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Anaesthetic and respiratory equipment — Compatibility with oxygen

Matériel d'anesthésie et respiratoire — Compatibilité avec l'oxygène

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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.

ISO 15001 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Introduction

Oxygen, pure or mixed with other medical gases, is widely used in medical applications. Because patients and clinical personnel are often in close proximity to devices used with oxygen, the risk of serious injury is high if a fire occurs in an oxygen-enriched atmosphere. A common cause of fire is the heat produced by adiabatic compression, and the presence of hydrocarbon and particulate contaminants facilitates ignition. Some combustion products, especially of some non-metals (e.g. plastics, elastomers and lubricants) are toxic and thus patients remote from that equipment who are receiving oxygen from a medical gas pipeline system might be injured when a problem occurs.

Other equipment which is in close proximity to the equipment using oxygen, or that utilizes oxygen as its source of power can be damaged or fail to function properly if there is a problem with the oxygen equipment.

Reduction or avoidance of these risks depends on the choice of appropriate materials and cleaning procedures and correct design and construction of equipment so that it is compatible with oxygen under the conditions of use.

This document establishes recommended minimum criteria for the safe use of oxygen and the design of systems for use in oxygen and oxygen-enriched atmospheres.

Annex F contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated into this International Standard. The clauses and subclauses marked with **R** after their number have corresponding rationale contained in Annex F. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

It is expected that particular device standards will make reference to this horizontal International Standard but may, if appropriate, strengthen these minimum requirements.

Particular device standards may specify that some requirements of this International Standard may apply for medical gases other than oxygen.

Anaesthetic and respiratory equipment — Compatibility with oxygen

1   R Scope

This International Standard specifies minimum requirements for the oxygen compatibility of materials, components and devices for anaesthetic and respiratory applications which can come in contact with oxygen in normal condition or in single fault condition at gas pressures greater than 50 kPa.

This International Standard is applicable to anaesthetic and respiratory equipment which are within the scope of ISO/TC 121, e.g. medical gas pipeline systems, pressure regulators, terminal units, medical supply units, flexible connections, flow-metering devices, anaesthetic workstations and lung ventilators.

Aspects of compatibility that are addressed by this International Standard include cleanliness, resistance to ignition and the toxicity of products of combustion and/or decomposition.

2   Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

3   Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
adiabatic compression
compression process that occurs without transfer of heat into or out of a system

3.2
auto-ignition temperature
temperature at which a material will spontaneously ignite under specified conditions

3.3
lethal concentration
LC_{50}
concentration of a gas (or a gas mixture) in air administered by a single exposure during a short period of time (24 h or less) to a group of young adult albino rats (males and females) which leads to the death of half of the animals in at least 14 days

[ISO 10298:1995]

3.4
oxygen index
minimum concentration of oxygen by percentage volume in a mixture of oxygen and nitrogen introduced at (23 ± 2) °C that will just support combustion of a material under specified test conditions

[ISO 4589-2:1996]

3.5
qualified technical person
person who by virtue of education, training or experience knows how to apply physical and chemical principles involved in the reactions between oxygen and other materials

3.6
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

3.7
threshold limit value
TLV
concentration in air to which nearly all workers may be exposed during an 8 h working day and a 40 h working week without adverse effect

3.8
oxygen-enriched mixture
mixture that contains more than 25 % volume fraction of oxygen or whose partial pressure exceeds 275 kPa

NOTE   The partial pressure value of 275 kPa is based on a maximum ambient pressure of 1 100 hPa.

4   Cleanliness

4.1   R Unless specified otherwise in particular device standards, surfaces of components that come in contact with oxygen during normal operation or single fault condition shall:

a)   **R** for applications in the pressure range of 50 kPa to 3 000 kPa, not have a level of hydrocarbon contamination greater than 550 mg/m^2;

The manufacturer should ensure that the level of particle contamination is suitable for the intended application(s).

b)   **R** for applications at pressure greater than 3 000 kPa:

  — not have a level of hydrocarbon contamination greater than 220 mg/m^2, and

  — not have particles of size greater than 50 μm.

These requirements shall be met either by an appropriate method of manufacture or by use of an appropriate cleaning procedure. Compliance shall be checked either by verification of the cleanliness of the components or by validation of the cleaning procedure or the manufacturing process.

NOTE 1   Annex A gives examples of cleaning procedures and Annex B gives examples of methods for validation of cleaning procedures.

NOTE 2   The values of 550 mg/m^2 and 220 mg/m^2 for hydrocarbon contamination are taken from ASTM G 93 – 96 and the value of 3 000 kPa is taken from EIGA IGC 33/97/E.

4.2   Means shall be provided to identify components and devices which have been cleaned for oxygen service in accordance with this International Standard.

4.3   Means (e.g. packaging and information supplied by the manufacturer) shall be provided to maintain the cleanliness of components and devices which have been cleaned for oxygen service in accordance with this International Standard.

5   R Resistance to ignition

Devices designed for pressures greater than 3 000 kPa shall not ignite when submitted to a pneumatic impact test according to procedures described in the relevant product standards at a test pressure of 1,2 times the maximum rated pressure.

If lubricants are used, the lubricated device shall be tested.

NOTE   Examples of ignition test methods are given in ISO 10524, ISO 10297 and ISO 7291.

6   Risk analysis

6.1   The manufacturer of medical devices shall carry out a risk analysis in accordance with ISO 14971. Attention is drawn to cleaning procedures (see Annex A), design considerations (see Annex C) and selection of materials (see Annex D).

6.2   The specific hazards of toxic products of combustion or decomposition from non-metallic materials (including lubricants, if used) and potential contaminants shall be addressed. Some potential products of combustion and/or decomposition for some commonly available non-metallic materials are listed in Table D.7.

NOTE   Typical "oxygen-compatible" lubricants can generate toxic products on combustion or decomposition.

Annex E gives details of suitable test and quantitative analysis methods for the products of combustion of non-metallic materials. Data from such tests shall be considered in any risk evaluation.

Annex A
(informative)

Examples of cleaning procedures

A.1 General

A.1.1 General guidelines

A cleaning programme that results in an increase in the degree of cleanliness of the component after each cleaning operation should be selected. It then becomes a matter of processing the component through a series of cleaning methods, or several cycles within a single cleaning method, or both, in order to achieve the desired final degree of cleanliness.

It may be possible to obtain the desired degree of cleanliness in a single operation, but many cleaning methods must progress in several stages, such as initial cleaning, intermediate cleaning and final cleaning. It is essential that each stage be isolated from previous stages by appropriate rinsing, drying and purging operations.

Of particular importance is the removal of lint, dust and organic matter such as oil and grease. These contaminants are relatively easily ignited in oxygen and oxygen-enriched atmospheres.

It is essential that cleaning, washing and draining methods ensure that dead-end passages and possible traps are adequately cleaned.

A.1.2 Initial cleaning

Initial cleaning should be used to remove gross contaminants such as excessive oxide or scale buildup, large quantities of oil, grease and inorganic particulate matter.

Initial cleaning reduces the quantity of contaminants, thereby increasing the useful life and effectiveness of the cleaning solutions used in subsequent cleaning operations.

A.1.3 Intermediate cleaning

Intermediate cleaning generally consists of subjecting the part to caustic or acid-cleaning solutions to remove solvent residues and residual contaminants. The cleaning environment and handling procedures used for intermediate cleaning operations are more critical than those used for initial cleaning. It is essential that the cleaning environment and solutions be appropriately controlled in order to maximize solution efficiency and to minimize the introduction of contaminants that might compromise subsequent cleaning operations.

