CGA

Compressed Gas Association

The Standard For Safety Since 1913

CGA M-3—2015

STANDARD FOR THE MANUFACTURER OF BULK MEDICAL GASES

FOURTH 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.

See the *United States Pharmacopeia and National Formulary* (*USP–NF*) for information on the USP and NF designations for medical gases [2].

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.

3.1.2 Should
Indicates that a procedure is recommended.

3.1.3 May
Indicate that the procedure is optional.

3.1.4 Will
Is used only to indicate the future, not a degree of requirement.

3.1.5 Can
Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Adulterated
Condition in which a drug product actually or potentially does not meet all required or claimed standards of purity, strength, identity, or quality, or contains a foreign substance that can be injurious to health.

NOTE—A drug product not manufactured in accordance with current good manufacturing practice (CGMP) may be considered adulterated. See Section 501 of the Federal *Food, Drug, and Cosmetic Act* [3].

3.2.2 Air liquefaction
Process by which air is separated into its component parts by cryogenic distillation.

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