GUIDELINE FOR DEFINING SPECIFICATIONS FOR NON-MEDICAL BREATHING GASES

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Table of Contents

Amendments to Doc 206/16

Section	Change
	This is a re-affirmation of the version Doc 206/16. No changes were made.

NOTE Technical changes from the previous edition are underlined.

1 Introduction

There are a number of different applications in the market involving non-medical breathing gases. It can be difficult for the industrial gases industry to know the requirements and how to meet them.

This publication is intended to provide a guideline for the industrial gases industry in defining specifications for non-medical breathing gases.

2 Scope and purpose

2.1 Scope

Non-medical breathing gases used in normal and hyper or hypo baric conditions, including but not limited to:

- Diving gases (recreational, technical and military);
- Aviation gases (leisure, commercial and military);
- Breathing air for surface applications such as confined space entry as well as for fire and rescue activities; and
- Gas mixtures for research for altitude and sports simulation tests.

This includes gases manufactured by the industrial gases industry for end users and raw material to be used by manufacturers and customers to produce their own mixtures,

Medical gases and mixtures produced by third parties are excluded from this publication.

2.2 Purpose

To provide guidance to EIGA members on the standards applicable to non-medical breathing gases and the interpretation of these standards.

3 Definitions

For the purposes 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

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 Breathing gas

Mixture of gaseous chemical elements, such as oxygen, nitrogen or/and helium, and compounds used for human respiration in non-medical applications.

3.2.2 Raw material

Gas with a specification that will allow its mixture to produce a breathing gas. The raw material itself may also be directly a breathing gas.

3.2.3 Recreational diving gas

Gas with a specification that is suitable for diving performed by non-professional users. It has limitations on the extent of depth and duration of the diving, compatible with those allowed by the non-professional diving licence.

NOTE Recreational diving or sport diving is a type of diving that uses self-contained underwater breathing apparatus (SCUBA) equipment for leisure purpose.

The definition of recreational diving varies among SCUBA training organizations. In general, a recreational dive can be defined by the following parameters:

- No deeper than 40 m;
- Allows a direct, near vertical, ascent to the surface at any point during the dive; and
- Stays within the time limit of No-Decompression Limit (NDL).

3.2.4 Technical diving gas

Gas with specification that is suitable for diving performed by professional users in accordance with EN 12021 Respiratory *equipment. Compressed gases for breathing apparatus*[1] [1].

NOTE Technical diving requires extensive experience, advanced training and specialized equipment. Technical diving also often involves breathing gases other than air or standard mixtures of nitrogen and oxygen.

3.2.5 Aviation breathing gases

Breathing gas used in commercial or military aviation.

3.2.6 Surface breathing gas

Breathing gas not used under water or for aviation (e.g. for confined spaces).

4 Regulation and standards for breathing gases

There are different standards and regulations depending on the user application. Examples of these are listed below, the list is not exhaustive and the versions are the last published while preparing this guide.

4.1 Health and safety legislation

- Regulation in France for protecting workers: 1990.03.28 Décret_n°90-277*_du_28_mars_1990 of*

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

protection of Workers in Hyperbaric conditions (article 6 defines the conditions of the gas to be inhaled) [2].

- United Kingdom Health and Safety Executive Diving Information Sheet Nº 9 *Diver's breathing air standard and the frequency of examination and tests* [3].

- United Kingdom Ministry of Defence, *Compressed Breathing Gases for Aircraft, Diving and Marine Life-Support Applications. Defence Standard 68-28*4 [4].

4.2 European standards

The European standard for breathing gases is EN 12021 [1] and does not include the medical and aerospace applications.

4.3 National standards

Italy: UNI 11366 *Health and safety in diving and hyperbaric professional activities for industry- Operating Procedures* [5]

Norway: NORSOK U-100N *Manned underwater operations* [6] and NORSOK U-101 *Diving respiratory equipment* [7].

