

# POSITION STATEMENT

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## FILLING AND DISTRIBUTING EMERGENCY OXYGEN CYLINDERS WITHOUT A PRESCRIPTION

### Background

The U.S. Food and Drug Administration (FDA) considers oxygen, USP a prescription drug. In the interest of public safety, FDA permits properly trained first responders and properly trained professionals (emergency medical service providers, facility/institution medical representatives, company CPR providers, etc.) to dispense oxygen, USP without a prescription for use in emergency situations (emergency oxygen).

As of the publication date of this position statement, FDA does not have specific regulations or active guidance documents regarding the filling and distribution of emergency oxygen. FDA's 2003 draft guidance document, *Current Good Manufacturing Practices for Medical Gases*, provides some specific labeling language for emergency oxygen as well as referring to labeling requirements for medical gases [1]. The rescinded FDA draft document published in the late 1970's, *Review Guidelines for Oxygen Generators and Oxygen Equipment for Emergency Use*, provided emergency oxygen system performance requirements [2]. FDA's 2015 draft guidance, *Certification Process for Designated Medical Gases, Guidance for Industry*, indicates a requirement for labeling emergency use oxygen [3]. Emergency oxygen fillers, distributors, and customers shall comply with all applicable state regulations, including state Boards of Pharmacy regulations, for the manufacture, distribution, sale, and administration of emergency oxygen.

This publication is based on the information contained in the previously mentioned documents and discussions with FDA personnel. It describes the responsibilities of the emergency oxygen filler, distributor, and user.

### Questions

1. What are the emergency oxygen system labeling requirements?
2. What are the required emergency oxygen system specifications?
3. What are the training and training documentation requirements for first responders?

### Answers

1. Fillers and distributors of emergency oxygen systems shall ensure the appropriate labeling is legibly displayed on the cylinder and, if necessary, visible on any external container/housing so as to be easily read and understood in conformance with section 502(c) of the Federal *Food, Drug and Cosmetic Act* [4]. Therefore, emergency oxygen shall bear:

- Current oxygen, USP drug label that includes the statement "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx Only", and contains the applicable handling and storage statements per [CGA C-7, Guide to Classification and Labeling of Compressed Gases](#) [5];
- Name and address of the filler or distributor in accordance with FDA requirements contained in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 201 [6]; and
- Current lot number and statement of the net quantity of contents.<sup>1</sup>

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<sup>1</sup> The lot number and/or the net quantity of contents may appear directly on the drug product label or may be contained on and applied as a separate sticker, in accordance with common industry practice.

2. The first responder shall ensure the:

- emergency oxygen system is capable of delivering gaseous oxygen at a flow rate of 6 L/min for a minimum of 15 min and include a contents gauge and an appropriate mask or administration device;
- emergency oxygen cylinder contains at least 180 L of gaseous oxygen; and
- emergency oxygen cylinder is fitted with a valve integrated pressure regulator (VIPR), or a plain CGA 540 or CGA 870 valve connected to a pressure regulator.

3. FDA requires that first responders have specific training and are able to produce their training documentation. Training shall include the use of emergency oxygen on all patients and the safe use and handling of emergency oxygen equipment. If the appropriate documentation cannot be provided, the emergency responder cannot receive emergency oxygen.

When purchasing emergency oxygen systems, the customer shall ensure proper training has been provided to their first responders. At the time of the transaction or contractual agreement, the customer shall present the following credentials to the distributor:

- company-specific identification credentials (ID badge, business card, purchase order, etc.); and
- current training certificates documenting that first responders completed a nationally recognized emergency oxygen training program (American Red Cross, National Heart Association).

## References

Unless otherwise specified, the latest edition shall apply.

[1] Draft Guidance, 2003, *Current Good Manufacturing Practices for Medical Gases*, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). [www.fda.gov](http://www.fda.gov)

[2] Draft Document, *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 Device and Radiological Health. [www.fda.gov](http://www.fda.gov)

[3] Draft Guidance, 2015, *Certification Process for Designated Medical Gases, Guidance for Industry*, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). [www.fda.gov](http://www.fda.gov)

[4] Federal *Food, Drug, and Cosmetic Act*, U.S. Food and Drug Administration, 5600 Fishers Ln., Rockville, MD 20857. [www.fda.gov](http://www.fda.gov)

[5] *CGA C-7, Guide to Classification and Labeling of Compressed Gases*, Compressed Gas Association, 14501 George Carter Way, Suite 103, Chantilly, VA 20151. [www.cganet.com](http://www.cganet.com).

[6] *Code of Federal Regulations*, Title 21 (Food and Drugs), Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401. [www.gpo.gov](http://www.gpo.gov).