



**CGA M-17—2016**  
**STANDARD FOR AUTOMATIC**  
**TRAILER FILL COMPLIANCE TO**  
**21 CFR PART 11 AND**  
**PIC/S ANNEX 11 REQUIREMENTS**

**FIRST EDITION**

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## 1 Introduction

This publication provides the requirements for validating automatic trailer fill (ATF) systems including systems used to document filling, sampling, testing, and release for compliance with Title 21 of the U.S. *Code of Federal Regulations* (21 CFR) Part 11 and Pharmaceutical Inspection Co-operation Scheme (PIC/S) *Guide to good manufacturing practice for medicinal products*, Annex 11 “Computerised Systems” when systems utilize electronic records (e-records) and electronic signatures (e-signatures) [1, 2].<sup>1</sup>

This publication is intended to provide a specific detailed outline requirement with regard to documentation for 21 CFR Part 11 and PIC/S Annex 11 compliance for use in ATF systems.

These requirements verify that the creation, modification, and deletion of records from the ATF system is in accordance with 21 CFR Part 11 and PIC/S Annex 11 to be able to generate accurate and ready retrieval of data throughout the records retention period [1, 2].

## 2 Scope

This publication applies to ATF systems and records, including trailers, microbulk vessels, railcars, and ISO containers at bulk medical gas and bulk food gas manufacturing facilities.

This publication does not cover the filling of compressed gas cylinders or small cryogenic containers.

## 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 Audit trail

(1) (ISO) Data in the form of a logical path linking a sequence of events, used to trace the transactions that have affected the contents of a record. (2) A chronological record of system activities that is sufficient to enable the reconstruction, reviews, and examination of the sequence of environments and activities surrounding or leading to each event in the path of a transaction from its inception to output of final results [3].

#### 3.2.2 Automatic trailer fill (ATF) system

System in the bulk gas distribution process, which may include automated sampling and analysis of a product along with automatic recording and/or storage of required quality control data.

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