A.1.4 Final cleaning

A.1.4.1   When components are required to meet very high degrees of cleanliness, they should be subjected to a final cleaning. Final cleaning is generally performed using chemical cleaning methods. At this stage, protection from recontamination by the cleaning solutions or the environment becomes critical and may require strict controls, such as those found in classified clean rooms.

A.1.4.2   The final cleaning stage involves drying and purging operations followed by sealing to protect against recontamination and packaging to prevent damage during storage and transportation.

A.2 Selection of cleaning methods

In order to decide on the most practicable methods of cleaning, the following factors should be considered:

a) the type (e.g. organic, inorganic) and form (e.g. particulate, film, fluid) of contaminants;

b) the configuration of the component;

c) the base material or coating of the part to be cleaned;

d) initial condition of the part to be cleaned;

e) the required final cleanliness of the part;

f) environmental impact and lawful disposal of hazardous waste products generated by the cleaning method;

g) effects of the selected cleaning methods on the mechanical, chemical and thermal properties of the part to be cleaned.

A.3 Cleaning methods

A.3.1 General

It is essential that the cleaning method ensure that all surfaces of the component are cleaned. The methods described are applicable to most metallic materials. However, special precautions may be necessary for non-metallic components.

A.3.2 Categories

Cleaning methods can be categorized as mechanical, chemical or both. Some cleaning operations are enhanced by combining mechanical and chemical methods, such as mechanical agitation of a chemical solution.

Some mechanical cleaning methods such as abrasive blasting, tumbling, grinding and wire brushing on finished machine components can damage surfaces, remove protective coatings and work-harden metals. It is essential that sensitive surfaces of the component be protected before such methods are used on that component.

Chemical cleaning methods can cause damage. Corrosion, embrittlement or other surface modifications can occur. Crevice corrosion can occur, particularly in brazed or welded assemblies. Solvent cleaning solutions are often damaging to non-metals. The supplier of the non-metals should be consulted or samples tested to ensure that the solvent will not cause damage. It is essential that, if acidic or caustic chemical cleaners are used, the chemical residue on the components be neutralized and/or removed immediately after cleaning.

A.3.3 Mechanical cleaning

A.3.3.1 General

Mechanical cleaning methods use mechanically generated forces to remove contaminants from the components. Examples of mechanical cleaning methods are rinsing, abrasive blasting, tumbling and blowing. Details of these and other methods are discussed in A.3.3.2 to A.3.3.8.

A.3.3.2   Abrasive blast cleaning

A.3.3.2.1   Abrasive blast cleaning entails the forceful impingement of abrasive particles against the surfaces to be cleaned to remove scale, rust, paint and other foreign matter. The abrasive particles are entrained in a gas or liquid stream. A variety of systems can be used to propel the abrasive, e.g. airless abrasive blast blades or vane-type wheels, pressure blast nozzles and suction (induction) blast nozzles. Propellant gases should be oil-free.

A.3.3.2.2   Typical abrasive particle materials include metallic grit and shot, natural sands, manufactured oxide grit, carbide grit, walnut shells and glass beads. The specific abrasive particle material used should be suitable for performing the intended cleaning without depositing contaminants that cannot be removed by additional operations, such as high velocity blowing, vacuuming and purging.

A.3.3.2.3   Care needs to be taken to minimize the removal of material from the component parent metal. This cleaning method might not be suitable for components or systems with critical surface finishes or dimensional tolerances.

A.3.3.3   Wire brush or grinding cleaning

A.3.3.3.1   Wire brushing or grinding methods generally use a power-driven wire brush, a non-metallic fibre-filled brush or an abrasive wheel. These are used to remove scale, weld slag, rust, oxide films and other surface contaminants. Wire brushes can be used dry or wet. The wet condition results when brushes are used in conjunction with caustic cleaning solutions or cold water rinses.

A.3.3.3.2   These mechanical methods can imbed brush or grinding material particles in the surface being cleaned. The selection of cleaning brushes depends upon the component or system parent material. Non-metallic brushes are suitable for most materials to be cleaned. Carbon steel brushes should not be used on aluminium, copper or stainless steel alloys. Any wire brushes previously used on carbon steel components should not be used subsequently on aluminium or stainless steel. Wire brushing and grinding can affect dimensions, tolerances and surface finishes.

A.3.3.4   Tumbling

This method involves rolling or agitation of parts within a rotating barrel or vibratory tub. An abrasive or cleaning solution is added to the container. The container action (rotation or vibration) imparts relative motion between the components to be cleaned and the abrasive medium or cleaning solution. This method can be performed with dry or wet abrasives. The component size may vary from a large casting to a delicate instrument component, but mixing different components in one container should be avoided. Damage can occur from one component impacting on another. Tumbling can be used for descaling, deburring, burnishing and general washing. Some factors to be considered in barrel cleaning are the component size and shape, type of abrasive, abrasive size, load size, barrel rotational speed and ease of component/abrasive separation.

A.3.3.5   Swab, spray and dip cleaning

These are three methods of applying cleaning solutions to the component surfaces. Each method has its particular advantages. Swabbing is generally used only to clean small selected areas. Spraying and dipping are used for overall cleaning. These methods are generally employed with caustic, acid or solvent cleaning methods that are discussed in A.3.4.5, A.3.4.6 and A.3.4.8.

A.3.3.6   Vacuuming and blowing

These methods remove the contaminant using currents of clean, dry, oil-free air or nitrogen. These methods can be used to remove loose dirt, slag, scale and various particles, but they are not suitable for the removal of surface oxides, greases and oils.

A.3.3.7 Pig cleaning

Long continuous pipelines can be cleaned *in situ* using pigs. A pig is a piston-like cylinder with peripheral seals that can be pushed through a pipeline using compressed gas, typically nitrogen. The pig can be equipped with scrapers and wire brushes. Pairs of pigs can carry slugs of liquid cleaning agents between them. Hence, a train of pigs can transport isolated slugs of liquids through a pipeline to produce various levels of cleanliness and rinsing. The mechanical and chemical suitability of the solvents, scrapers and wire brushes should be ensured.

A.3.3.8 Ultrasonic cleaning

Ultrasonic energy can be used in conjunction with a variety of chemical cleaning agents to produce intimate contact between the components and the cleaning agent. The ultrasonic agitation aids the removal of lightly adhering or embedded particles from solid surfaces. It is generally employed in solvent cleaning of small components, precious metals and components requiring a very high degree of cleanliness.

A.3.4 Chemical cleaning

A.3.4.1 General

The methods described in A.3.4.2 to A.3.4.9 are based on achieving an interaction between the cleaning solution and the surface of the component to produce the removal of the contaminant by subsequent mechanical methods. The interaction can involve surface activation, contaminant breakdown, oxide conversion and hydrophobic or hydrophilic transformations.

A.3.4.2 Hot water cleaning

Hot water cleaning is used to remove gross organic and particulate contamination from components by the use of low to moderate heat, detergent and some mechanical agitation. Equipment used during hot water cleaning consists of a spray system or a cleaning vat with or without suitable agitation of the solution. Hot water cleaning with detergent can be used where steam is not necessary to free and fluidize contaminants. Consideration should be given to the size, shape and the number of components to assure adequate contact between surfaces of the components and the solution. The solution temperature should be that recommended by the manufacturer of the detergent. Water-soluble contaminants are removed by prompt flushing with sufficient quantities of clean water before the cleaning agents have had time to precipitate. The components are then dried by blowing with dry, oil-free air or nitrogen, which can be heated to shorten the drying time.

