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AMENDMENT 1
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Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning

AMENDMENT 1: Cylinder valve outlets for gases for medical use

Raccords de sortie de robinets de bouteilles à gaz et mélanges de gaz — Choix et dimensionnement

AMENDEMENT 1: Raccords de sortie de robinets de bouteilles à gaz à usage médical

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 5145:2004 was prepared by Technical Committee ISO/TC 58, *Gas cylinders*, Subcommittee SC 2, *Cylinder fittings*.

Introduction

This amendment to ISO 5145:2004 is intended to indicate how to determine with the help of a flowchart the cylinder valve outlets for gases for medical use. Six examples are given to explain the flowchart.

Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning

AMENDMENT 1: Cylinder valve outlets for gases for medical use

Add the following annex after Annex C:

Annex D
(informative)

Cylinder valve outlets for gases for medical use

D.1 Scope

This annex gives examples of how to allocate cylinder valve outlets in the case of gases for medical use to ensure patient safety. Such gases are treated differently depending on whether they are gases for inhalation or for other purposes. Allocation is based on the pharmacological and therapeutic properties of the gases and not physical aspects such as pressure.

D.2 Definitions

The following definitions apply.

D.2.1 Gas for medical use

Any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes, with or without pharmacological action, or to be used for surgical tools. It covers both medicinal and medical gases.

D.2.2 Medicinal gas

Any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes using pharmacological action and classified as a medicinal product, e.g. according to Article 1.2 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use.

D.2.3 Gas for inhalation

Medicinal gas intended for introduction into the body through respiration. The gas is administered alone directly or after mixing at the point of use with oxygen or air.

D.2.4 Medicinal gas mixture containing oxygen

Gas mixture in which the oxygen content is taken into account in order to limit the duration of the inhalation under standard atmospheric conditions, for example binary mixtures (from nitrogen, helium, nitrous oxide, carbon dioxide) or ternary mixtures or more used e.g. for lung function testing (LFT). Medicinal gas mixtures containing oxygen can be classified as follows.

— Hypoxic mixtures (mixtures with lower than normal O_2 content): gas with O_2 < 20 %[1)] for short-term inhalation.

— Hyperoxic mixtures (mixtures with greater than normal O_2 content): gas with O_2 > 23,5 % for continuous inhalation.

— Normoxic mixtures (mixtures with normal O_2 content): 20 %[1)] $\leqslant$ O_2 $\leqslant$ 23,5 % for continuous inhalation.

D.2.5 Analytical gas

Gas which is used for analysis calibration or for the purpose of supplying energy (flame, oven, etc.) and other similar purposes (for example, gas chromatography, atomic absorption spectrophotometer) in biological or pharmaceutical research laboratories.

D.2.6 Breathable gas

Gas which supports life to be used in breathing or diving apparatus in a non-standard atmospheric medium such as water, at high altitude, in space or in a confined or polluted medium, but not for therapeutic, diagnostic or prophylactic uses. For example, air, oxygen and gas mixtures (nitrogen/oxygen, helium/oxygen, nitrogen/helium/oxygen, etc.) with normal or greater than normal oxygen content.

D.3 Rules of safety

In hospitals, the simultaneous presence of medicinal, medical, analytical and industrial gas cylinders increases the risk of occurrence of serious safety issues for the patient. The following requirements apply.

— Staff involved in the administration of gases for medical use shall be appropriately trained to ensure that the correct gas is used.

— The different gases and gas mixtures shall be easily identified and stored in separate areas.

— Labelling and colour coding of the gas cylinder shall be checked before use.

— As a general rule, cylinders containing non-breathable gases for industrial or medical use shall not be fitted with the same valve outlet connection as those medical gases used for breathing. This then preserves the integrity of the gas-specific safety system (designed to prevent the delivery of non-breathing or hypoxic gas mixtures) and thus protects against the possibility of inadvertently connecting such gases to breathing medical device delivery systems.

