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CGA M-17—2022
STANDARD FOR AUTOMATIC
TRAILER FILL COMPLIANCE TO
21 CFR PART 11 AND PIC/S
ANNEX 11 REQUIREMENTS

SECOND EDITION

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Work Item 21-020
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined

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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 and electronic signatures [1, 2].¹

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.

In addition to the guidance in this publication, see CGA M-27, *Guideline for Complying with Data Integrity Regulatory Expectations*, for more information on compliance with data integrity requirements for ATF systems [3].

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 whenever 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) “SOX 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 [4].

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