A.3.4.3 Detergent cleaning

This method relates to the cleaning of vessels, piping system, or components either externally or internally. Detergents are supplied in powder, crystal or concentrated liquid form. They are prepared for use by mixing with water to form aqueous solutions. Prepared solutions can be used in static tanks or vessels for the immersion of components, or the solution can be re-circulated by pump or jetted onto or through the component. Some types of detergent are toxic and/or corrosive. Properties of detergent materials should be checked with their manufacturer or supplier.

A.3.4.4 Steam cleaning

Steam cleaning is used to remove contaminants, especially organic and particulate, from components by the use of pressure, heat and sometimes detergents. Some organic contaminants are removed by decreasing their viscosity or thinning them with steam heat. A detergent that disperses and emulsifies the organic contaminants, allowing the rinsing off of the contaminants by the condensed steam, can be added. The system should provide control over the flows of the steam, water and detergent to maximize the efficiency of the detergent's chemical action, the heating effect of the steam and the scrubbing action of the steam jet.

A.3.4.5 Caustic cleaning

A.3.4.5.1 Caustic cleaning uses solutions of high alkalinity for the removal of organic contaminants, such as hydrocarbons, oils, greases and waxes. There are many effective cleaning products available for caustic cleaning. The water used for rinsing should be free from substances or impurities that may cause reactions with the caustic cleaner. It is recommended that distilled water be used to minimize problems. The cleaning solution can be applied by spraying, immersing, or swabbing. Usually caustic cleaning solutions are applied at temperatures up to 80 °C. It is important that the cleaning solution reach all areas of the components to be cleaned. The cleaning solution can be reused until it becomes ineffective, as determined by pH measurement or contaminant concentration analysis. Experience will establish a contaminant level of the cleaning solution above which a surface cannot be acceptably cleaned.

A.3.4.5.2 It is essential that the cleaning solution be thoroughly rinsed from the component to prevent the cleaning solution and contaminants from re-depositing on the surface. The surface should not be allowed to dry between the cleaning phase and the rinsing phase. Frequently, some form of water rinsing helps to remove the cleaning solution and aids the drying process. A method of determining when the rinsing is complete is to monitor the used rinse water until a pH of $\pm$ 0,2 of that of the starting pH is achieved. Drying, if required, can be accomplished with heated or unheated dry, oil-free air or nitrogen.

A.3.4.6 Acid cleaning

A.3.4.6.1 Acid cleaning is a process in which a solution of a mineral acid, organic acid or acid salt (often in combination with a wetting agent and detergent) is used to remove oxides, oils and other contaminants from components with or without the application of heat. It is essential that acid cleaning be carefully controlled to avoid damage to the surface of components, such as undesired etching or pickling. The type of cleaning agent selected will depend in most cases on the material or component to be cleaned. A general guide to the use of acid cleaning is given in A.3.4.6.2 to A.3.4.6.5.

A.3.4.6.2 Phosphoric acid cleaning agents can be used for most metals. These agents will remove oxides, rust, soils and fluxes.

A.3.4.6.3 Hydrochloric acid cleaning agents are recommended for carbon and low alloy steels only. These agents will remove rust, scale and oxide coatings and will strip chromium, zinc and cadmium platings. Certain acidic solutions, including hydrochloric or nitric acids, should contain an inhibitor to prevent harmful attacks on base metals. Hydrochloric acid should not be used on stainless steel because it may cause stress corrosion or stress-corrosion cracking.

A.3.4.6.4 Chromic acid and nitric acid cleaning compounds are recommended for aluminium, copper and their alloys. These compounds are not true cleaning agents, but are used for deoxidizing, brightening, and for removing the black residue that forms during cleaning with a caustic solution. Some compounds are available as liquids and others as powders. They are mixed in concentrations of 5 % to 50 % volume fraction in water, depending on the cleaning agent and the amount of oxide or scale to be removed.

A.3.4.6.5 A storage or immersion tank, recirculation pump, associated piping and valves compatible with the cleaning solution are required. Common techniques for acid cleaning are immersion, swabbing and spraying. Acid cleaning compounds should not be used unless their application and performance are known or are discussed with the cleaning compound manufacturer. The manufacturer's recommendations regarding concentration and temperature should be followed. After acid cleaning, it is essential that the surfaces be thoroughly rinsed with water to remove all traces of the acid and thoroughly dried after the final rinse. To minimize staining, surfaces should not be permitted to dry between successive steps of the acid cleaning and rinsing procedure.

A neutralizing treatment may be necessary under some conditions. It is essential that neutralization be followed by repeated water rinsing to remove all traces of the neutralizing agent. If drying is required, it can be completed with heated or unheated dry, oil-free air or nitrogen.

A.3.4.7 Emulsion cleaning

Emulsion cleaning is a process for removing contamination from the surface of components by using organic solvents dispersed in an aqueous medium by an emulsifying agent. Emulsion cleaners are composed of petroleum-derived solvents and surfactants. The cleaning action of emulsion cleaners combines the advantages of both the aqueous and organic phases. A variety of emulsion cleaners is available. Some emulsion cleaners tend to separate into individual solutions if left standing for extended periods of time so it may be necessary to agitate the cleaner periodically. Emulsion cleaners are normally applied to components by methods such as immersion, spraying or swabbing. It is essential that emulsion cleaners be removed by rinsing and subsequent cleaning operations.

A.3.4.8 Solvent cleaning

A.3.4.8.1 Solvent cleaning or degreasing is considered to be the principal procedure for the removal of soluble organic contaminants from components to be used in oxygen service and is suitable for use with most metals.

However, many of the solvents that have been used for this method of cleaning are now banned under the "Montreal Protocol". Alternative cleaning methods that use acceptable solvents should be identified and put into practice as soon as possible.

Solvent cleaning is limited by the ability of the solvent to reach and dissolve any contaminants present. Before starting a solvent cleaning procedure, a portion of fresh clean solvent should be set aside to be used as a reference. At intervals throughout the procedure aliquots of used solvent can be compared with the reference to determine the level of contamination and the effectiveness of the cleaning. Clean glass bottles should be used to store the reference and used solvents. Methods for determining the concentration of hydrocarbon contaminants are discussed in Annex B.

A.3.4.8.2 After the completion of any method of solvent cleaning, it is essential that all gross residual cleaning fluid be drained from the component to prevent drying in pools. The component should then be purged and dried with warm, dry, oil-free air or nitrogen. Small components can be air-dried if appropriate.

A.3.4.8.3 Solvent cleaning can be performed using methods such as swabbing and spraying. Cleaning can also be effected by immersing the component in a tank of solvent and applying a means of agitation. Disassembled components can be cleaned by this method. The process may be improved by the use of ultrasonic cleaning techniques. Cleaning by forced circulation of the solvent through the component can also be carried out. Cleaning by circulation should be continued, using clean solvent, until the used solvent emerges from the component as clean as the reference sample.

A.3.4.8.4 Solvents frequently require inhibitor(s) to control corrosive reactions. The addition of inhibitor(s) may require monitoring to ensure continued effectiveness of the inhibitor. This method is often applied to assemblies that cannot be disassembled, to large components and to prefabricated circuits, pipe works, etc.

