DESIGN CONSIDERATIONS TO MITIGATE THE POTENTIAL RISKS OF TOXICITY WHEN USING NON-METALLIC MATERIALS IN HIGH PRESSURE OXYGEN BREATHING GAS SYSTEMS

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GLOBALLY HARMONISED DOCUMENT

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1 Introduction

This document is part of a programme of harmonisation of industry standards and other regional gas associations have published regional versions which reflect differences in formatting, spelling and references to regional regulatory requirements.

Non-metallic materials such as plastics, elastomers, and lubricants are known to be the most critical materials used in high pressure oxygen and oxygen mixture supply systems. Such materials are typically found in valve, regulator, and no return valve seats; seals; regulator diaphragms; and flexible hoses.

The risk of ignition inherent in this use has been well known for many years and applies to any high pressure oxygen application. As a consequence, toxic gases could be generated by ignition (or decomposition) of some non-metallic materials in high pressure oxygen breathing gas systems. Depending on the type of non-metallic material, application, quantity of toxic gases produced, concentration levels, and the duration of exposure, these gases could cause serious injury or death. Consequently, certain countries such as France and Japan have issued regulations to avoid toxicity accidents resulting from the use of certain non-metallic materials. Those who plan to design these breathing systems should refer to any applicable regulations or legislation.

High pressure breathing oxygen and breathing oxygen mixture supply systems require specialized design, proper maintenance, and adherence to proven safe operating procedures. Important considerations include material specifications, velocity limitations, impingement, adiabatic compression, and cleaning for oxygen service.

2 Scope and purpose

2.1 Scope

This publication addresses high pressure oxygen breathing gas systems with pressures higher than 435 psig (30 bar) and with oxygen content above 23.5% by volume. It applies in particular to non-metallic materials which if they ignite or decompose could contaminate the gas stream with toxic products. The recommendation of this document can be beneficially applied at pressures lower than 435 psig (30 bar).

NOTE—Ceramics and glass are excluded from the scope of this document.

2.2 Purpose

This publication is intended to help prevent accidents/incidents resulting from toxic products, either of sufficient quantity or significant toxicity that could be created by the ignition or decomposition of non-metallic materials in high pressure oxygen breathing gas systems. Such toxic products in this type of breathing gas system are difficult to detect; therefore, it is important to prevent them from being generated.

3 Definitions

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

3.1 Halogenated compounds

Any non-metallic material that is manufactured using a halogen.

NOTE—The halogens typically used are fluorine and chlorine.

3.2 High pressure oxygen breathing gas system

The gas distribution system (equipment) used for supplying breathable high pressure oxygen (for medical or any other applications) or any other breathing gas mixture with an oxygen content above 23.5% by volume.

4 Safety considerations

To avoid incidents/accidents, four main areas of safety shall be considered:

- system design,
- system cleanliness,
- material susceptibility to combustion or decomposition, and
- toxicity risks associated with non-metallic materials decomposition.

In addition it is essential to adhere to approved operating and maintenance procedures for the system.

4.1 System design

Non-metallic materials have successfully demonstrated a superior capability of maintaining leak-free systems and, as a result, enhancing safety. However, non-metallic materials, as compared to metals, have lower auto-ignition temperatures in oxygen and much lower thermal conductivity. This is why their use in high pressure oxygen systems can be problematic. The type and quantity of plastics, elastomers, and lubricants should be carefully considered in the design of high pressure applications.

Plastic or elastomeric components should be kept out of the gas flow as much as practical. When this is not practical, it is necessary to consider the areas of the design where adiabatic compression can occur. Areas of the oxygen system that could trap debris should be identified and their adiabatic compression risk assessed in the design. Certain cavities are created deliberately to add extra cooling surface area adjacent to a vulnerable plastic component to reduce the risk of ignition by adiabatic compression.

In general, when designing oxygen equipment, specific standards such as ISO 21010, Cryogenic vessels—Gas/materials compatibility; ASTM G88-90, Standard Guide for Designing Systems for Oxygen Service; ASTM G63-99, Standard Guide for Evaluating Non-metallic Materials for Oxygen Service; or CGA V-9, Compressed Gas Association Standard for Compressed Gas Cylinder Valves, recommend careful consideration of the following factors affecting the design [1, 2, 3, 4]: [1]

- elevated pressure, temperature, and velocity,
- oxidizing ability of the gas or gas mixture,
- ability to clean the system for oxygen service,
- potential for contaminant accumulation,
- potential for particle impact,
- potential for adiabatic compression,
- benefits and risks when using filters (particle/contaminant accumulation),
- corrosion, component galling, and friction between moving components,

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

- natural frequencies or resonance in systems,
- use of proven components,
- static electric discharge,
- ability to fabricate and maintain the system, and
- quantity, type, and location of non-metallic materials.

In the case of high pressure equipment (higher than 435 psig (30 bar), it is essential to check that the equipment as used in the system is able to resist adiabatic compression for whichever gas flow direction might arise during system operation (intended or unintended). Valves, regulators, check valves, and non-metallic flexible hoses designed for high pressure shall successfully pass the adiabatic compression test. As an example for cylinder valves, the adiabatic compression test is defined in ISO 10297:2006, Transportable gas cylinders—Cylinder valves—Specification and type testing [5]. For non-metallic flexible hoses, the adiabatic compression test is defined in ISO 21969:2005, High-pressure flexible connections for use with medical gas systems [6].

