

CGA M-8—2011

**GUIDELINE FOR
THE MANUFACTURER OF
CALIBRATION GAS
STANDARDS USED TO
ANALYZE MEDICAL GASES**

SECOND EDITION



**COMPRESSED GAS ASSOCIATION, INC.
4221 Walney Road, 5th Floor
Chantilly, VA 20151
Phone: 703-788-2700
Fax: 703-961-1831
E-mail: cga@cganet.com**

PLEASE NOTE:

The information contained in this document was obtained from sources believed to be reliable and is based on technical information and experience currently available from members of the Compressed Gas Association, Inc. and others. However, the Association or its members, jointly or severally, make no guarantee of the results and assume no liability or responsibility in connection with the information or suggestions herein contained. Moreover, it should not be assumed that every acceptable commodity grade, test or safety procedure or method, precaution, equipment or device is contained within, or that abnormal or unusual circumstances may not warrant or suggest further requirements or additional procedure.

This document is subject to periodic review, and users are cautioned to obtain the latest edition. The Association invites comments and suggestions for consideration. In connection with such review, any such comments or suggestions will be fully reviewed by the Association after giving the party, upon request, a reasonable opportunity to be heard. Proposed changes may be submitted via the Internet at our web site, www.cganet.com.

This document should not be confused with federal, state, provincial, or municipal specifications or regulations; insurance requirements; or national safety codes. While the Association recommends reference to or use of this document by government agencies and others, this document is purely voluntary and not binding unless adopted by reference in regulations.

A listing of all publications, audiovisual programs, safety and technical bulletins, and safety posters is available via the Internet at our website at www.cganet.com. For more information contact CGA at Phone: 703-788-2700, ext. 799. E-mail: customerservice@cganet.com.

Work Item 10-063
Medical Gases and Equipment Committee

NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendix A (Normative) is a requirement.

SECOND EDITION: 2011

FIRST EDITION: 2006

© 2011 The Compressed Gas Association, Inc. All rights reserved.

All materials contained in this work are protected by United States and international copyright laws. No part of this work may be reproduced or transmitted in any form or by any means, electronic or mechanical including photocopying, recording, or any information storage and retrieval system without permission in writing from The Compressed Gas Association, Inc. All requests for permission to reproduce material from this work should be directed to The Compressed Gas Association, Inc., 4221 Walney Road, Suite 500, Chantilly VA 20151. You may not alter or remove any trademark, copyright or other notice from this work.

Contents	Page
1 Introduction.....	1
2 Scope	1
3 Definitions.....	1
4 Raw materials.....	2
4.1 Component raw materials.....	2
4.2 Cylinders and valves	3
5 Methods of manufacture.....	3
5.1 Cylinder prefill inspection.....	3
5.2 Evacuation and purge cycles.....	4
5.3 Cylinder filling methods	4
5.4 In-process controls	5
5.5 Postfill inspection.....	5
6 Types of calibration standards	5
6.1 Nationally recognized standards (NRS)	5
6.2 Primary standards	5
6.3 Certified standards	6
6.4 Carrier gases	7
7 Equipment qualification	7
7.1 Analytical equipment calibration	7
7.2 Performance checks.....	7
7.3 Instrument calibration	7
7.4 Analytical equipment maintenance.....	8
7.5 Production equipment.....	8
7.6 Scales.....	8
7.7 Scale performance check.....	8
7.8 Pressure/vacuum gauges.....	8
7.9 Master gauge calibration	9
7.10 Thermometers	9
7.11 Gravimetric weights	9
7.12 In-process analyzers	9
8 Labeling and packaging	9
8.1 Product labeling.....	9
8.2 Protective packaging	10
9 Records	10
10 References	10
Appendix	
Appendix A—Production tolerances, analytical uncertainty, and reported concentrations for standards manufactured for medical gases listed in the USP–NF	12

This page is intentionally blank.

1 Introduction

This publication establishes the minimum requirements for the manufacture, analysis, and qualification of calibration gas standards used to qualify medical gases. The intent of this publication is to ensure consistent manufacture of calibration gas standards.

For the purpose of this publication, the term manufacturer shall mean calibration gas manufacturer unless it is preceded by a specific qualifier, e.g., equipment manufacturer.

2 Scope

This publication applies to the manufacture and analysis of primary gas standards used to calibrate analytical equipment used to verify the concentration of standards. It also applies to the manufacture and analysis of certified gas standards used to calibrate analytical instruments used to test medical gases.

This publication does not apply to the manufacture of calibration gas standards classified as medical devices.

3 Definitions

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

3.1 Accuracy

How close the reported value of the component concentration is to the actual concentration.

3.1.1 Absolute

Degree of variance independent of comparison to a reported value.

NOTE—Example: If the reported concentration of a gas standard is $5\% \pm 2\%$ absolute, the actual concentration lies in the range of 3% to 7%.

3.1.2 Relative

Degree of variance dependent on comparison to a reported value.

NOTE—Example: If the reported concentration of a gas standard is $5\% \pm 2\%$ relative, the actual concentration lies in the range of 4.9% to 5.1%, which is $5\% \pm (2\% \text{ of } 5\%)$ or $5\% \pm 0.1\%$ absolute.

3.2 Calibration

Comparison of a measurement standard or instrument of known accuracy and precision with a measurement standard or instrument of unknown accuracy and precision.

NOTE—Used to detect, correlate, report, and eliminate by adjustment any variation in the accuracy and precision of the unknown item.

3.3 Calibration standard

Material of a known value to which other materials are compared.

3.4 Calibration gas standard

Gases that have been analyzed and certified to appropriate levels of accuracy using standards that are traceable to a national standards organization and are used to calibrate gas analysis equipment.

3.5 Certified standard

Calibration gas standard analytically qualified against a primary standard.

3.6 Evacuation

Process of removing residual product by mechanical means, creating a negative atmospheric pressure.