A.3.4.9 Vapour degreasing

Vapour degreasing is the removal of soluble organic materials and subsequent washing action of the surfaces of components by the continuous condensation of solvent vapour on the cold component. Vapour degreasing equipment consists essentially of a vaporizer for generating clean vapour from a contaminated solvent and a container for holding the components in the vapour. Refrigerant grade solvents should not be used because they have been known to contain oils. Some of these solvents are flammable in air under certain conditions and have various degrees of toxicity; therefore caution should be exercised in their use. It is essential that the temperature of the component be below the boiling point of the solvent, so that the solvent vapours will condense and wash down by gravity over the surfaces of the component. The component should be positioned and connected so that the condensate will drain freely from the ports. Continuous circulation of the condensate and its transport back into the vaporizer will carry the dissolved contaminants into the vaporizer where they will remain. No further cleaning will occur after the temperature of the component reaches the temperature of the vapour.

A.3.4.10 Purging

A.3.4.10.1   It is very important to purge the component to ensure that all residues from the previous cleaning operation(s) are removed before subsequent cleaning operations or final packaging is performed. This can be achieved by rinsing, drying and blowing. Rinsing is dependent upon the cleaning solutions used, but in most cases filtered water can be used. Drying can be achieved by the application of heat to the component using ovens or infrared lights, or by blowing with clean, oil-free, dry air. Under no circumstances should compressed air for pneumatic tools be used for drying, since it can contain traces of oil or other contaminants. Removal of solvents at elevated temperatures requires additional attention, because the solvents are more likely to attack the component surfaces or to decompose and deposit undesirable films on the component. It is important that the purging medium have a better cleanliness level than the desired cleanliness level of the component.

A.3.4.10.2   A more effective purging can be performed using clean, dry, oil-free nitrogen. This can require dryness verification by measuring the dew point of the effluent drying gas. The duration of the purge, the number of purging operations, and the type of purging operations depend upon the component to be cleaned, the cleaning methods employed and the final application.

A.3.4.11 Low-pressure plasma cleaning

The components to be cleaned are placed in a vacuum chamber into which oxygen is introduced at a pressure between 0,5 hPa and 2 hPa. This gas is transformed into an ionized state by applying a high-frequency alternating voltage. During the gas discharge, chemical radicals are formed that react with the component surface. The volatile compounds developed during this reaction are removed by a vacuum pump. When oxygen is applied as a reaction gas, the oxygen plasma reacts with organic contaminants, such as oil and grease, and burns them to form CO_2 and water vapour. Because low-pressure plasma cleaning can remove only organic substances, inorganic residues arising from the treatment of the components shall be removed by suitable cleaning and washing methods before cleaning with low-pressure plasma.

A.4 Environmental considerations

A.4.1   It is essential that devices intended for oxygen service be handled carefully during all phases of the cleaning procedure. The environment should be clean and dust-free. Nearby grinding, welding and sanding should be prohibited. Components should not be allowed to stand. Care should be taken to avoid oil deposits from rotating machinery or oil aerosols in the air. Surfaces that will be in contact with oxygen should not be touched except with clean gloves or handling devices.

A.4.2   In some cases, laminar-flow cleanrooms in which the entire room is purged with filtered air are necessary. In horizontal-flow cleanrooms, components are cleaned and verified in a sequence that employs successive cleaning operations at locations progressively closer to the filtered air source, so that the component and the environment both become steadily cleaner. In laminar-flow cleanrooms, the layout of the successive cleaning operations is not critical.

Annex B
(informative)

Typical methods for validation of cleaning procedures

B.1 General

The selection of the test method should take into consideration parameters such as the method of manufacture, the type and size of the device to be checked, and the level of accuracy required.

B.2 Typical methods

B.2.1 Direct visual inspection (white light)

This is the most common test method used to detect the presence of contaminants such as preservatives, moisture, corrosion products, weld slag, scale filings and chips, and other foreign matter. The component is observed for the absence of contaminants with normal or corrected-to-normal vision under strong white light. This method will detect particulate matter of size in excess of 50 µm, moisture, and hydrocarbon contamination down to 500 mg/m^2.

B.2.2 Direct visual inspection (ultraviolet light)

WARNING — Avoid prolonged exposure to ultraviolet light because it is hazardous to eyes and to unprotected skin.

Ultraviolet light causes many common hydrocarbon or organic oils or greases to fluoresce and become visible when they cannot be detected by other visual means. Therefore, the ultraviolet light test is the most commonly used test to detect the presence of hydrocarbon or organic oils or greases. The surface is observed in darkness or subdued light using a source radiating ultraviolet light of wavelength between 0,32 µm and 0,37 µm. Ultraviolet light inspection should be able to indicate that cleaned surfaces are free of any hydrocarbon fluorescence. However, not all organic oils fluoresce and some materials, such as cotton lint, that fluoresce are acceptable unless present in excessive amounts.

If fluorescence appears as a blotch, smear, smudge or film, the fluorescing area should be re-cleaned. Accumulations of lint or dust that are visible under ultraviolet light should be removed by blowing with dry, oil-free air or nitrogen, wiping with a clean lint-free cloth or vacuuming.

B.2.3 Wipe test

This test can be used to detect contaminants on visually inaccessible areas as a supplement to the visual inspections described in B.2.1 and B.2.2. The surface is rubbed lightly with a clean white paper or lint-free cloth which is examined under white and ultraviolet lights. The area should not be rubbed hard enough to remove any oxide film, as this material could be confused with normal surface contamination. No paper or cloth particles should be left on the surface.

B.2.4 Water break test

This test can be used to detect oily residues not found by other means. The surface is wetted with a spray of clean water. This should form a thin layer and remain unbroken for at least 5 s. Beading of the water droplets indicates the presence of oil contaminants. This method is generally limited to horizontal surfaces.

B.2.5 Solvent extraction test

Solvent extraction can be used to supplement visual techniques and to check inaccessible surfaces. The procedure is limited by the ability of the liquid solvent to reach, dissolve and dislodge the contaminants present, without attacking the components themselves and giving erroneous results. In quantitative terms, its usefulness is limited to surfaces whose dimensions can be readily calculated, e.g. flat surfaces and the inside of tubing. In qualitative terms, however, repetition of the procedure with fresh solvent will incrementally reduce contamination to an acceptably low level.

In general terms, the surface of the component is flushed, rinsed or immersed in a known volume of low-residue solvent, and the used solvent is analysed to determine the amount of non-volatile residue.

An aliquot of the used solvent is passed through a pre-weighed filter, the filtrate evaporated to dryness in a weighed vessel without overheating and the vessel reweighed. An identical aliquot of unused solvent is treated in an identical manner. The difference in mass of the two filters and evaporated residues, the quantity of solvent used for the extraction, and the surface area of the components, if determined, are used to calculate the concentration of insoluble and soluble contaminants extracted per square metre of surface cleaned.

Alternatively, the light transmission through equal volumes of the filtered used and unused solvent can be compared simultaneously. There should be little or no difference in colour. This procedure can be quantified if the surface dimensions of the component are known, by measuring the absorbance of the used solution and comparing it to solutions of known concentration prepared from a reference hydrocarbon in the same solvent. The concentration of insoluble contaminants can be calculated from the residue on the filter.

B.2.6 Gas extraction test

In gas-extraction tests, a clean, particle-free gas stream is used to entrain contaminants and transport them to a detection device. As with the solvent extraction test, this method is limited by its ability to remove all of the contaminants present. Because physical entrainment is not totally effective, this approach is more suitable for demonstrating inadequate cleanliness than for quantifying the amount of contamination present. It is principally useful for inspection for particles, the presence of oil being more effectively detected by solvent extraction.

B.2.7 Instrumental analysis

B.2.7.1   General

There are many instrumental analysis systems, such as light scattering, light interruption and infrared (IR) absorption spectroscopy, available to determine size and distribution of particles and hydrocarbon concentration in the solvent.