4.4 Gas Associations' references

- Compressed Gas Association - CGA G-7.1 *Commodity Specification for Air* [8]

4.5 Military references for diving

- United States *Navy Diving manual* SS521-AG-PRO-010 [9]

- NATO Standard STANAG 1458 Ed.1, *Diving gas quality*, [10]

4.6 Aerospace applications

The most common standards used are the military standards Aviation MIL PRF 27210H, *Performance specification: oxygen, aviator's breathing, liquid and gas* - SAE AS8010 *Aviator's Breathing Oxygen Purity Standard* – STANAG 7106E *Characteristics of gaseous breathing oxygen, liquid breathing oxygen and supply pressures, hoses and replenishment couplings* and ISO 2046 *Gases breathing oxygen supplied for aircraft*. [11, 12, 13, 14]

5 Specifications of breathing gases

Unless there are restrictions or local legislation, the applicable standards for breathing gases by applications are:

- Diving gases (recreational, technical and military): EN 12021[1] applies, though this publication provides an additional methodology in Section 7; and

- Breathing air for surface applications such as confined space entry as well as for fire and rescue activities: EN 12021 [1] can be applied, though this publication provides an additional methodology in Section 7.

The UK HSE Diving Information Sheet mentions that a risk assessment should be carried out to establish if any other contaminants should be tested in addition to those specified in EN 12021 [1]. There are two points to note:

- The compressor lubricant safety data sheet and/or the compressor manufacturer's operation and maintenance manual should be checked to see if there are any specific substances that should be tested for.

- The location of the compressor inlet should be in a position that is unlikely to allow contaminated air to be drawn in. Local potential sources of contamination should be identified, such as ventilation exhausts, and the owners asked what is being exhausted into the atmosphere. If there is any doubt, additional tests for the likely contamination and increased frequency of tests may be necessary.

Gas mixtures for research for altitude and sports simulation tests, are also breathing gases for surface applications, hence EN 12021[1] can be used, though this publication provides an additional methodology in Section 7.

Aviation gases (commercial and military): Aviation MIL PRF 27210H - SAE AS8010 – STANAG 7106E and ISO 2046 [11, 12, 13, 14]

6 Diving Gases

The 2014 edition of EN 12021 [1] defines tables with specifications for diving gas composition of the following:

- Table 4 – Oxygen compatible air
- Table 5 – Nitrogen depleted air and oxygen enriched air
- Table 6 – Breathing oxygen
- Table 7 – Oxygen and nitrogen gas mixtures
- Table 8 –Oxygen and helium gas mixtures
- Table 9 – Oxygen, helium and nitrogen gas mixtures
- Table 10 –Helium

Section 6.1 of EN 12021: 2014 [1] states:

"Compressed gas for breathing shall not contain contaminants at a concentration which can cause toxic or harmful effects. In any event, all contaminants shall be kept to as low a level as possible and shall be less than one tenth of a national 8 h exposure limit. For breathing air only the limit shall be less than one sixth of a national 8 h exposure limit. For breathing at hyperbaric pressures greater than 10 bar or exposure times greater than 8 h the levels shall be revised to take into account the effect of exposure times."

As a general rule concerning harmful contaminants, all contaminants should be kept to as low a level as possible. Thus ensuring that once corrected with the specific conditions of use, such as hyperbaric conditions, time of exposure, the exposure for the final user, that is. the person who breathes the breathing gas, remains below the usual limit of the 8-hour Time Weighted Average (TWA) Workplace Exposure Limits (WELs).

Since there are various specifications for each diving gas use in the documents referenced in Section 4, this publication explains a generic methodology to determine the maximum exposure limits for harmful impurities based on the depth and other specific application conditions, in case of not applying EN12012 [1] values which are derived based on the most stringent working conditions or other considerations. The methodology is in line with the general requirements of the EN12012 [1].

This publication therefore, provides guidance to the gas manufacturer to inform the customer in order to allow the final user to define by themselves the safe use for the diving application depending on their diving conditions of depth and time under water.

Some examples of differences in standards and specifications are given in Appendix 1.

7 Methodology for determining the limits of exposure for harmful impurities relevant to breathing and according to the diving conditions

The Workplace Exposure Limits value (WELs) is expressed as a Time Weighted Average (TWA). The reference exposure limit is the 8-hour TWA.

