✓ If an expiration date is present on the COA, all records should be retained for at least one (1) year after the expiration date of the batch.
✓ If no expiration date is present on the COA, all records should be retained for at least three (3) years after distribution of the batch.

NOTE: If any of the above records are involved in litigation, refer to the Company policy on record retention.
STORAGE AND HANDLING: COMPRESSED GASES

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013

Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. to comply with the standards set forth by the Compressed Gas Association, Uniform Fire Code (UFC), National Fire Protection Association (NFPA), Food and Drug Administration, and local fire authorities. If conflicts should arise in the interpretation of standards, the more stringent should always apply.

Compressed Gas Storage: 400 - 20,000 cubic feet. Cylinders must be:

- Stored in an assigned area that is dry and is well ventilated in order to prevent a buildup of gas should tanks leak or in the event of a fire.

- Separated from other combustible materials: Either by 20 feet or behind a five-foot high wall with a half-hour fire resistance rating. Materials, which possess this type of rating, are normally made of gypsum wallboard or cinder blocks. Special attention must be paid to oil, grease, and other flammable materials.

- Protected from abnormal mechanical shock and ignition sources. Cylinders should not be placed near elevators, gangways, or in locations where heavy moving objects may cause damage.

- Protected from extreme temperatures. NFPA specifies that tanks should not be heated above 125°F.

- Protected from tampering or vandalizing. Signs should be placed in the area to confirm the presence of oxygen.

- Stored at least five feet away from heat-generating sources.

- Be posted with signs regarding safety precautions such as "No Smoking" and "No Open Flames". Client/patient's homes should also be appropriately posted when oxygen therapy is in use.

- Not be used as "rollers", supports or for any other purpose than that for which the supplier intends them.
➢ Stored in a manner that will prevent tipping, rolling, or falling. Small tanks (D & E) should be stored in bins or racks. If racks are not available, small cylinder will be packed in boxes or crates. Large tanks (H tanks) should be anchored and chained to the wall in an appropriate manner. If a small volume is kept on site, H tank stands are acceptable to secure tanks.

➢ Stored without regulators attached and with protective caps (H tanks), if appropriate.

➢ Stored so that valves are closed on empty cylinders to prevent entry of contaminants.

➢ Assure proper ventilation of any enclosure containing oxygen control or operating equipment.

➢ Stored in the order they are received from the manufacturer or supplier.

➢ Separated and tagged to identify as "EMPTY" or "FULL".

➢ Should be discarded after one year. Filled cylinders expire after this time period.

➢ Secured to a handcart with a chain or appropriate restraint when moving or loading.

➢ Transported in such a way that damage (e.g., walls, furniture) to client/patient's home is avoided.
TESTING: AFTER REPAIR

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 = 2/09/2013

Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. to perform testing of cryogenic home units after they have been returned from the manufacturer and before being placed in client/patient's home.

Upon return of a unit to the Location, the following procedures will be performed to ensure that the unit is acceptable for client/patient use. Documentation should be placed the Equipment Set-up and Maintenance Log.

- **Visual Inspection**
  
  Check unit for damages (e.g., cracks, dents, etc.) Inspect unit for loose, bent, or missing components General cleanliness

- **Valve Inspection**
  
  Inspect flow control knob and valves for cracks. Verify that knob on valve shaft is tight.

- **Gauge Inspection**
  
  Confirm that gauge is patent and shows appropriate contents.

- **External Cleaning**
  
  Clean external portions of equipment with appropriate germicide agent.

- **Label Check**
  
  Verify the presence and legibility of all warning labels. If not present, replace or return unit to Location for processing.
➢ **Identity Testing**

Perform identity testing on any gas currently in reservoir. If the reservoir is empty, add sufficient quantity to allow identity testing. Record the reading on the Quality Control Log Form.
VERIFICATION OF SUPPLIER'S ANALYSIS

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. to periodically verify the reliability of the oxygen supplier's analysis. Documentation of this verification should indicate the test method and/or air liquefaction process utilized.

This verification should be performed at least annually by:

a) Witnessing the testing performed at the supplier. The employee responsible for the witnessing should have received training specific to the analytical methodology utilized.

b) If the Location is not knowledgeable of the analytical methodology, then a sample from a delivery should be taken to a third party for analysis for conformance with USP specifications.

The verification should be documented on the Annual Oxygen Supplier Audit form and stored with the FDA inspections reports in the Location.
PRESCRIPTION TRACKING AND ROTATION

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 = 2/09/2013

Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. to track all prescription drugs that are sold in accordance with the policies set forth by the FDA. Prescription drugs include prescription solutions and oxygen USP. Prescription solutions will be tracked on a form titled Prescription Solutions Tracking Form. Oxygen USP will be tracked on a form titled Oxygen Tank Tracking Log. All prescription drugs will be checked before delivery to verify the lot number and expiration date.

In order to assure that oldest approved stock is distributed first, all solutions and oxygen will be rotated on a first-in-first-out method (FIFO). As supplies, solutions and oxygen are delivered; the staff member who puts up the stock must check dates on the items and rotate the stock so that the oldest-dated items are used first. If the items are not dated, the stock is to be rotated using the FIFO method.

All solutions shall be stored in an area where the temperature can be controlled. The area shall be clean and free of insects and pests. Solutions shall be stored off of the floor on pallets and/or shelves.

Expiration dates on all cylinders are to be examined when delivered from the supplier, prior to delivery to a client/patient, and during each client/patient visit. Any cylinder that is outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined immediately.
CALIBRATION: DIAGNOSTIC EQUIPMENT

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission Standard:

It is the policy of Oxygen Plus, Inc. that all diagnostic equipment be calibrated and maintained per manufacturer specifications and FDA, DOT and state regulatory requirements.

Oxygen Analyzers

Calibrated prior to use with reference standard cylinders utilizing the Calibration Procedure per manufacturer guidelines.

Calibration must be recorded on the Oxygen Analyzer Calibration Log.

The manufacturer's instruction manual must be maintained for each brand of analyzer utilized in the Location.
CERTIFICATE OF ANALYSIS

APPROVED BY: Board of Directors
DATE EFFECTIVE: 3/30/05 DATE(S) REVISED: 2/03/2007 – 2/09/2013
Joint Commission:

It is the policy of Oxygen Plus, Inc. to obtain Certificates of Analysis (COA's) for all liquid oxygen deliveries.

Each COA must contain the following information to be considered valid:

1) Supplier's name and address.

2) Name of the product.

3) Air liquefaction statement.

4) Lot or other unique identification number.

5) Actual analytical results obtained for identity and strength. (Note that a statement indicating, "Meets the minimum purity of 99.0%" is not acceptable.)

6) Test method used for analysis (with model # of analyzer listed)

7) Supplier's signature and date.

8) Signature of Oxygen Plus, Inc. employee that witnesses testing (if applicable)

For reference gases used to calibrated analyzers, the following minimum information must be included on the COA:

a. Supplier's name and address

b. Name of product

c. Lot or other unique identification number

d. Actual analytical results obtained for identity and strength

e. Supplier's signature and date.

© 2005 Affordable Health Care Consultants