



CGA M-5—2013
GUIDE FOR HOME
RESPIRATORY CARE FIRMS
FILLING OR DISTRIBUTING
LIQUID OXYGEN USP

SECOND EDITION

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NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendices A and B (Informative) are for information only.

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1 Introduction

The information in this guide is an aid for complying with the applicable regulations of the U.S. Food and Drug Administration (FDA) and Health Canada for filling, packaging, testing, labeling, and holding liquid oxygen USP by home respiratory care (HRC) firms to ensure that product is manufactured and distributed in accordance with United States and Canadian current good manufacturing practices (CGMP) and meets all United States Pharmacopoeia (USP) specifications. See the *United States Pharmacopoeia* and *National Formulary (USP–NF)* [1].¹

This publication describes the processes, procedures, and documentation typically recognized by the HRC industry as the minimum regulatory requirements needed for compliance.

2 Scope

This publication is intended to address operations typical to an HRC firm and is not all inclusive. It is primarily intended for firms engaged in the filling (manufacture) and distribution of liquid oxygen USP to patients at their residences. Portions of this publication may apply to those HRC firms that also distribute other compressed medical gases (CMG). This publication includes the minimum regulatory requirements that shall be described in an HRC firm's written standard operating procedures (SOP) for the firm to receive, fill, test, and distribute liquid oxygen USP and includes the following:

- establishment and responsibilities of the quality control unit (QCU);
- qualifications of the person(s) performing and supervising the receipt, filling, testing, release, and distribution of liquid oxygen USP;
- quality records;
- building and facility requirements (including vehicles);
- manufacturing equipment design and maintenance;
- test equipment;
- record and report requirements;
- use of computer and other electronic equipment;
- receipt and testing of vendor-supplied product into the HRC's storage tank;
- receipt and testing of vendor-supplied product into vehicle-mounted vessels (VMVs) or other large cryogenic containers;
- receipt and testing of vendor-supplied product into cryogenic home vessels (CHVs);
- HRC filling and testing of VMVs and/or large cryogenic containers from an HRC company's storage tank;
- HRC filling and testing CHVs; and
- labeling requirements.

This publication is not applicable to the receipt, testing, release, and distribution of high pressure oxygen filled by HRC firms. Firms engaged in filling high pressure medical gas cylinders (either gas-to-gas or liquid-to-gas) should refer to CGA M-2, *General Guide for the Manufacture of Medical Gases Classified as Drugs* [2].

This publication is typically not applicable to non-HRC firms unless those firms are engaged in activities similar to those of HRC firms. Non-HRC firms engaged in oxygen USP liquid-to-liquid filling for home care use should also refer to CGA M-2 for additional guidance and potential additional regulatory requirements [2].

¹ References are shown by bracketed numbers and are listed in order of appearance in the reference section.