CGA

Compressed Gas Association

The Standard For Safety Since 1913

CGA M-19—2017

STANDARD FOR BIOCOMPATIBILITY OF MATERIALS FOR MEDICAL GAS EQUIPMENT

FIRST EDITION

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1 Introduction

This publication will assist in meeting existing and new Food and Drug Administration (FDA) requirements on biocompatibility of materials, including conformance to the provisions of ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* [1]. This publication does not explicitly exempt any material and gas combination from testing.

Materials used in the manufacture or delivery of medical gases have the potential to react with the medical gas and can create a potentially hazardous condition for patients or caregivers. This publication provides guidance on basic considerations for material evaluation specifically related to the biocompatibility of material in medical devices used in the manufacture or delivery of medical gases. The FDA has issued a guidance document, *Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, for compliance to this standard [2].

Certain metals (e.g., brass, stainless steel, steel, aluminum, copper) have a long and established history of use associated with medical gas service in both low and high pressure systems. While there are specific material selection requirements for some applications, the use of metals is generally considered to be safe with no expectation of off-gassing or entrainment of harmful compounds into the medical gas. Similarly, the use of certain nonmetallic materials in medical devices has also been generally regarded as safe for use (e.g., hydrocarbon-free polytetrafluoroethylene [PTFE] for seals) when used in accordance with appropriate standards.

Use of any material in medical devices requires specialized design, maintenance, and adherence to proven safety considerations. Important considerations include the material specification, design requirement, reactivity with the process medical gas, toxicity, and biocompatibility of the material.

2 Scope

This publication applies to medical devices that come into direct or indirect contact with the human body and are subject to Premarket Application (PMA) and Premarket Notification (510(k)) requests in order to determine potential toxicity. This publication may be used for evaluation of other medical devices.

This publication addresses high and low pressure gas systems. It applies to both metallic and nonmetallic materials including lubricants, ceramics, and glass that contact the caregiver or the patient using the medical device. Contact can include direct contact with the material or contamination of the gas stream with potentially toxic materials. The gas stream can be contaminated through contact with a wetted component or through a reaction of the gas with an internal component of the medical device. See CGA G-4.10, *Design Considerations to Mitigate the Potential Risks of Toxicity When Using Nonmetallic Materials in High Pressure Oxygen Breathing Gas Systems* for use of nonmetallic materials in oxygen as it relates to ignition [3].

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.