7.1 Methodology for breathing air for surface applications

EN 12021 [1] provides in Tables 1 to 3 the composition of compressed breathing air for surface applications. For these reasons, a maximum oil concentration is given, but no levels for toxics.

If non-oil lubricated air compressors are used the testing for oil could be omitted similar to the European Pharmacopoeia for medicinal air (compressed air), the same shall apply for synthetic air.

Therefore for surface breathing synthetic air, that is the 21% oxygen mixture with pure oxygen with pure nitrogen, the following composition can be applied in line with the EN standard,

Breathing air synthetic (1) (EN 12021 :2014 [1])	21% O_2 in N_2	± 1% O_2	CO < 5 ppm CO_2 < 500 ppm H_2O < 25 ppm

7.2 Methodology for diving gases

For breathing air used for diving, the limits of exposure for harmful impurities can be defined as one sixth of the reference exposure limit that is the national 8h exposure limit, as quoted in EN12021 [1].

For the other diving gases, the limits of exposure for harmful impurities have to be set at the lowest value between the two following calculations:

1. One tenth of the reference exposure limit (corresponding to diving conditions limited at 10 bar of pressure, that corresponds to 90 m depth of diving, and standard 8-hour max diving time per working day), or
2. The value calculated with the following formula, based on the HSE publication *Occupational exposure limits for hyperbaric conditions- fourth edition* [15], in case the diving conditions deviate from conditions in point 1 above (*):

$$\text{Maximum limit} = (\text{reference exposure limit} \times 8 \times 5) / (ET \times P_{dive})$$

Where

- ET represents the Max Hours of Exposure time within a week
- P_{dive} represents the pressure at the max depth of diving

*: in line with the statement of EN 12021 [1] : For breathing at hyperbaric pressures greater than 10 bar or exposure times greater than 8 h the levels shall be revised to take into account the effect of exposure times.

For examples of calculations refer to Appendix 2.

7.2.1 Rebreather systems

A rebreather is a SCUBA system in which the diver recirculates the exhaled gases through a carbon dioxide absorption media and the system tops up the oxygen
In a rebreather there is the potential for accumulation and concentration of impurities, that can be difficult to evaluate and quantify, Therefore, for sake of simplification in this specific case of the use of rebreathers, preference shall be given to the strict compliance of the oxygen specification from the EN 12021 Standard [1] instead of the application of the methodology of Section 7.

8 Good practices

The information to be supplied to the customer should allow the user to check the suitability of the gas for its intended purpose.

It is important for the gas industry to state in its documentation a limitation of responsibilities for the supply of the gases and provide the product specifications to the customer, to allow them to define the safe use of the application. This will assist the customer in defining the blending specification limits and safe use of the product for their particular application

Gas companies can decide to apply the EN standard that leads to a single quality grade or to apply the methodology of Section 7 that can lead to the definition of several applicable quality grades

9 References

Unless otherwise specified the latest edition shall apply.

[1] EN 12021:2014 *Respiratory equipment. Compressed gases for breathing apparatus* www.cen.eu

[2] Décret_n°90-277_du_28_mars_1990 *of protection of Workers in Hyperbaric conditions* www.legifrance.gouv.fr

[3] United Kingdom Health and Safety Executive Diving Information Sheet Nº 9 *Diver's breathing air standard and the frequency of examination and tests* www.hse.gov.uk

[4] United Kingdom Ministry of Defence, *Compressed Breathing Gases for Aircraft, Diving and Marine Life-Support Applications. Defence Standard 68-284*

[5] UNI 11366 *Health and safety in diving and hyperbaric professional activities for industry Operating Procedures* www.uni.com

[6] NORSOK U-100N (2009) *Manned underwater operations* www.standard.no

[7] NORSOK U-101 *Diving respiratory equipment* www.standard.no

[8] Compressed Gas Association - CGA G-7.1 *Commodity specification for air* www.cganet.com

[9] United States *Navy diving manual* -AG-PRO-010

[10] NATO Standard STANAG 1458 Ed.1, *Diving gas quality*

[11] MIL PRF 27210H Performance specification: oxygen, aviator's breathing, liquid and gas