B.2.7.2   Light scattering

This method uses variations in the intensity of light scattered (by reflection and refraction) by particles in the direction of a sensor. This method is suitable for the detection of particles of diameter 0,5 µm and smaller, depending on the equipment used. The disadvantages of this method are that the sensing angle is critical; changes in colour and density of the fluid medium affect detection; and the system cannot detect particles when the refractive indices of the fluid and particle are identical.

B.2.7.3   Light interruption

With this method, particle size is determined by the change in light intensity produced by the particle as it passes between a light source and a light sensor. This system has several major advantages, including the ability to measure particles in a gas or liquid, the lack of dependence upon particle characteristics and close discrimination of particle size. A disadvantage is the inability to detect particles when the refractive indices of the particle and fluid are identical. Particles of diameter 0,5 µm and larger can be detected using this method.

B.2.7.4   Infrared (IR) absorption spectroscopy

This test method is based on the quantitative determination of organic substances in a solution by means of IR absorption. The component to be tested is completely covered with the solvent [e.g. Freon 113 (trichlorotrifluoroethane)] in a clean glass container. The test container is treated twice in an ultrasonic bath for 5 min each time. The absorption of the test solvent is measured in a quartz cuvette. The amount of hydrocarbon is determined by reference to a calibration curve of a standard hydrocarbon in the same solvent at a specified wavelength or wavelengths.

Annex C
(informative)

Design considerations

C.1 General

The purpose of this annex is to furnish qualified technical personnel with pertinent information to use in designing oxygen-containing systems. It emphasizes factors that cause ignition and/or enhance propagation throughout a system's service life so that these conditions can be avoided or minimized. It is not intended as a specification for the design of oxygen-containing systems.

The designer of an oxygen-containing system should understand that it is essential for oxygen, fuel and heat (source of ignition) to be present to start and propagate a fire. Since combustible materials and oxygen are usually present, the design of a system for oxygen or oxygen-enriched service is primarily a matter of understanding the factors that are potential sources of ignition or which promote propagation of combustion. The goal is to eliminate these factors or compensate for their presence. Preventing fires involves both minimizing system environments that enhance ignition and propagation and maximizing the use of materials with properties that resist ignition and propagation.

C.2 Factors affecting the design for an oxygen-containing system

C.2.1 Temperature

As the temperature of a material increases, the amount of energy required to produce ignition decreases. Operating a system at locally or generally elevated temperatures reduces this safety margin. The ignition temperature of the most easily ignited material in a system is a function of the system pressure, configuration, operation and the thermal properties of the material. Elevated temperature also facilitates sustained combustion of materials that might otherwise be self-extinguishing.

C.2.2 Pressure

As the pressure within a system increases, the ignition temperatures of its components typically decrease, and the rate of fire propagation increases. Therefore, operating a system at elevated pressures increases the probability and consequences of a fire. It should be noted that oxygen even at lower-than-atmospheric pressure can still pose a significant hazard with incompatible materials.

C.2.3 Oxygen concentration

As oxygen concentration decreases from 100 %, with the balance being inert gases, the likelihood and intensity of a potential reaction decreases. Greater latitude can therefore be exercised in the design of a system for use with a lower oxygen concentration.

C.2.4 Contamination

Contaminants can be present in a system because of inadequate initial cleanliness, introduction during assembly or service life, or generation within the system, for example by abrasion or flaking. Contaminants can be liquids, solids or gases. Such contamination can be readily ignitable and highly flammable, and is therefore likely to ignite and promote system fires. However, even normally inert contaminants, such as rust, can produce ignition through particle impact or friction or through augmentation of resonance heating effects.

C.2.5 Particle impact

Collisions of inert or ignitable solid particles entrained in an oxidant stream are associated with potential ignition. Such ignition can result from the particles being flammable and igniting upon impact and, in turn, igniting other system materials. Ignition can also result from heating of the particles and subsequent contact with plastics and elastomers within the system. The hazard associated with particles increases with both heat of combustion and the kinetic energies of the particles. Total removal of particles is not possible. In addition, particles can be either introduced into or generated within the system. The quantity of particles in a system will tend to increase with the age of the system. Hence, it is important that a system be designed to tolerate the presence of at least some particles.

C.2.6 Adiabatic compression

C.2.6.1   High temperatures can result when a gas is quickly compressed. This can occur when high-pressure oxygen is released into a dead-ended tube or pipe, quickly compressing the residual oxygen that was in the tube ahead of it. The elevated temperatures produced can ignite contaminants or elevate system components above their ignition temperatures. The hazard arising from adiabatic compression increases with system pressure.

C.2.6.2   A formula for the theoretical maximum temperature that can be developed when pressurizing a gas rapidly without heat dissipation from one pressure and temperature to a higher pressure is as follows:

$$T_f/T_i = (p_f/p_i)^{(n-1)/n}$$

where

T_f is the final temperature, in kelvin;

T_i is the initial temperature, in kelvin;

p_f is the final absolute pressure, in kilopascals;

p_i initial absolute pressure, in kilopascals.

$n = C_p / C_V = 1,40$ for oxygen

where

C_p is the specific heat at constant pressure;

C_V is the specific heat at constant volume.

C.2.6.3   Table C.1 gives the theoretical temperature attained when compressing oxygen adiabatically from 60 °C and one standard atmosphere to the pressures shown.

C.2.7 Friction

The rubbing together of two surfaces can produce heat and can generate particulate matter. Such heating can elevate a system component above its ignition temperature. The hazards associated with friction generally increase with the loading, friction coefficient and the relative speed of rubbing.

C.2.8 Resonance

Oscillations within resonant cavities can result in high temperatures at particular points in the system. The temperature rises more rapidly and achieves higher values where particles are present or where there are high gas velocities. Resonance phenomena in oxygen-containing systems are documented, but there are few design criteria.

Table C.1 — Theoretical final temperature with adiabatic compression

Pressure	Final temperature [a, b]
kPa	°C
100	131
200	181
300	220
400	252
500	280
600	305
700	328
800	348
900	367
1 000	385
1 400	446
2 000	519
2 500	568
5 000	747
7 500	870
10 000	967
12 500	1 048
15 000	1 118
17 500	1 180
20 000	1 237
22 500	1 288
25 000	1 335
27 500	1 380
30 000	1 421

[a] The theoretical temperatures shown in this table are much higher than the auto-ignition temperature of all non-metallic materials used for high and ultra high pressure oxygen service. This indicates that successful performance depends on many other factors.

[b] Starting temperature 60 °C.

C.2.9 Static electricity

Electrical discharge from static electricity, possibly generated by high gas velocity under certain conditions, can occur, especially when particulate matter is present. An example is arcing between components of the system which are electrically isolated from each other.

C.3 Principles

C.3.1 Avoidance of unnecessarily elevated temperatures

Systems should be located at a safe distance from heat or radiation sources.

Monitoring equipment and automatic shutdown devices should be provided, where needed, for example on heaters, bearings and compressor heads.

Design should take efficient dissipation of heat into account.

C.3.2 Avoidance of unnecessarily elevated pressures

Pressure should be reduced near the supply point rather than near the use point, so that intermediate equipment is at minimum pressure.

C.3.3 Design for system cleanliness

The system should be designed so that it can be disassembled into components that can be easily cleaned and maintained in a clean condition.

The presence of unnecessary dead-ends and traps likely to accumulate debris should be avoided.

Filters should be used to limit the introduction of particles and to capture particles generated in service.

Filters should be fitted at oxygen entry points into a system, at points where particles are likely to be generated and at critical points where particle presence produces the greatest risk, such as at the inlet side of compressors or pressure regulators.

