



**CGA M-16—2016**  
**GUIDANCE FOR ELECTRONIC**  
**RECORDS & SIGNATURES IN**  
**THE U.S. & CANADIAN FOOD,**  
**DRUG, & MEDICAL DEVICE GAS**  
**& GAS EQUIPMENT INDUSTRY**

**FIRST EDITION**

**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 13-099  
Medical Gases Committee

---

FIRST EDITION: 2016

© 2016 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., 8484 Westpark Drive, Suite 220, McLean, VA 22102. 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 Purpose of e-Regs and applicability.....	2
4.1 Predicate rule and conditions that affect product quality .....	2
4.2 “Typewriter rule” .....	2
4.3 FDA enforcement discretion .....	2
4.4 Electronic submissions and e-records.....	2
4.5 Validation requirements.....	2
4.6 Risk management and mitigation .....	3
4.7 Documented rationale .....	3
5 Risk assessment and risk management and mitigation of requirements .....	3
5.1 New system.....	3
5.2 Legacy system.....	3
5.3 Gap analysis.....	4
6 Generation or storage of e-records .....	4
7 E-signatures .....	4
7.1 Equivalent to handwritten .....	4
7.2 Security.....	4
8 Security .....	5
8.1 Data integrity .....	5
8.2 Restricted (limited) access to authorized individuals.....	5
8.3 Prevention of loss, damage, and unauthorized changes.....	5
8.4 Validation of security systems .....	5
9 Records on the e-Regs system in use .....	5
10 Vendor qualification (includes supplier audit) including industry relevant examples.....	6
11 Validation and periodic verification.....	6
12 Management of change for technical hardware and software.....	6
12.1 System or component changes during the validation execution process.....	7
12.2 System or component changes after approval of the validation.....	7
12.3 Life cycle approach.....	7
13 References .....	8
<b>Appendix</b>	
Appendix A—21 CFR Part 11 and PIC/S Annex 11 assessment worksheet (Informative).....	9

This page is intentionally blank.

## 1 Introduction

This publication discusses the general requirements for bulk and packaged gas operations manufacturing and filling medical (drug or device) or food grade gases that are required to comply with the electronic record and electronic signature requirements found in Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 11 and Pharmaceutical Inspection Co-operation Scheme (PIC/S) *Guide for good manufacturing practice for medicinal products*, Annex 11 “Computerised Systems” [1, 2].<sup>1</sup> Additional publications may be developed to address in greater detail the requirements of certain sub-systems that utilize electronic records (e-records) and electronic signatures (e-signatures).

## 2 Scope

This guideline is based upon FDA’s August 2003 *Guidance for Industry Part 11, Electronic Records; Electronic Signatures—Scope and Application* and satisfies the criteria of 21 CFR Part 11, § 11.1 (a) “The regulations in this part set forth the criteria under which the agency considers e-records, e-signatures, and handwritten signatures executed to e-records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper” [3, 2].

This guideline also harmonizes with PIC/S *Guide for good manufacturing practice for medicinal products*, Annex 11 “Computerised Systems” (as adopted in Canada) [2].

NOTE—These regulations and guidance will be referred to as e-Regs in this publication.

## 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

Indicates 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 Computer system

Includes hardware, software, and firmware.

#### 3.2.2 Computerized systems

Includes computer system plus the function or process that is being controlled.

---

<sup>1</sup> References are shown by bracketed numbers and are listed in order of appearance in the reference section.