1) 19,5 % for some national pharmacopoeia.

D.4 Rules for outlet allocation

A number of valve outlets have already been allocated for the commonly used gases for medical use. The allocation of valve outlets from the limited possibilities comes from risk analysis, mainly asphyxia in the case of connection with gases with lower than 20 %[2)] oxygen content resulting from the simultaneous presence of industrial gases and gases for medical use in hospitals, and also the presence in gas mixtures of components limiting the duration of inhalation.

Where there is no specific allocation to a given gas or gas mixture, the following rules may be applied:

— For oxygen-enriched ternary or higher gas mixtures intended for inhalation without a specific valve outlet allocation, Figure D.1 allows the valve outlet allocation to be determined as a function of the type of gas according to Table D.1.

— For other gases or gas mixtures, the shared valve outlet assigned to an FTSC gas group according to Tables 2 and 3 may be proposed, e.g. No. 4 (see Table 4) for all inert gases and gas mixtures of FTSC code 0150 (except inert gases and gas mixtures that have a specific valve outlet such as N_2, He, NO/N_2 (100 ppm < NO < 1 000 ppm) or 1050.

Table D.1 lists the maximum thresholds for the components used in oxygen-enriched premixed gases for short-term and continuous inhalation under standard atmospheric conditions.

Figure D.1 is a logical flowchart for the selection of valve outlets for gases for medical use.

Table D.1 — Maximum thresholds for the components used in oxygen-enriched premixed gases for short-term and continuous inhalation in standard atmospheric conditions

Component	LC 50[a]	Medical use	Recommended maximum volume fraction for continuous inhalation
N_2O	—	Anaesthesia or analgesia if 50/50	80 %
CO	3 760 ppm	LFT premixture	0,4 %
CO_2	—	LFT premixture	7 %
NO	115 ppm	Neonatal intensive care In premixture with N_2	0,1 %
C_2H_2	—	LFT premixture	0,4 %
H_2	—	Gut function testing in premixture with air Gas for calibration	Not applicable
CH_4	—	LFT premixture	0,4 %

[a] LC 50 is the concentration of gas in air that will kill 50 % of test subjects.

2) 19,5 % for some national pharmacopoeia.

