

CGA P-8.2—2018

**GUIDELINE FOR VALIDATION OF  
AIR SEPARATION UNIT AND  
CARGO TRANSPORT UNIT FILLING  
FOR MEDICAL OXYGEN AND  
MEDICAL NITROGEN**

**SIXTH EDITION**

**CGA**

**Compressed Gas Association**

*The Standard For Safety Since 1913*

## PREFACE

As part of a program of harmonization of industry standards, the Compressed Gas Association (CGA) has published CGA P-8.2, *Guideline for Validation of Air Separation Unit and Cargo Transport Unit Filling for Medical Oxygen and Medical Nitrogen*, jointly produced by members of the International Harmonization Council.

This publication is intended as an international harmonized standard for the worldwide use and application of all members of the Asia Industrial Gases Association (AIGA), Compressed Gas Association (CGA), European Industrial Gases Association (EIGA), and Japan Industrial and Medical Gases Association (JIMGA). Each association's technical content is identical, except for regional regulatory requirements and minor changes in formatting and spelling.

### 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](http://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](http://www.cganet.com). For more information contact CGA at Phone: 703-788-2700, ext. 799. E-mail: [customerservice@cganet.com](mailto:customerservice@cganet.com).

Work Item 17-038  
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

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

SIXTH EDITION: 2018  
FIFTH EDITION: 2013  
FOURTH EDITION: 2008  
THIRD EDITION: 2003

© 2018 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., 14501 George Carter Way, Suite 103, Chantilly VA 20151. You may not alter or remove any trademark, copyright or other notice from this work.

| <b>Contents</b>   | <b>Page</b> |
|---|-------------|
| 1 Introduction.....   | 1           |
| 2 Scope .....   | 1           |
| 3 Definitions.....  | 1           |
| 4 Overview of process.....  | 4           |
| 4.1 Background .....  | 4           |
| 4.2 Process description .....   | 5           |
| 5 Plant and process assumptions .....   | 6           |
| 6 Approach to process validation .....  | 6           |
| 7 Stage 1—Process design.....   | 6           |
| 7.1 Incoming air study .....  | 7           |
| 7.2 Risk analysis.....  | 7           |
| 7.3 Hazard analysis and critical control point .....                                      | 7           |
| 7.4 Critical control points .....   | 7           |
| 7.5 Variations.....   | 7           |
| 7.6 Change control .....  | 7           |
| 8 Stage 2—Process qualification .....   | 8           |
| 8.1 Validation master plan .....  | 8           |
| 8.2 Validation protocols .....  | 8           |
| 8.3 Typical validation requirements for identified critical control points.....           | 8           |
| 8.4 Sampling.....   | 8           |
| 8.5 Development of PQ (PPQ) (objective measures).....                                     | 8           |
| 8.6 Validation summary report.....  | 10          |
| 8.7 Bridge from legacy validation to new validation model.....                            | 10          |
| 8.8 Additional support documentation .....  | 10          |
| 9 Stage 3—Continued process verification .....  | 10          |
| 10 References .....   | 11          |
| <br><b>Tables</b>   |             |
| Table 1—IQ requirements .....   | 9           |
| Table 2—OQ requirements .....   | 9           |
| Table 3—PQ requirements .....   | 10          |
| <br><b>Appendices</b>   |             |
| Appendix A—Simplified typical air separation unit process flow diagram (Informative)..... | 12          |
| Appendix B—Failure mode and effects analysis (Informative) .....                          | 13          |
| Appendix C—Hazard analysis and critical control point (Informative) .....                 | 22          |
| <br><b>Appendix Tables</b>  |             |
| Table B-1—Criteria for FMEA .....   | 13          |
| Table B-2—FMEA .....  | 14          |
| Table C-1—HACCP decision tree.....  | 22          |