[12] SAE AS 8010 *Aviator's Breathing Oxygen Purity Standard* www.sae.org

[13] STANAG 7106E *Characteristics of gaseous breathing oxygen, liquid breathing oxygen and supply pressures, hoses and replenishment couplings*

[14] ISO 2046 *Gases breathing oxygen supplied for aircraft* www.iso.org

[15] United Kingdom Health and Safety Executive *Occupational exposure limits for hyperbaric conditions- fourth edition* www.hse.gov.uk

[16] Dir 2009/61/EU *Establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/ EC* www.europa.eu

Appendix 1 - Examples of differences in standards and specifications for diving gases

- The Health and Safety Executive in the United Kingdom requires that no more than 10% of the TWA limit is found in breathing air.

- EN 12021:2014 [1] standard defines some limits for impurities to each type of breathing gases. These limits are defined for some of the impurities such as carbon monoxide after calculating the most restricted conditions of exposure time breathing the gas and in extreme depth (pressure) conditions.

  Quality levels of some other impurities are defined in EN 12021 [1] by other criteria such as the good practices in manufacturing processes, for example carbon dioxide.

  For example, the carbon monoxide impurity in helium is considering saturation factors depending on depth (at 300 m it is 31 times higher pressure than at the surface so one should reduce with the same factor the impurities acceptable level) and longer exposure time, for example 24 hours 7 days a week instead of 8 hours 5 days a week with some additional safety margin.

  0,2 ppm CO = 30 ppm / (31 times x 4,2 longer exposure 24/7)

  NOTE: EN 12021 [1] uses 5 instead of 4,2 as an additional uncertainty factor

  This is less than 1% of the 30 ppm TWA 8 hours 5 days a week,Dir 2009/61/EU *Establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/ EC* [16].

  NOTE Helium is usually used for technical diving below 50 m as it aims at covering extreme conditions like long stay in deep-diving conditions

- STANAG 1458 Ed1 [10] defined different grade A and B specifications for each of the diving gases. Grade B is defined as the maximum limit of impurity to be accepted in the gas (or mixture) while Grade A is the one preferred in this standard. The STANAG standard is similar to EN 12021 [1].

- Legislation such as the French Decree n°90-277 [2], does not define limits of gas specification. Article 6 defines the conditions of the gas to be inhaled for example for carbon monoxide in the mixtures breathed, the partial pressure should be less than 0,05 mbar).

In summary, EN 12021[1] defines a single specification based in worst conditions, STANAG 1458 [10] defines similar recommended specification for all type of situations but a flexible other one in which there are established maximum allowed limits for intermediate situations, and the French decree adjust the limits of the gas quality to the specific use of the diving gas.

Appendix 2 - Examples of calculation of impurities of diving gases

Examples of calculations for carbon monoxide, (CO):

Case 1:

- Reference exposure limit : 30 ppm
- Exposure time : Full week, full time
- Max depth: 60 metres → 7 bar

Maximum limit = (30*8*5)/(7*24*7) = 1,02 ppm, less than 3 ppm (one tenth), so the limit of exposure for such conditions is CO < 1 ppm

Case 2:

- Reference exposure limit : 30 ppm
- Exposure time : 12 hours per day, 5 days
- Maximum depth: 40 metres → 5 bar

Maximum limit = (30*8*5)/(5*12*5) = 4 ppm, higher than 3 ppm, so the limit of exposure for such conditions is CO < 3 ppm

Concerning the consistency of this approach with the French Decree requirements:

Maximum diving depth covered by the decree: 60 m

Taking the case of two impurities (CO and CO_2)

- Partial pressure of CO shall be below 0.05 mbar

The maximum value obtained with the above methodology is 3 ppm, corresponding at maximum depth (pressure = 7 bar) is 0.021 mbar, significantly below 0.05 mbar

- Partial pressure of CO_2 shall be below 10 mbar

The maximum value obtained with the above methodology is 500 ppm, corresponding at maximum depth (pressure = 7 bar) is 3,5 mbar, significantly below 10 mbar

So, the formula covers also the French Decree.