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

SECOND EDITION

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Work Item 21-002
Medical Gases Committee

NOTE—Technical changes from the previous edition are underlined.

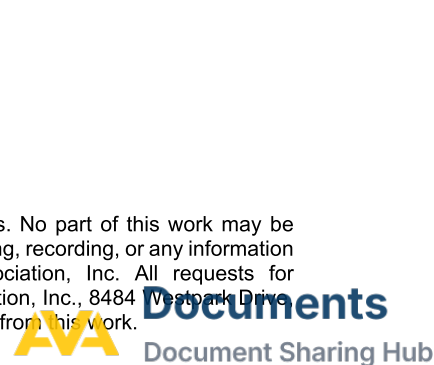
NOTE—Appendices A and B (Informative) are for information only.

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Contents	Page
1 Introduction.....	1
2 Scope	1
3 Potential contaminants	1
4 Physical and chemical properties of contaminants	2
5 ASU impact on contaminants	2
6 Oxygen concentration factors.....	3
7 Concentration levels of contaminants remaining in oxygen	4
8 Particulates.....	4
9 Conclusions.....	5
10 References	5

Figures

Figure 1—Full range of oxygen concentration factors	3
Figure 2—Typical range of oxygen concentration factors.....	4

Appendices

Appendix A—Compounds and elements present in ambient air (Informative)	7
Appendix B—Compounds and elements remaining after the ASU process (Informative)	14

Appendices Tables

Table A-1—Exposure limits for compounds and elements present in ambient air.....	7
Table B-1—Effect of ASU process on LP oxygen sump contaminants.....	14

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.

established. For the purpose of this study, a worst case concentration of the U.S. Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) at the ASU property boundary was assumed.

The PEL limit is the amount of any substance an individual can be exposed to for 40 hours per week for a lifetime without an adverse health impact and identifies the highest concentration that can exist without initiating governmental requirements to control and contain the substance or to notify surrounding populations.

If an accidental release of a HAP substance that can cause a temporary increase of local concentrations above the PEL occurs, an ASU facility expects to be notified by local civil authorities. Once notified, the facility will implement appropriate action plans to prevent the accidental release from impacting product quality and safety.

The CAA further identifies six criteria pollutants: ozone, particulate matter, carbon monoxide, nitrogen dioxide, sulfur dioxide, and lead. EPA monitors these six criteria substances at numerous monitoring stations around the United States. EPA makes this data available publicly through its web site. The measured levels of the six criteria substances do not change substantially on an annual basis. The levels in most areas have generally held steady or declined slightly over the last 5 years. During the initial ASU design process, facility owners should evaluate the EPA data to determine if a concentration above a typical level exists in their locale. If a higher than normal concentration exists, the facility should make appropriate design modifications.

Over 100 years of ASU operations experience yields information on elements and compounds in ambient air. The industry recognizes that naturally occurring substances in ambient air must be addressed in ASU design and operational procedures to ensure safe and efficient operations.

Air is a mixture of different gaseous elements in fixed proportions. Approximately 257 compounds and elements that can be present in ambient air are identified in Appendix A.

4 Physical and chemical properties of contaminants

Each potential contaminant was reviewed to determine its unique physical and chemical properties at ambient air conditions. Generally accepted standard ambient air conditions are 14.7 psia at 70 °F (101 kPa, abs at 21 °C).²

Nearly all substances can exist in one of three states of matter: solid, liquid, or gaseous. Each substance exhibits unique characteristics at standard conditions. Many substances can co-exist in two states of matter simultaneously, for example ice and water. Substances that exist as a liquid or solid at standard conditions can typically have a small amount of vapor present. The quantity of the vapor (gaseous state) of the substance in ambient air at standard conditions is determined by the partial pressure of the substance.

The ASU process uses ambient air in a gaseous state as the source material. The ASU process does not take in solids or liquids and is not designed to process them. Therefore, a key way to determine what enters the ASU process is by vapor pressures. A review of physical and chemical properties determined the specific vapor pressure for each substance. Substances that had no vapor pressure at standard conditions were eliminated from further evaluation. For substances that exhibited only a partial vapor pressure at standard conditions, this partial vapor pressure at the inlet air concentration level was further evaluated.