NOTE—At the time that IGC DOC 79/08 ‘ Leak detection fluids – Cylinder packages’ was written, the adiabatic compression test as defined in ISO 10297 was under review.

Lubricants are another possible source of ignition and should be avoided when possible. If a lubricant is needed, only those specifically developed for oxygen service should be used. Lubricants specifically developed for oxygen service normally contain fluorine and/or chlorine compounds. Consequently, if lubricants decompose, they present similar risks of toxicity as some plastics and elastomers. The quantity of lubricants should be limited to a practical minimum, and their application should be closely controlled during the production of the equipment in which they are used.

4.2 Cleanliness

Oxygen systems shall be cleaned before initial use and shall remain clean during service. Oil or grease contamination is widely known to contribute to ignition in oxygen systems. There are some difficulties when cleaning high pressure equipment for oxygen service. Because of the *Montreal Protocol*, many solvents (chlorofluorocarbons [CFCs]) cannot be used [7]. Some solvents or cleaning agents are more dangerous in oxygen than oils and grease. Consequently, only oxygen-compatible solvents shall be used, and it shall be ensured that they are completely removed before the system is used.

Examples of standards that specify cleanliness requirements for oxygen service include ISO 15001:2003, *Anaesthetic and respiratory equipment—Compatibility with oxygen*; CGA G-4.1, *Cleaning Equipment for Oxygen Service*; EIGA Doc 33/97 and AIGA 012/04, *Cleaning of equipment for oxygen service guideline*; ASTM G93-03, *Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments*; and ISO 23208, *Cryogenic vessels—Cleanliness for cryogenic service* [8, 9, 10, 11].

4.3 Material susceptibility and toxicity risks

Non-metallic materials can ignite as a result of local heating such as heating caused by adiabatic compression. Therefore, designers optimize their material selection by choosing materials with high auto ignition temperature, low heat of combustion, and high oxygen index. However, several materials with a comparatively high auto-ignition temperature such as polytetrafluoroethylene (PTFE) and polychlorotrifluoroethylene (PCTFE) contain high proportions of fluorine or chlorine. Other widely used non-metallic materials contain nitrogen (polyamide, polyurethane) or sulfur (polyphenylene sulfide [PPS]). All non-metallic materials can release toxic gases when they burn. The gases that are released depend on the chemical composition and the conditions of combustion/decomposition, particularly temperature, pressure, and the concentration of oxygen. The concentration and toxicity of the components must be weighed against the resistance to ignition of the non-metallic material for optimal safe system design. If the exact composition of the gases (toxicity and quantity) is not known or is not available, then the following two paragraphs provide some general guidelines.

- The quantity of toxic combustion/decomposition products from a given weight of material will be in proportion to the weight of fluorine, chlorine, nitrogen, or sulfur in the material. Hydrocarbons that contain only carbon, hydrogen, and oxygen atoms are likely to produce carbon dioxide and water during combustion in high concentrations of oxygen. However, carbon monoxide will be produced under combustion in limited oxygen concentrations.

- Non-metallic material combustion/decomposition gases are toxic in their pure form. Non-metallic materials that contain nitrogen or sulfur produce combustion products that are generally less toxic than materials containing fluorine and chlorine. Combustion/decomposition of non-metallic materials inside medical equipment might not be immediately apparent, and the products created might be contained within the system. In such cases, toxic products might either be delivered to patients as a bolus of high concentration or alternatively might be absorbed into other materials (for example, moisture) and slowly released over a long period.

When taking into account both the mechanical requirements and their toxicity in a fire, the selection of the correct non-metallic materials sometimes results in a choice between two conflicting requirements: either use a less ignitable material with higher toxicity potential or use a more easily ignitable material with lower toxicity potential.

When solvents are used to clean oxygen systems or components, care must be taken to ensure they are completely removed before the system is used. Many solvents are toxic in themselves, and many give rise to toxic products of combustion after an ignition.

One of the most commonly overlooked components in an oxygen system is the lubricant, and all of the most oxygen-compatible lubricants also are halogenated. Therefore, it is preferable to use as little as possible of the selected oxygen-compatible lubricants.

Proper maintenance of the equipment should permit the amount of lubricant to be kept to a minimum, and care should be exercised to ensure that the originally specified lubricant (or an approved replacement) is used.

5 Recommendations

5.1 Risk analysis

It is essential that a risk analysis be carried out on breathing gas systems according to the requirements and methods of ISO 14971:2000, *Medical devices—Application of risk management to medical devices* [12]. The risk analysis shall include an assessment, by application, of the risk of ignition of oxygen gas wetted non-metallic components and lubricants and the risk of toxic combustion/decomposition products for: toxicity, quantity, and danger to the user. Where the toxicity or quantity of the toxic products is not known or not available, 4.3 provides some general guidelines. It should be recognized that reducing the risk associated with toxic combustion/decomposition products in a high pressure oxygen breathing system could increase both the risks of oxygen ignition and leakage, with the possible result being a failure to supply oxygen to the user. Therefore, the designer must evaluate the risk in the design of ignition against the potential toxicity and quantity of combustion/decomposition of non-metallic materials.

