

CGA M-12—2014

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

SECOND EDITION

CGA

Compressed Gas Association

The Standard For Safety Since 1913

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NOTE—Technical changes from the previous edition are underlined.

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Contents	Page
1 Introduction.....	1
2 Scope	1
3 Identifying and assessing OOS test results—Phase 1: Laboratory investigation.....	1
3.1 General.....	1
3.2 Responsibility of the analyst.....	2
3.3 Responsibilities of the analyst supervisor.....	2
4 Investigating OOS test results—Phase 2: Full scale OOS investigation	3
4.1 General.....	3
4.2 Review of production	3
4.3 Additional laboratory testing	3
4.4 Reporting testing results.....	4
5 Concluding the investigation	4
5.1 General.....	4
5.2 Interpretation of investigation results.....	5
5.3 Conclusion.....	5
6 References	5

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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.

For purposes of this publication, the term laboratory means the area at a facility where analytical testing is performed.

3 Definitions

For the purpose of this publication, the following definitions apply.

3.1 **Can**

Indicates a possibility or ability.

3.2 **May**

Indicate that the procedure is optional.

3.3 **Shall**

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.4 **Should**

Indicates that a procedure is recommended.

4 Identifying and assessing OOS test results—Phase 1: Laboratory investigation

4.1 General

The investigation is intended to determine the root cause of the OOS result including whether it occurred during the manufacturing process or the testing process. Product rejection does not preclude the need to do the OOS investigation. The documented investigation should include conclusions and follow-up.

Phase 1 of an OOS investigation should include an evaluation of the accuracy of the test data. When possible, use the same test materials (e.g., calibration standards, detector tubes, orsat test solutions, etc.) to evaluate for

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