Compressed Gas Association
The Standard For Safety Since 1913

CGA TR-3—2023

THE IMPACT OF AMBIENT AIR CONTAMINANTS ON VALIDATION REQUIREMENTS FOR THE AIR SEPARATION PROCESS

SECOND EDITION

PLEASE NOTE:

The information contained in this document was obtained from sources believed to be reliable and is based on technical information and experience currently available from members of the Compressed Gas Association, Inc. and others. However, the Association or its members, jointly or severally, make no guarantee of the results and assume no liability or responsibility in connection with the information or suggestions herein contained. Moreover, it should not be assumed that every acceptable commodity grade, test or safety procedure or method, precaution, equipment or device is contained within, or that abnormal or unusual circumstances may not warrant or suggest further requirements or additional procedure.

This document is subject to periodic review, and users are cautioned to obtain the latest edition. The Association invites comments and suggestions for consideration. In connection with such review, any such comments or suggestions will be fully reviewed by the Association after giving the party, upon request, a reasonable opportunity to be heard. Proposed changes may be submitted via the Internet at our web site, www.cganet.com.

This document should not be confused with federal, state, provincial, or municipal specifications or regulations; insurance requirements; or national safety codes. While the Association recommends reference to or use of this document by government agencies and others, this document is purely voluntary and not binding unless adopted by reference in regulations.

A listing of all publications, audiovisual programs, safety and technical bulletins, and safety posters is available via the Internet at our website at www.cganet.com. For more information contact CGA at Phone: 703-788-2700, ext. 799. E-mail: customerservice@cganet.com.

Work Item 21-002
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

NOTE—Appendices A and B (Informative) are for information only.

SECOND EDITION: 2023
FIRST EDITION: 2014

Contents **Page**

Figures

Appendices

Appendices Tables

1 Introduction

This publication describes how potential contaminants in the air separation process are eliminated or minimized to low level concentrations that pose no hazard or risk in medical oxygen USP or nitrogen NF.

As a prerequisite step to conducting a full risk assessment of the air separation process, CGA conducted a study of contaminants that can be found in ambient air and the impact of the air separation process on these contaminants. Developing an in-depth understanding of possible sources of ambient air contamination and the role of the air separation unit (ASU) in controlling and eliminating these contaminants significantly increases the accuracy of the conclusions developed during the risk assessment process.

This publication is intended to accompany CGA P-8.2, *Guideline for Validation of Air Separation Unit and Cargo Transport Unit Filling for Medical Oxygen and Medical Nitrogen,* which contains ASU process validation requirements and the associated industry guidance [1].[1]

2 Scope

This publication evaluates possible sources of ambient air contamination and the role of the ASU in controlling and eliminating these contaminants.

The ASU contaminant evaluation includes:

- identifying potential contaminants;
- physical and chemical properties of the contaminants;
- ASU impact on contaminants;
- oxygen concentration factors;
- concentration levels of contaminants remaining in oxygen;
- particulates; and
- conclusions/data evaluation by a third-party toxicologist and by industry.

3 Potential contaminants

The elements and compounds that can enter the ASU are listed in Appendix A. The list includes nitrogen, oxygen, and argon, which are the desired end products of the ASU process. The list is based on established scientific data, the U.S. Environmental Protection Agency (EPA) and other governmental sources of data on constituents and pollutants of ambient air, and experience derived from 100 years of ASU operation. Particulate substances, which can be generated inside the ASU, are also identified.

Nearly all identified substances either do not enter the ASU or are eliminated by the actions of the ASU process. A small number of substances have physical and chemical properties that can result in their being in solution in the liquid oxygen (LOX) contained in the low pressure column. Only a handful of the substances found in the LOX have the potential to concentrate to levels approaching a threshold concentration. Industry has established consensus standards for safe operational limits for these substances in LOX. Facility operating practices conforming to these standards result in contaminant concentrations significantly lower than the threshold concentrations that affect product safety.

The starting point for determining the elements and compounds that can reside in ambient air is the EPA *Clean Air Act* (CAA) [2]. The CAA documents identify a list of the 189 hazardous air pollutants (HAP) identified on the EPA website. The EPA does not routinely monitor ambient air in the United States for HAP substances because they are not typically present in measurable quantities. But because emissions of HAP substances are regulated and subject to a stringent permitting process, a starting or inlet air concentration for HAP substances had to be

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