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USE OF NON-METALLIC MATERIALS IN HIGH PRESSURE OXYGEN BREATHING GAS APPLICATIONS

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As part of a programme of harmonization of industry standards, the Asia Industrial Gases Association (AIGA) has issued this publication, 059, "*Use of Non-Metallic Materials in High Pressure Oxygen Breathing Gas Applications*", jointly produced by members of the International Harmonisation Council and originally published by the European Industrial Gases Association (EIGA) as IGC Doc 73, *Use of Non-Metallic Materials in High Pressure Oxygen Breathing Gas Applications.*

This publication is intended as an international harmonized publication for the worldwide use and application by all members of Asia Industrial Gases Association (AIGA), Compressed Gas Association (CGA), EIGA, and Japan Industrial and Medical Gases Association (JIMGA). Each association's technical content is identical except for regulatory requirements and minor changes in formatting and spelling.

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Note: Technical changes from the previous edition are underlined

1 Introduction

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. These materials are typically found in valves, regulators, non-return valves and flexible hoses where their uses include seat inserts, O-ring, gaskets, and regulator diaphragms.

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 products could be released by ignition or thermal decomposition of 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 reduce toxicity incidents 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, appropriate maintenance, and adherence to proven safe operating procedures. Important considerations include:

- Material specifications;
- Galling and friction;
- Velocity limitations;
- Impingement;
- Static discharge;
- Electric arcs;
- 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 greater than or equal to 30 barg (435 psig) and with an 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 publication can be beneficially applied at pressures lower than 30 barg (435 psig)

This publication is to be applied to high pressure customer breathing installations (for example, hospitals and homecare) where the ignition of non-metallic materials creates an immediate risk of inhalation of toxic products. This includes all elements of that installation from cylinder valve to point of use.

This publication is not intended to apply to cylinder filling centres though it is recommended that the toxicity issue is addressed by a risk assessment of the filling system design.

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

2.2 Purpose

This publication is intended to help prevent 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. 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 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.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Adiabatic compression testing

Test to evaluate the ignition sensitivity of the equipment by exposure to a number of rapid pressurizations of heated oxygen.

3.2.2 Halogenated compounds

Any non-metallic material that contains a halogen.

NOTE The halogens typically contained in non-metallic material are fluorine and chlorine

3.2.3 High pressure breathing gas system

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

3.2.4 Toxicity

Tendency of a substance to product adverse biochemical or physiological effects.

4 Safety considerations

To avoid incidents, involving release of toxic products in oxygen breathing gas systems the following areas shall be considered:

- System design;
- System cleanliness;
- Material susceptibility to combustion or decomposition; and
- Oxygen compatibility of the material and the toxicity risks associated with non-metallic material.

In addition, approved operating and maintenance procedures for the system shall be followed at all times.

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 and the type and quantity of plastics, elastomers, and lubricants shall 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 can 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, *Standard Guide for Designing Systems for Oxygen Service*; ASTM G63, *Standard Guide for Evaluating Nonmetallic Materials for Oxygen Service*; ISO 10297 *Gas cylinders -- Cylinder valves -- Specification and type testing* or ISO 10524-3 *Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves* , recommend careful consideration of the following factors affecting the design [1, 2, 3, 4, 5]: [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,
- Natural frequencies or resonance in systems,

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

- 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 (greater than or equal to 30 barg (435 psig), it is essential to check that the equipment as used in the system is able to resist adiabatic compression for whichever gas flow direction can 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. For example, for cylinder valves, the adiabatic compression test is defined in ISO 10297, [4]. For non-metallic flexible hoses, the adiabatic compression test is defined in ISO 21969, *High-pressure flexible connections for use with medical gas systems* [6].

NOTE—In the United States, the Food and Drug Administration (FDA) specifies in their guidance, *Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices* that medical oxygen regulators be tested to meet consensus standard ASTM G-175, *Standard for promoted oxygen safety* and ISO 15001, *Anaesthetic and respiratory equipment—Compatibility with oxygen* . This standard requires both an adiabatic compression test and a promoted ignition test [7, 8, 9].

Lubricants are another possible source of ignition and shall be avoided. 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 shall be limited to a minimum, and their application shall be controlled during the production of the equipment in which they are used.

4.2 Cleanliness

Oxygen systems shall be cleaned for oxygen service 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 [10]. Some solvents or cleaning agents are more dangerous in oxygen than oils and grease. Consequently, it shall be ensured that solvents are completely removed before the system is used.

Examples of standards that specify cleanliness requirements for oxygen service include ISO 15001:, *Anaesthetic and respiratory equipment—Compatibility with oxygen*; AIGA 012, *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* [9, 11, 12,13].

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 temperatures, low heats of combustion, and high oxygen indices. However, several materials with a comparatively high auto-ignition temperatures 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 shall 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, 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 can be toxic in their pure form and less so when diluted.. 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 could be contained within the system. In such cases, toxic products can either be delivered to patients as a bolus of high concentration or alternatively can 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. See *Combustion Products Toxicity of Non-Metallic Materials Used for Medical Oxygen Equipment* [14].

When solvents are used to clean oxygen systems or components, care shall 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.

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, *Medical devices—Application of risk management to medical devices* [15]. 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 shall evaluate the risk of ignition during the design of the equipment against the potential toxicity and quantity of combustion/decomposition of non-metallic materials.

5.2 Specific recommendations

Specific recommendations are:

- 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, for example ISO 13341, *Transportable gas cylinders—Fitting of valves to gas cylinders* [16].

- 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 including seals and valve seats. When parts are made from non-metallic materials, additives could 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* www.iso.org

[2] ASTM G88, *Standard Guide for Designing Systems for Oxygen Service*, www.astm.org

[3] ASTM G63, *Standard Guide for Evaluating Non-metallic Materials for Oxygen Service*, www.astm.org

[4] ISO 10297 *Gas cylinders -- Cylinder valves -- Specification and type testing* www.iso.org

[5] ISO 10524-3 *Pressure regulators for use with medical gases -- Part 3: Pressure regulators integrated with cylinder valves* www.iso.org

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

[7] U.S. Food and Drug Administration, *Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices*, 10903 New Hampshire Avenue, Silver Spring, MD 20993. www.fda.gov

[8] ASTM G-175, *Standard for promoted oxygen safety*

[9] ISO 15001*, Anaesthetic and respiratory equipment—Compatibility with oxygen,*. www.iso.org

[10] *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

[11] AIGA 059, *Cleaning of equipment for oxygen service guideline*; www.asiaiga.org

[12] ASTM G93, *Standard Practice for Cleaning Methods and Cleanliness Levels for Material and Equipment Used in Oxygen-Enriched Environments* www.astm.org

[13] ISO 23208, *Cryogenic vessels—Cleanliness for cryogenic service* www.iso.org

[14] Barthélémy, Hervé, *Combustion Products Toxicity of Non-Metallic Materials Used for Medical Oxygen Equipment*, 100 Barr Harbor Dr., West Conshohocken, PA 19428. www.astm.org

[15] ISO 14971, *Medical devices—Application of risk management to medical device* www.iso.org

[16] ISO 13341, *Transportable gas cylinders—Fitting of valves to gas cylinders www.iso.org*

7 Additional references

ISO 14113, *Gas welding equipment. Rubber and plastics hose and hose assemblies for use with industrial gases up to 450 bar (45 MPa)* www.iso.org

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

ISO 10524-2, *Pressure regulators for use with medical gases—Part 2: Manifold and line pressure regulators* www.iso.org