

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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Work Item 21-012
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

FIFTH EDITION: 2021
FOURTH EDITION: 2015
THIRD EDITION: 2009
SECOND EDITION: 2007

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Contents	Page
1 Introduction.....	1
2 Scope	1
3 Definitions.....	1
4 Health and safety considerations	5
5 Key laws, regulations, and guidelines	5
5.1 Federal	5
5.2 State/Local.....	6
6 Standard operating procedures.....	6
7 Organization/Personnel (21 CFR Part 211 Subpart B)	7
7.1 Quality control unit (21 CFR Part 211.22)	7
7.2 Personnel qualifications (21 CFR Part 211.25)	8
7.3 Personnel responsibilities (21 CFR Part 211.28)	8
7.4 Consultants (21 CFR Part 211.34)	9
8 Buildings and facilities (21 CFR Part 211 Subpart C)	9
8.1 General.....	9
8.2 Design and construction features (21 CFR Part 211.42(a))	9
8.3 Lighting (21 CFR Part 211.44)	9
8.4 Building maintenance (21 CFR Part 211.58).....	9
8.5 Security.....	9
9 Equipment (21 CFR Subpart D)	10
9.1 Equipment design, size, and location (21 CFR Part 211.63)	10
9.2 Equipment construction (21 CFR Part 211.65).....	10
9.3 Equipment cleaning and maintenance (21 CFR Part 211.67).....	10
9.4 Automatic, mechanical, and electronic equipment (21 CFR Part 211.68).....	11
9.5 Filters (21 CFR Part 211.72)	12
10 Control of components and drug product containers and closures (21 CFR Subpart E)	12
10.1 General requirements (21 CFR Part 211.80)	12
10.2 Receipt and storage of untested components, drug product containers, and closures (21 CFR Part 211.82).....	12
10.3 Testing and approval or rejection of components, drug product containers, and closures (21 CFR Part 211.84).....	13
10.4 Certificate of analysis	13
10.5 Use of approved components, drug product containers, and closures (21 CFR Part 211.86).....	14
10.6 Retesting approved components, drug product containers and closures (21 CFR Part 211.87).....	14
10.7 Rejected components, drug product containers, and closures (21 CFR Part 211.89)	14
11 Production and process controls (21 CFR Subpart F)	14
11.1 Written procedures/Deviations (21 CFR Part 211.100).....	14
11.2 Change in of components (21 CFR Part 211.101).....	14
11.3 Calculation of yield (21 CFR Part 211.103).....	14
11.4 Equipment identification (21 CFR Part 211.105).....	14
11.5 Sampling and testing in-process materials and drug products (21 CFR Part 211.110)	15
11.6 Time limitations on production, control of microbiological contamination, and reprocessing	15
12 Packaging and label controls (21 CFR Subpart G)	15
12.1 Materials examination and usage criteria (21 CFR Part 211.122) and labeling issuance (21 CFR Part 211.125).....	15
12.2 Packaging and labeling operations (21 CFR Part 211.130).....	15
12.3 Tamper evident (21 CFR Part 211.132).....	15
12.4 Drug product inspection (21 CFR Part 211.134).....	16
12.5 Expiration dating (21 CFR Part 211.137)	16

13	Holding and distribution (21 CFR Part 211 Subpart H)	16
13.1	Warehousing procedures (21 CFR Part 211.142).....	16
13.2	Distribution procedures (21 CFR Part 211.150).....	16
14	Laboratory controls (21 CFR Part 211 Subpart I)	16
14.1	General requirements (21 CFR Part 211.160)	16
14.2	Specifications	17
14.3	Sampling plans	17
14.4	Testing.....	17
14.5	Calibration of testing equipment.....	17
14.6	Calibration gas standards.....	18
14.7	Certificate of calibration—Gas calibration standards.....	18
14.8	Testing and release for distribution (21 CFR Part 211.165).....	19
14.9	Stability testing (21 CFR Part 211.166).....	19
14.10	Special testing requirements, reserve samples, laboratory animals, and penicillin contamination ...	19
15	Records and reports (21 CFR Subpart J).....	19
15.1	General requirements (21 CFR Part 211.180)	19
15.2	Equipment cleaning and use log (21 CFR Part 211.182).....	21
15.3	Component, drug product container, closure, and labeling records (21 CFR Part 211.184)	21
15.4	Master production and control records (21 CFR Part 211.186).....	22
15.5	Batch production and control records (21 CFR Part 211.188)	22
15.6	Production record review (21 CFR Part 211.192)	23
15.7	Laboratory records (21 CFR Part 211.194).....	24
15.8	Distribution records (21 CFR Part 211.196).....	25
15.9	Complaint files/procedures (21 CFR Part 211.198).....	25
16	Returned and salvaged drug products (21 CFR Subpart K)	25
16.1	Returned drug products (21 CFR Part 211.204)	25
16.2	Drug product salvaging (21 CFR Part 211.208)	25
17	References	26

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.