CGA

Compressed Gas Association

The Standard For Safety Since 1913

CGA M-3—2021

STANDARD FOR THE MANUFACTURER OF BULK MEDICAL GASES

FIFTH EDITION

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Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

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THIRD EDITION: 2009
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1 Introduction

This publication is a standard for compliance with the applicable regulations of the U.S. Food and Drug Administration (FDA) for the manufacture of bulk medical gases classified as drugs as described in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) [1].[1] It outlines the requirements for manufacturing bulk medical gases classified as drugs; however, it may not contain all information necessary to comply with FDA regulations. It is the responsibility of each gas manufacturer to ensure that their standard operating procedures (SOP) comply with all applicable federal, state, and local regulations.

2 Scope

This publication applies to the bulk manufacturing of medical gases as follows:

- bulk air separation (oxygen, USP and nitrogen, NF) manufacturing and distribution facilities;
- bulk carbon dioxide, USP manufacturing and distribution facilities;
- bulk helium, USP manufacturing and distribution facilities; and
- bulk nitrous oxide, USP manufacturing and distribution facilities.

This publication is intended to address current good manufacturing practice (CGMP) requirements for:

- Designated medical gases as defined in Section 575(1) of the *Federal Food, Drug, and Cosmetic Act* (Act) or combinations thereof; and
- Other medical gases as defined in Section 575(2) of the Act that may be approved via a new drug application (NDA) or abbreviated new drug application (ANDA) for which the sponsor has shown through a science based risk management plan that this standard provides appropriate CGMPs [2].

Throughout this publication the terms medical gas or medical gases are used to refer to these categories of products.

This publication does not apply to:

- Firms that engage in the filling, repackaging, transfilling, mixing, and/or relabeling of compressed medical gas (CMG) classified as drugs. See CGA M-2, *Standard for the Manufacture of Medical Gases Classified as Drugs* [3];
- Refrigerated liquid oxygen USP that is filled at a patient's residence or is filled, repackaged, transfilled, and/or relabeled by home respiratory care companies; and
- Drugs that are defined as Investigational New Drug Applications.

See the *United States Pharmacopeia and National Formulary* (*USP–NF*) for information on the USP and NF designations for medical gases [4].

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

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