Filters should not be fragile. If complete blockage is possible, the filter should be able to withstand the full differential pressure to which it can be subjected.

Preventive maintenance of filters should be frequent enough to limit the hazard associated with particles collected on the filter element.

Preventive maintenance of filters should be easy to perform. Means should be provided to indicate an excessive pressure drop across the filter. If the system cannot be shut down, duplexed filters should be fitted to facilitate maintenance.

Filters should be made of highly fire-resistant material (see Annex D).

C.3.4 Reduction of the effects of particle impacts

Gas velocities should be limited to reduce kinetic energies of particles.

Highly fire-resistant materials should be used where velocities cannot be minimized, such as in flow-control valves.

Highly fire-resistant materials should be used at particle impact points, such as where a gas stream flows into a tee from the side port.

Gas streams should not impinge on non-metallic components such as seats or seals.

Potential impact surfaces should be designed with shallow input angles so that the kinetic energy absorbed by the impact surface is spread over a greater area.

C.3.5 Reduction of heat of compression

Rapid increases in pressure should be avoided.

Fast-opening valves, such as standard ball valves, should be avoided.

If fast-opening valves are used, small bypass valves should be fitted across them to allow equalization of the pressure before they are opened.

Line restrictors, such as orifice plates, should be installed to limit the rate of pressure increase.

Gas should not be compressed against components which could be easily ignited.

Distance pieces should be used to isolate components which could be easily ignited from points where high temperatures may occur.

C.3.6 Avoidance of friction and galling

The use of rubbing components should be limited to reduce galling and the production of heat and generation of particles.

Where rubbing cannot be avoided, highly fire-resistant materials and/or materials with a low friction coefficient and/or high resistance to galling should be used.

C.3.7 Avoidance of corrosion

Joints between dissimilar metals should not be used.

C.3.8 Avoidance of resonance

If significant resonance occurs means should be provided to reduce its effect.

C.3.9 Use of proven components

Components which have a trouble-free history in oxygen service under similar operating conditions should be used.

Components or systems should be pre-tested in controlled situations.

C.3.10 Reduction of available fuel and/or oxygen

The mass of non-metallic components should be as small as possible and these components should be well shielded.

The internal volume of the system should be minimized.

C.3.11 Considerations during construction

Sharp edges and burrs should be avoided or removed, because they are more easily ignited than smoother base materials.

Components with thin walls should not be used, as they can be easily ignited.

The generation of particles should be minimized during manufacture and assembly.

Dead ends should be avoided.

Electrical arcing should be minimized.

Unless otherwise specified by a particular International Standard, a final purge to displace particles and to test systems should be carried out with an inert gas as a means to seat surfaces, prove mechanical integrity and test the system for leaks.

Annex D
(informative)

Selection of materials

D.1 General

The purpose of this annex is to furnish qualified technical personnel with information for use in selecting materials for oxygen service in order to minimize the probability of ignition and/or propagation of a fire. It is not intended to serve as a specification for approving materials for oxygen service.

When selecting materials, application-specific material tests and configurations should be considered. The ability of a material to undergo specific cleaning procedures without damage should also be considered.

The selection of a material for use with oxygen or oxygen-enriched atmospheres is primarily a matter of understanding the circumstances that cause oxygen to react with the material. Most materials in contact with oxygen will not ignite without a source of ignition energy. When an energy-input rate, as converted to heat, is greater than the rate of heat dissipation, and the temperature increase is continued for sufficient time, ignition and combustion can occur. The material's minimum ignition temperature and the energy sources that will produce an increase in temperature of the material should be viewed in the context of the entire system design, so that specific factors listed below will assume the proper relative significance. To summarize, it depends on the application.

D.2 Differences in oxygen compatibility of metals and non-metals other than ceramics

There are several fundamental differences between the oxygen compatibility of metals and non-metals as a result of differences in their flammability characteristics. These differences in flammability characteristics are listed in Table D.1.

In general metals are harder to ignite than non-metals. They have auto-ignition temperatures in the range of 900 °C to 2 000 °C. By comparison, most combustible non-metals have auto-ignition temperatures in the range of 150 °C to 500 °C.

Metals have high thermal conductivities that help to dissipate local heat so that they do not ignite. For a similar local heat input, the low thermal conductivity of a non-metal can allow the local temperature to rise above the auto-ignition temperature so that the material will ignite.

Many metals also develop protective oxide coatings that interfere with ignition and propagation.

Metal combustion can be highly destructive. Flame temperatures for metals are much higher than for most non-metals. The greater density of most metals provides potential for greater heat release from components of comparable size.

Many metal oxides do not exist as oxide vapours, as they largely dissociate upon vaporization.

Combustion of metals yields primarily liquid metal oxides of high heat capacity in the flame zone at the oxide boiling point. There may be very little gaseous metal oxide. In comparison, combustion of non-metals yields gaseous combustion products that tend to dissipate the heat released.

Contact with a mixture of liquid metal and oxide at high temperature results in a large heat transfer relative to that possible upon contact with hot, low heat capacity, gaseous combustion products of non-metals.

Finally, because most non-metals produce large volumes of gaseous, inert combustion products, there is substantial dilution of the oxygen in the flame. This inhibits combustion and, in a stagnant system, can even extinguish a fire. For many metals, combustion produces a molten oxide of negligible volume condensing in the flame front. Hence, oxygen dilution is much less.

Table D.1 — Comparison of flammability characteristics for metals and non-metals

Characteristic	Metals	Non-metals
Combustion products	Molten metal oxide	Hot gases
Auto-ignition temperature	900 °C to 2 000 °C	150 °C to 500 °C
Thermal conductivity	High	Low
Flame temperature	High	Low
Heat release	High due to density	Low
Surface oxides	Can be protective	Not formed

D.3 Factors affecting selection of materials

The selection of a material for use with oxygen or oxygen-enriched atmospheres is primarily a matter of understanding the circumstances which cause oxygen to react with the material. Most materials in contact with oxygen will not ignite without a source of ignition energy. When an energy input exceeds the configuration-dependent threshold, then ignition and combustion can occur. Thus, the flammability properties of the materials and the sources of ignition energy within a system need to be considered. These should be viewed in the context of the entire system design so that the specific factors listed in this guide will assume the proper relative significance. To summarize, it depends on the application.

In addition to the factors affecting the design for an oxygen-containing system, as described in C.2, other factors should be taken into account for the selection of materials. Such factors, specific for metals and non-metals, are described in D.4 and D.5.

D.4 Selection of metallic materials

D.4.1 Factors affecting selection of metals

D.4.1.1 Ease of ignition

Although metals are typically harder to ignite than non-metals, potential structural materials exhibit a wide range of ignition properties and some metals are more difficult to ignite than others. The principal recognized sources of metal ignition include:

a) contamination where the contaminant itself can be ignited by mechanical impact, adiabatic compression, sparks or resonance and ignition is then transferred to the metal;

b) particle impact where a particle can ignite and transfer ignition to the metal;

c) friction resulting from mechanical failure, cavitation or rubbing;

d) bulk heating to ignition temperature.

D.4.1.2   Melting temperature

Most metals have to be molten in order to burn. It follows that the higher the melting temperature the lower the likelihood of ignition. However, the melting temperature of metals (see Table D.2) is not directly correlated with the ranking given for the oxygen compatibility of metals and alloys using data from tests of particle impact, friction ignition, promoted ignition and oxygen index (see Table D.3).