5 ASU impact on contaminants

In most cases, there is no single step of the ASU process where a substance is removed entirely. See CGA P-8, *Guideline for Safe Practices for Cryogenic Air Separation Plants*, and CGA P-8.4, *Safe Operation of Reboilers/Condensers in Air Separation Units* [4, 5]. Rather, the ASU process is a layered system where there are multiple opportunities to reduce or eliminate substances as air is processed. Each step in the ASU process typically can capture specific classes or types of substances. The ASU process includes the following actions on substances in ambient air:

- Filtration—primarily captures particulate matter entering the ASU process;

² psi, bar, and kPa shall indicate gauge pressure unless otherwise noted as (psia; bar, abs; and kPa, abs) for absolute pressure or (psid; bar, dif; and kPa, dif) for differential pressure. All kPa values are rounded off per CGA P-11, *Guideline for Measurement Practice in the Compressed Gas Industry* [3].

- Compression and separation—primarily captures water vapor and water soluble compounds. It can also capture fine particulates;
- Prepurification unit (PPU)—primarily captures water vapor, carbon dioxide, nitrous oxide, bromides, chlorides, and high boiling point hydrocarbons;
- Heat (reversing) exchanger—primarily captures substances with a freezing point warmer than cryogenic temperatures, typically substances with a freezing point of -250°F (-157°C) and warmer; and
- High pressure (HP)/low pressure (LP) column—primarily removes noncondensable gases, such as helium, hydrogen, and neon.

The 38 substances listed in Appendix B are not fully mitigated by the multi-layered interaction of the ASU process steps and have some ability to pass through the ASU process. This includes the end products of the ASU process; oxygen, nitrogen, argon, and other trace materials.

6 Oxygen concentration factors

The inherent design of the ASU process results in substances that are not captured in the process steps collecting in the LP column oxygen sump. Substances in the sump can become concentrated, depending on plant design and operational procedures. To determine the level to which a substance can concentrate, it is first necessary to develop concentration factors (or ratios), which are determined by design and operational parameters of individual plants.

The ratio of gaseous oxygen to liquid oxygen production rates from a plant's columns system is the determining factor used for developing concentration factors. Plants that manufacture all their oxygen as a gaseous product for delivery to pipeline customers can potentially concentrate substances in the LP sump to a dangerous level. To ensure safe operations, production plants making only gaseous oxygen must maintain a liquid oxygen purge equal to 1% of total oxygen production from the LP column sump to atmosphere (this may also be referred to as 0.1% to 0.2% of the incoming air). See CGA P-8.4 [4]. By maintaining a 1% purge rate, the calculated concentration factor for a 100% gas production ASU is held to a maximum of 477 to 1. At the other end of the concentration factor spectrum are ASU facilities that produce 100% of their oxygen as liquid product. By constantly moving the liquid oxygen from the sump to finished product storage, trace contaminants do not concentrate substantially. The calculated concentration factor for an ASU facility producing 100% of its oxygen as liquid is 4.77 to 1. Oxygen USP is produced predominantly at plants with a liquid to gas production rate of 50% and higher. An ASU facility that produces 50% of its product as liquid has a calculated concentration factor of less than 10 to 1, which is used in the risk assessment process.

The following figures illustrate potential oxygen concentration factors at ASU facilities. Figure 1 shows the full range of potential concentration factors for all ASU facilities from 100% gas production to 100% LOX production. However, most oxygen USP liquid is produced at facilities that have a higher percentage of total production as LOX. Figure 2 shows a more typical range of concentration factors for plants that produce oxygen USP liquid. For plants that only produce half their total production as liquid product, the concentration factor remains below 10 to 1.

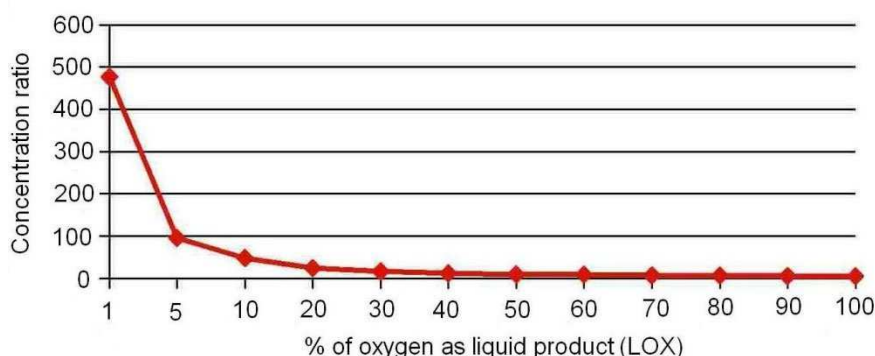


Figure 1—Full range of oxygen concentration factors