

# Virginia Beach Department of EMS

## Oxygen and Oxygen Systems Guidance Document

This policy details use and safety precautions for oxygen and oxygen delivery and transfilling (cascade) equipment. This policy applies to all oxygen pressure vessels utilized in the performance of patient care and transportation, regardless of ownership of those vessels.

Oxygen delivery systems are a potential source of serious hazard if the distribution system and cylinders are not properly stored, installed and maintained. Oxygen systems in EMS vehicles need to be maintained in accordance with the original equipment manufacturer's (OEM) specifications and applicable regulation. These systems must be inspected periodically for leaks, cleanliness and system integrity as well as flow calibration. Any unexplained noise or loss of oxygen should be investigated thoroughly and repaired before returning the delivery system or component to service. Caution should be exercised when replacing any component in the system to avoid installing an incompatible or incorrect piece of equipment.

### **General Storage, Maintenance and Handling:**

- ?? Do not allow smoking around oxygen.
- ?? Store oxygen in clean, dry locations away from direct sunlight.
- ?? Do not allow post valves, regulators, gauges, and fittings to come into contact with oils, greases, organic lubricants, rubber or any other combustible substance.
- ?? Make sure that any cleaning, repair or transfilling of oxygen equipment is performed by qualified, properly trained staff.
- ?? Do not work on oxygen equipment with ordinary tools. Designate special tools, clean them and store them for Use With Oxygen Equipment Only.
- ?? Ensure that any components added to the regulator, e.g., gauge guards, are installed so that they do not block the regulator vent holes.
- ?? Use plugs, caps and plastic bags to protect "off duty" equipment from dust and dirt.
- ?? Particulate migration from the cylinder can be minimized by the installation of a standoff tube (bayonet) at the inlet of the post valve.

### **Oxygen Regulators, Flow Meters and Combination (portable) Units**

Poorly stored, maintained or incorrectly installed and used oxygen delivery system components can be hazardous to providers and patients. The Department recommends that all providers become familiar with the safe handling and use of oxygen components.

Services and personnel should take all necessary measures to ensure oxygen delivery system reliability and safety. Specific attention should be given to the following areas concerning oxygen delivery systems:

- a. Oxygen leaks shall be immediately secured and corrected before the unit is returned to service.
- b. Physical presence of damage, rust, corrosion or deformity to any oxygen system component shall be repaired before the system is returned to service.
- c. Unqualified personnel shall make no alterations to oxygen delivery systems.
- d. No alterations to oxygen delivery systems shall be made with improper components.
- e. Foreign substances or residues, such as dirt, oil, dust, moisture or organic products on oxygen equipment shall be immediately cleaned and removed.
- f. Worn, damaged or inappropriate o-ring gaskets or gasket materials shall be replaced with only a rubber type sealing, metal washer style gasket.<sup>1</sup>
- g. All oxygen delivery devices should meet current industry standards.<sup>2</sup>

The failure to ensure compliance with these measures may hamper the ability of the oxygen delivery equipment to work properly and, in some cases, may have the serious potential to cause a fire or explosion or deterioration of patient condition.

### **Installed Oxygen Systems With Humidifiers**

The Department recommends that single patient use, disposable type oxygen humidifiers are utilized when humidified oxygen is required. At no time is water to be stored in a “refillable” or “reusable” humidifier. Any refillable system must be dry unless it is currently in active use providing humidified oxygen delivery as open sterile water can quickly become contaminated with microorganisms.

### **Oxygen Cylinders**

Poorly stored, maintained or incorrectly handled oxygen cylinders can be hazardous to providers and patients. The Department recommends that all providers become familiar with the applicable Federal DOT regulations (49CFR100-190) pertaining to the maintenance of pressure cylinders.

Services and personnel should take all necessary measures to ensure cylinder integrity. Specific attention should be given to the following areas concerning oxygen cylinders:

- a. Cylinder leaks, abnormal bulging, defective or inoperative valves or safety devices.
- b. Physical presence of damage, rust, corrosion or dents on a cylinder, cylinder neck, yoke, stem, valve, ports or pins.
- c. NO cylinder or cylinder component should be altered by the removal of the cylinder material (eg, stamping or engraving) unless specified and approved by DOT regulations.

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<sup>1</sup> There are two types of CGA 870 (Compressed Gas Association), seals in common use today. One type is a single use plastic crush gasket (usually Nylon? ). DEMS only recommends the rubber style gasket surrounded by a brass or aluminum washer. Examples are Brass and Viton or Aluminum and Buna N.

<sup>2</sup> If you are presently using high-pressure oxygen regulators that contain any aluminum exposed to high-pressure oxygen, replace them with regulators made of brass. Consult the manufacturer if you don't know what material is used in your regulators.

- d. Any foreign substances or residues, such as adhesive tape around the cylinder neck, yoke, stem, valve, ports or regulator assembly
- e. Worn, damaged or inappropriate o-ring gaskets or gasket materials.<sup>1</sup>
- f. All oxygen cylinders must have proper hydrostatic testing and be marked appropriately. Services need to be aware of the different and specific requirements for the testing of their style cylinders. (eg. ten (10) years initial testing for steel cylinders and five (5) years for aluminum cylinders).

Any cylinder placed in service, whether or not it is currently on a vehicle, must be within test requirements as evidenced by a valid hydrostatic test date imprinted on the cylinder.<sup>3</sup>

Any cylinder that has aged beyond its hydrostatic test date limit shall be immediately removed from service, regardless of the amount of product still residing in the cylinder, and labeled as out of service until such time as the cylinder is properly retested, stamped and filled.