Table D.2 — Melting temperature, heat of combustion and thermal conductivity of typical metals

Metal	Melting temperature °C	Heat of combustion J/g	Thermal conductivity W/(m·K)
Aluminum	660	31 000	209
Brass 20/40	900	3 500	79
Bronze 10/2	1 020	2 700	46
Carbon steel	1 500	7 400	52
Cast iron	1 150	7 400	58
Chromium	1 890	10 900	a
Copper	1 083	2 500	407
Nickel	1 453	4 100	58
Silver	960	150	418
St steel 18/8 AISI 304	1 400	7 700	15
a No data available			

Table D.3 — Rank order of resistance to ignition of metals and alloys

Particle impact (ASTM /NASA)	Friction/rubbing (ASTM/NASA)	Promoted ignition (ASTM/NASA)	Promoted ignition (UCC Linde)	Oxygen index (Zabrenski)
	Nickel	Nickel	Nickel 200	Monel 400
Monel 400	Inconel 600			
			Nichrome V	
			Monel 400	
		Copper	Monel K500	
			Naval brass	
		Monel 400	Copper	Copper
	Tin bronze		90-10 Cu/Ni	
Tin bronze		Tin bronze	70-30 Cu/Ni	
Yellow brass			Free cutting brass	Yellow brass
			2 % Be/Cu	
	Nodular cast iron	Yellow brass	INCO 141 Filler	
			Inconel X-750	
		Red brass	Admir Brass	
	13-4 St Steel		Tin Bronze G	
			Tin Bronze GM	
Inconel 600		Inconel 600	Inconel 600	Inconel 600
	Monel K500		Berylco 440	
	Monel 400		Tin Bronze, NM	
			Silicon Brass	
	WC Coating		Hastelloy C276	
	Gray cast iron		Stellite 6B	
	Leaded tin bronze	Stellite 6B	MP 35N	Stellite 6
7 % Al Bronze	AISI 4140 Steel		Inconel 625	
Inconel 625		Inconel 625	Hastelloy C-22	
		Waspaloy	Haynes 25	
	Hastelloy X	440C St Steel	Inconel 625	
		17-4 PH Steel	Incoloy 825	Incoloy 800
			Incoloy 65	
	14-5 PH Steel	Incoloy 800	Inconel 718	
Inconel 718	Yellow brass		Hastelloy X	
Nodular cast iron			Hastelloy G3	
Incoloy 800			Hastelloy G	
	Stellite 6B		Elgiloy	
			Silicon Brass	
	304 St Steel		Hastelloy G30	
	410 St Steel		Hastelloy B	
	Invar 36		Carpenter 20 Cb3	
	17-4 PH Steel		410 St Steel	
316 St Steel		321 St Steel	430 St Steel	430 St Steel
304 St Steel	Nitronic 60		SAF 2205 Steel	
		316 St Steel	316 St Steel	304 St steel
Nitronic 60	7 % Al Bronze		310 St Steel	316 St Steel
		304 St Steel	304 St Steel	201 St Steel
13-4 St Steel	Carbon steel	Inconel 718	17-4 PH Steel	
14-5 St Steel		Nodular cast iron	Invar	Zinc
		Nitronic 60		10 % Al Bronze
		9 % Ni Steel	Carbon steel	9 % Ni Steel
	C355 Al Alloy		Ni-Al Bronze	1018 Steel
	SAE 11 Babbitt	7 % Al Bronze	Al Bronzes	
	6061 Al Alloy	2219 Al Alloy	A356 Al Alloy	
6061 Al Alloy	T-6A1-4V	6061 Al Alloy	1100 Aluminium	6061 Al alloy
NOTE 1 Materials are listed in order of decreasing resistance to ignition.				
NOTE 2 From ASTM STP 1197 – 1993, Table 2, p. 7.				

D.4.1.3 Melting-point burn ratio

Since many metals have to be molten in order to burn, then to sustain combustion such a metal has to produce sufficient heat to melt itself. The melting-point burn ratio (BR_{mp}) is a ratio of the heat released during combustion of a metal to the heat required to both heat metal to its melting point and provide the latent heat of fusion. It is defined by:

$$BR_{mp} = H_{comb} / (H_{rt-mp} + H_{fus})$$

where

H_{comb} is the heat of combustion;

H_{rt-mp} is the heat required to warm the metal from room temperature (rt) to the melting point (mp);

H_{fus} is the latent heat of fusion.

A metal with a low BR_{mp} will burn less vigorously than one with a high BR_{mp}. Calculated BR_{mp} are given in rank order in Table D.4. This rank order is broadly similar to that given by various test parameters.

Table D.4 — Calculated melting-point burn ratios

Material	Melting-point burn ratio (BR_{mp})
Silver	0,40
Copper	2,00
90:10 copper-nickel	2,39
CDA 938 Tin bronze	2,83
CDA 314 Leaded commercial bronze	2,57
Monel 400	3,02
Cobalt	3,50
Monel K 500	3,64
Nickel	3,70
CDA 828 Beryllium copper	4,49
AISI 4140 Low alloy steel	5,10
Ductile iron	5,10
Cast iron	5,10
AISI 1025 Carbon steel	5,10
Iron	5,10
17-4 PH	5,32
410 SS	5,39
CA 15 St steel	5,39
Titanium	13,10
Lead	18,60
Zinc	19,30
Lead babbit	20,60
Magnesium	22,40
Aluminium	29,00
Tin babbit	42,60
Tin	44,80
NOTE Table X1.5 from ASTM G 94 -1990.	

D.4.1.4   Heat of combustion

The combustion of a metal releases heat, and the amount of heat has a direct effect on the destructive nature of the fire. On a mass basis, numerous metals and non-metals release about the same amount of heat. However, because of the much larger mass in most systems, combustion of many metals has the potential for release of the major amount of heat in a fire. The heats of combustion for various metals and alloys are given in Table D.2. In general, the lower the heat of combustion, the greater the oxygen compatibility of the metal.

D.4.1.5   Thermal conductivity

The thermal conductivities of metals vary widely but are generally higher than the thermal conductivities of non-metals. The dissipation of heat by conduction through the metallic components of an assembly can be an important means of cooling. Local heat dissipation to cool non-metallic components requires that these components are in close contact with metallic components of higher thermal conductivity. Values for the thermal conductivities of different metals are given in Table D.2.

D.4.1.6   Auto-ignition temperature

In general the auto-ignition temperatures of metals are much higher than those for non-metals. Typical values for auto-ignition temperatures of metals are in the range of 900 °C to 2 000 °C.

Low auto-ignition temperature of any material is directly correlated with low oxygen compatibility. However this relationship is influenced by the formation of protective oxide coatings on the surface of metals. For some metals the auto-ignition temperature increases with increasing oxygen pressure, but for most metals the auto-ignition temperature is either constant or decreases with increasing oxygen pressure.

Ignition mechanisms that damage the protective oxide coating, such as friction, abrasion or chemical reaction may lead to metal ignition at temperatures lower than expected.

D.4.1.7   Kindling chains

A chain of ignition can occur when an easily ignited material such as a contaminant is ignited, for example by adiabatic compression. This can release enough heat to ignite a small non-metallic component, such as a valve seat, which in turn might ignite a larger non-metallic component, such as a bush, finally leading to the release of sufficient heat to ignite a metal valve body. Once a metallic component has been ignited there is danger of catastrophic failure and loss of life.