5.2 Specific recommendations

Specific recommendations are as follows:

- Carefully consider the quantity and location of plastics, elastomers, and lubricants used in new designs of equipment and their application and limit their quantity to the practical minimum;

- Critically consider the quantity and location of halogenated plastics, elastomers, and lubricants used in new designs of equipment and their application, specifically in the seats of valves, regulators, and check valves;

  NOTE—Due to its location and quantity, PTFE tape used for valve-to-cylinder connection has proven to be safe provided it is applied in accordance with the appropriate standards, e.g., ISO 13341, *Transportable gas cylinders—Fitting of valves to gas cylinders* [13].
- After a risk analysis has been performed in accordance with the specifications in 5.1, the equipment under consideration may be deemed acceptable if the following conditions are met:

  - The equipment has successfully passed adiabatic compression tests,

  - The surface area of any non-metallic materials exposed to the gas is considered during the design process and the non-metallic material is protected by ignition-resisting metal (heat sink) to help dissipate heat generated by adiabatic compression or other phenomenon and to quench, contain, or otherwise avoid burning propagation,

  - Heat generation such as that caused by flow friction, rapid pressurization, dead ending obstructions, and constriction is managed by equipment or system design,

  - The risk of ignition from particle impact or other ignition mechanisms has been considered; and

  - The amount of non-metallic materials used in the equipment is limited to the practical minimum.

When designing new systems:

- Consider the full composition including additives of final products made from non-metallic materials such as seals, valve seats, etc. When parts are made from non-metallic materials, additives might have been added to the raw material. These additives can release gases other than those released by the basic material when subject to thermal decomposition or combustion; and

- Establish a quality assurance procedure with the supplier for these materials so they meet the approved specification.

6 References

Unless otherwise specified, the latest edition shall apply.

[1] ISO 21010, Cryogenic vessels–Gas/materials compatibility

[2] ASTM G88-90, Standard Guide for Designing Systems for Oxygen Service, ASTM International, 100 Barr Harbor Dr., West Conshohocken, PA 19428. www.astm.org

[3] ASTM G63-99, Standard Guide for Evaluating Non-metallic Materials for Oxygen Service, ASTM International, 100 Barr Harbor Dr., West Conshohocken, PA 19428. www.astm.org

[4] CGA V-9, Compressed Gas Association Standard for Compressed Gas Cylinder Valves, Compressed Gas Association, Inc., 4221 Walney Rd., 5th Floor, Chantilly, VA 20151. www.cganet.com

[5] ISO 10297:2006, Transportable gas cylinders—Cylinder valves—Specification and type testing

[6] ISO 21969:2005, High-pressure flexible connections for use with medical gas systems

[7] The Montreal Protocol on Substances that Deplete the Ozone Layer, United Nations Environment Programme, Ozone Secretariat, P.O. Box 30552, Nairobi, Kenya. www.unep.org/ozone

[8] CGA G-4.1, Cleaning Equipment for Oxygen Service, Compressed Gas Association, Inc., 4221 Walney Rd., 5th Floor, Chantilly, VA 20151. www.cganet.com

[9] EIGA Doc 33/97, Cleaning of equipment for oxygen service guideline

[10] ASTM G93-03, Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments, ASTM International, 100 Barr Harbor Dr., West Conshohocken, PA 19428. www.astm.org

[11] ISO 23208, Cryogenic vessels—Cleanliness for cryogenic service

[12] ISO 14971:2000, Medical devices—Application of risk management to medical devices

[13] ISO 13341, Transportable Gas Cylinders—Fitting of valves to gas cylinders

[14] AIGA 012/04, Cleaning of equipment for oxygen service guideline

7 Additional references

CGA PS-15, Toxicity Considerations of Non-metallic Materials in Medical Oxygen Cylinder Valves, Compressed Gas Association, Inc., 4221 Walney Rd., 5th Floor, Chantilly, VA 20151. www.cganet.com

ISO 15001:2003, Anaesthetic and respiratory equipment—Compatibility with oxygen

CGA E-9, Standard for Flexible, PTFE-Lined Pigtails for Compressed Gas Service, Compressed Gas Association, Inc., 4221 Walney Rd., 5th Floor, Chantilly, VA 20151. www.cganet.com

CGA E-7, Medical Gas Pressure Regulators, Flowmeters, and Orifice Flow Selectors, Compressed Gas Association, Inc., 4221 Walney Rd., 5th Floor, Chantilly, VA 20151. www.cganet.com

ISO 10524-1, Pressure regulators for use with medical gases—Part 1: Pressure regulators and pressure regulators with flow-metering devices

ISO 10524-2, Pressure regulators for use with medical gases—Part 2: Manifold and line pressure regulators

ISO 10524-3, Pressure regulators for use with medical gases—Part 3: Pressure regulators integrated with cylinder valves