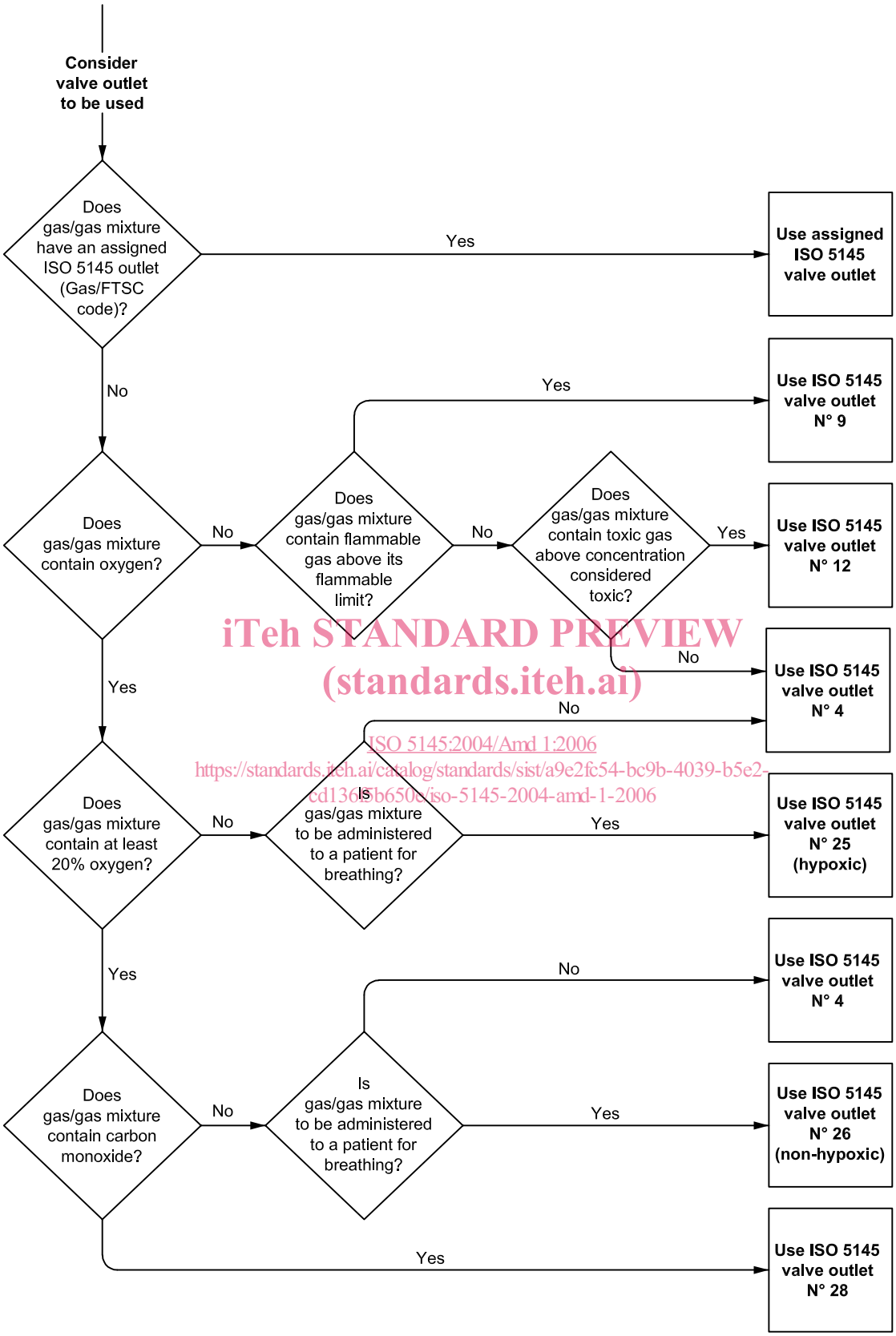

Figure D.1 — Flowchart for the selection of valve outlets for gases for medical use

D.5 Examples of valve outlets selected with the help of Figure D.1

D.5.1 Example 1: anaerobic cellular culture (not for breathing)

Typical mixture composition: 10 % H_2, 5 % CO_2, balance N_2.

Does gas or gas mixture have an assigned outlet (gas/FTSC code)?	No
Does gas contain oxygen?	No
Does gas contain a flammable component above its flammable limit?	Yes
Outlet allocation	**Outlet 9**

D.5.2 Example 2: toxic hypoxic gas/gas mixture

Typical composition: 100 % nitric oxide (NO).

Does gas or gas mixture have an assigned outlet (gas/FTSC code)?	No
Does gas contain oxygen?	No
Does gas contain a flammable component above its flammable limit?	No
Does gas contain component above its critical concentration where it is considered toxic?	Yes
Outlet allocation	**Outlet 12**

D.5.3 Example 3: hypoxic lung function test mixture (with no flammable components)

Typical mixture composition: 4 % CO_2, 16 % O_2, balance N_2.

Does gas or gas mixture have an assigned outlet (gas/FTSC code)?	No
Does gas contain oxygen?	Yes
Is oxygen content at least 20 %?	No
Is gas to be administered for breathing?	Yes
Outlet allocation	**Outlet 25**

D.5.4 Example 4: non-hypoxic lung function test mixture (with no flammable components)

Typical mixture composition: 9 % He, 35 % O_2, balance N_2.

Does gas or gas mixture have an assigned outlet (gas/FTSC code)?	No
Does gas contain oxygen?	Yes
Is oxygen content at least 20 %?	Yes
Does gas contain carbon monoxide?	No
Is gas to be administered for breathing?	Yes
Outlet allocation	**Outlet 26 (non hypoxic)**