CGA M-12—2020

GUIDELINE FOR INVESTIGATING OUT-OF-SPECIFICATION TEST RESULTS FOR FOOD AND MEDICAL GAS MANUFACTURING

THIRD EDITION

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NOTE—Technical changes from the previous edition are underlined.

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1 Introduction

This out-of-specification (OOS) guidance describes how a food or medical gas OOS test result shall be investigated including the role of laboratory personnel, the laboratory stage of the investigation, any additional testing that is needed, expansion of the investigation beyond the laboratory, and the final evaluation of all test results.

2 Scope

This publication provides guidance on how a food or medical gas manufacturer shall evaluate OOS test results. Although this publication is based on FDA's October 2006 *Guidance for Industry Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production*, CGA M-12 also applies to device and food gas OOS test results obtained during testing of these products [1].[1]

OOS test results include all test results that fall outside the specifications or acceptance criteria of the official compendia or that do not satisfy the manufacturer's definition of acceptance. An OOS condition within a food or medical gas production facility is generally considered any failure of a batch, a lot, or finished product. Provided the plant's automated or manual systems are qualified, operated as designed, and do not allow out-of-specification product to be produced into product storage, OOS investigations are not required for process plant upsets.

This publication applies to traditional batch test release and not to Process Analytical Technology models, since they use process controls and in-process data as the release mechanism. It also applies to chemistry-based laboratory testing of food and medical gases as well as contract firms that perform testing of food or medical gases.

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 Laboratory
The area at a facility where analytical testing is performed.

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