All oxygen cylinders used by the Department and services should bear the modified federal caution statement indicated in 21 CFP 201.(b)(1) and 211.130 and the FDA's September 19, 1996 letter to the Compressed Gas Association regarding the final decision reached on its citizen petition:

*For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal law prohibits dispensing without prescription.*

Full cylinders shall have in place their bonnets or a "dust cap" protecting the valve stem opening. In-use cylinders not actively being used in the provision of patient oxygenation shall be appropriately stowed and secured (connected to a regulator, turned off and the residual bled) indicating to providers that the pressure remaining is within the specific parameters as outlined by OEMS regulation. Empty cylinders shall be clearly labeled as EMPTY and properly stored for either replacement or transfilling. A cylinder shall be classified as EMPTY when it no longer meets the delivery parameters as outlined in OEMS regulation.

### **Oxygen Cylinder Use:**

- ?? Make sure that staff using oxygen equipment are adequately trained in its operation and in oxygen safety and have knowledge of manufacturers instructions for using the equipment.
- ?? Visually inspect the post valve gasket and regulator inlet prior to installation. If they are not visually clean they should not be used.
- ?? Momentarily open and close ("Crack") the post valve to blow out debris prior to installing a regulator.

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<sup>3</sup> Paper labels on a cylinder usually indicate a gas expiration date and are not a valid cylinder test date.

- ?? Ensure that the regulator is set with the flow knob in the off position before attaching it to the cylinder.
- ?? Position the equipment so that valve is pointed away from the user and any other persons.
- ?? Open the cylinder valve slowly and completely to minimize the heat produced and achieve the desired flow conditions within the equipment.
- ?? Do not look at the regulator pressure gauge until the cylinder valve is fully opened.

**Minimum Supply/Cylinder Pressure**

An adequate supply of oxygen must be available at the beginning, and at all times during a shift. An EMS vehicle with less than the required equipment as per regulation must be considered out of service until restocked unless otherwise directed.

To meet the requirements of 12 VAC 5-31-860, the Department requires a minimum of 2,000 psi in any combination of portable cylinders (eg. 1 @ 1,700 psi +1 @ 700 psi = 2,400 psi total) on a vehicle at the beginning of the shift. Units with only one portable D cylinder must contain at least 1500 psi whenever it is not actively being used for administration.

A review of installed cylinder sizes was conducted in December of 2005. Based upon such review, the following are installed cylinder minimum pressures to meet OEMS regulation, listed by station:

Station	Installed Cylinder Type	Minimum Pressure (psi)
1	3AA – H/K	400
2	3AA – M	600
4	3AA – H/K	400
5	3AA – M	600
6	MULTIPLE TYPES	600
9	3AA – H/K	400
13	3AA – M	600
14	MULTIPLE	600
16	MULTIPLE	600
17	3A – M	600

As you can see, the 500 psi rule no longer applies.

**Oxygen Cylinder Securing Devices**

Each pressurized gas cylinder in any EMS vehicle must be mechanically secured in accordance with OEM manufacturer recommendations and applicable standards. For installed oxygen systems, this must be accomplished by using the OEM supplied securing system or a similar replacement system that is maintained in proper condition. Portable and spare cylinders must be mechanically secured in place **at all times**. It is strongly recommended that all ambulance stretchers be fitted with an OEM approved oxygen caddy that will securely hold an oxygen cylinder while providing oxygen therapy.

In use portable cylinders may be placed in a closed rigid or padded protective case and then stored in a cabinet or strapped to the ambulance cot with the head of the cot in the elevated position when not in use. Care should be taken to ensure that the oxygen system does not come into contact with petroleum dressings and other contaminants.

In all situations, the cylinder neck, stem and regulator are to be protected. At no time are spare oxygen cylinders to be stored in a cabinet or under a seat solely held in place by other items of equipment without being fastened in an approved OEM securing device.

### **Transfilling Stations**

Services that utilize a transfilling or cascade system should familiarize all their personnel on applicable DOT, FDA and Virginia regulations and Current Good Manufacturing Practices (CGMP) for medical gases. Additionally, services utilizing a transfilling station shall establish and implement the following minimum requirements:

- a. Establish written procedures covering all operations including within the organization, recalls, labeling, training, etc as referenced in the CGMP for Medical Gases
- b. Establish records documenting the above.

References:

A Memo on Current Good Manufacturing Practice Issues on Human Use Pharmaceuticals. Human Drug CGMP Notes. U.S. Department of Health and Human Services, Food and Drug Administration. 4, Number 4 (1996).

Berg, Michael. Virginia Board of Pharmacy and Transfilling of Oxygen Memo. Virginia Office of Emergency Medical Services. 20 December 2005.

Compressed Medical Gases Guideline. Human Drug CGMP Notes. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. February 1989.

Current Good Manufacturing Practice. 21 CFR 210 and 211. Federal Register. Government Printing Office. 68, Number 87 (2003).

Explosions and Fires in Aluminum Oxygen Regulators. FDA and NIOSH Public Health Advisory. 4 February 1999.

FDA Letter to Compressed Gas Association. U.S. Department of Health and Human Services, Food and Drug Administration. 19 September 1996.

Guidance for Industry, Current Good Manufacturing Practice for Medical Gases. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. May 2003.

Research and Special Programs Administration. 49 CFR 100-190. Federal Register. Government Printing Office. Volume 2. 1 October 2004.

Review Guidelines for Oxygen Generators and Oxygen Equipment for Emergency Use. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. undated.

Sylvia, Duane, Fresh Air '2000', A Look at FDA's Medical Gas Requirements, Presentation Transcript, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. 15 March 2000.

Research and Special Programs Administration. 49 CFR 100-190. Federal Register. Government Printing Office. Volume 2. 1 October 2004.

Virginia Emergency Medical Service Regulations. 12 VAC 5-31, January 2003.

WHA Fire Investigation Report, Wendell Hull and Associates, WHA 05H040, 25 October 2005.

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