D.4.1.8   Tests for oxygen compatibility

In the past decade, largely as a result of interest from the aerospace industry, specific test methods to evaluate the oxygen compatibility of a selected group of metals and alloys have been proposed. Three methods were investigated, each related to known mechanisms of ignition, namely particle impact, friction/rubbing and promoted ignition. With a few exceptions, these test methods produced a similar ranking for the oxygen compatibility of the metals which were tested. The reproducibility of the results and the cost of testing vary between these methods and for such reasons the promoted ignition test is now the standard test. There are, however, many possible variants in the test procedure such as oxygen pressure, dimensions of the test specimen and the mass and identity of the promoter (i.e. an easily ignited material).

Many metals and alloys of general industrial interest have now been tested for oxygen compatibility by the promoted ignition method, and a ranking list is given in Table D.3. The higher on the list, the greater is the resistance to promoted ignition. Since this mechanism of ignition is probably more relevant to medical devices than either particle impact or friction/rubbing, the metals used for high-pressure oxygen systems in medical devices should be as high on this list as possible.

D.4.2 Metal selection method

D.4.2.1 Selection

To select a material for an application, the application should first be reviewed to determine the probability that the chosen material will be exposed to significant ignition phenomena in service. The material's susceptibility to ignition, and its destructive potential or capacity to involve other materials once ignited, should be considered together with the potential effects of an ignition on the system environment. Finally, the demands of the application and the level of performance expected from the material should be compared in the context of the need to avoid ignition. Examples of relevant parameters are given in Tables D.2, D.3 and D.4.

D.4.2.2 Principles

The least reactive material available consistent with sound engineering and economic practice should be used. When all other things are equal, the greatest attention should be paid to the properties most important to the application. Oxygen index should be maximized. Heat of combustion, rate of propagation, flame temperature and melting point burn ratio should be minimized. If one or more potential ignition mechanisms have a relatively high probability of occurrence, a material with a high resistance to those ignition mechanisms should be used (see Table D.3).

Metals of greater fire resistance should be chosen whenever a system contains large quantities of non-metals, when less than optimum non-metals are employed, or when sustained scrupulous cleanliness cannot be guaranteed. The higher the maximum operating pressure, the more critical is the metal's resistance to ignition and propagation.

For rotating machinery, metals with the highest PV (product of pressure and linear velocity) values at ignition that are consistent with practical, functional capability are preferred.

Materials with high oxygen indices are preferable to materials with low oxygen indices. When a metal is used at an oxygen concentration below its pressure-dependent oxygen index, greater latitude can be exercised with other parameters. The use of materials of intermediate oxygen index is a matter of judgement involving consideration of all significant factors in the particular application.

Experience with a given metal in a similar or more severe application, or with a similar material in the same application, frequently forms a sound basis for material selection. However, discretion should be used in the extrapolation of conditions. Similarities can be inferred from comparisons of test data, burn ratios, or use of the periodic table of the elements. Because flammability properties of metals can be very sensitive to small fractions of constituents, it may be necessary to test each alloy or even each batch, especially where very flammable elements are minor components.

Operational factors may also be important. It cannot be assumed that successful use of a material in an industrial environment will transfer to a health care environment.

D.5 Selection of non-metallic materials (plastics, elastomers, lubricants and thread compounds)

D.5.1 Factors affecting selection of non-metals

D.5.1.1 General

In considering a material for a specific oxygen service application, one of the most significant factors is its auto-ignition temperature. Other factors that will affect its ignition are relative resistance to impact, geometry, configuration, specific heat, relative porosity, thermal conductivity, pre-oxidation or passivation and "heat sink effect". The latter is the heat transfer from the material to the mass in intimate contact with it, with the respect to both the size and the physical arrangement of each component and to their respective physical properties. For instance, a gasket material can have a relatively low ignition temperature but be extremely resistant to ignition when contained between two metallic flanges.

D.5.1.2 Auto-ignition temperature

The auto-ignition temperatures of some non-metals under specific test conditions are given in Tables D.5 and D.6. The values obtained for auto-ignition temperatures depend to some extent upon the test procedure. A test method to determine the autogenous ignition temperature of non-metallic materials in pressurized gaseous oxygen is given in ISO 11114-3. Differences between the results obtained by different test laboratories are being studied. However, the rankings for non-metals obtained from different laboratories are essentially the same. For most non-metals the auto-ignition temperature decreases with increasing oxygen pressure up to a pressure of about 4 000 kPa and then becomes approximately constant. The test pressure should be in excess of the maximum in-use pressure.

The auto-ignition temperatures of most non-metallic materials are much lower than the theoretical temperatures which can be attained by adiabatic compression in high pressure oxygen systems. For this reason devices such as pressure regulators should be subjected to adiabatic pressure shocks and then examined to ensure that ignition of small non-metallic components has not occurred.

Table D.5 — Auto-ignition temperature oxygen index and heat of combustion of typical groups of polymers

Polymer group	Auto-ignition temperature °C	Oxygen index	Heat of combustion J/g
Acrylonitrile-butadiene-styrene (ABS)	204 [a]	18,8 to 39	35 500
Chloroprene neoprene rubber	175 to 190 [a]	26,3	12 500
Ethylene-propylene (EPDM)	200 to 210 [a]	21,9	39 500
Nitrile rubber NBR	290 to 310 [a]	18	22 500 / 35 500
Polyacetal	200 to 210 [a]	14,2	[b]
Polyamide	200 to 220 [a]	21 to 30,1	33 000
Polycarbonate	300 to 315 [a]	22,5 to 44	[b]
Polychlorotrifluoroethylene (PCTFE)	410 to 425 [a]	95	9 500
Polymethylmethacrylate	430 [a]	16,7 to 21,5	25 000
Polypropylene	150 to 160 [a]	17,4 to 29,2	46 000
Polytetrafluoroethylene (PTFE)	460 to 490 [a]	95	7 000
Polyvinylidene fluoride	250 to 330 [a]	43,7 to 57	15 000
Silicone rubber	300 to 320 [a]	25,8 to 39,2	16 500
Vinylidene fluoride-hexafluoropropylene	323 [c]	56 to 100	14 000
Polyetheretherketone (PEEK)	300 to 350 [a]	[b]	[b]
Polyethylene (PE)	180 to 200 [a]	17,5	[b]
Where values are given as ranges, the exact value should be determined for the particular polymer.			

[a] Test pressure 12 000 kPa.

[b] No data available.

[c] Test pressure 6 800 kPa.

Table D.6 — Auto-ignition temperature of typical lubricants and thread compounds

Lubricant or thread compound	Temperature [a] °C
Colloidal graphite powder	350 to 360
Epoxy cement	210 to 230
Fluorocarbon oil	380 to 400
Fluorocarbon grease	380 to 420
Graphite grease	170 to 180
Perfluoroalkylpolyether oil	230 to 360
Molybdenum disulfide dry	400 to 500
Perfluoroalkylpolyether grease	400 to 500
PTFE pipe tape	420 to 427
Polyester thread sealant	140 to 150
Silicone grease	190 to 215
[a] Test pressure 12 000 kPa	

D.5.1.3 Heat of combustion

The properties and conditions that could affect potential resultant damage if ignition should occur should be evaluated. Of particular importance is the total heat release potential, the material's heat of combustion (see Table D.5) multiplied by its mass. The mass of individual components with a high heat of combustion should therefore be kept as low as possible.

D.5.1.4 Oxygen index

The oxygen index is a measure of the ability of a material to sustain combustion. Materials with high oxygen index values should be used.

D.5.1.5 Internal flexing

Continuous and rapid flexing of a material can generate heat. Such heat can increase the possibilities of ignition. An example is a gasket protruding into the gas stream.

D.5.1.6 Toxicity of the products of combustion

One of the known risks in the use of medical devices with high and ultra-high-pressure oxygen is that their non-metallic components can ignite as the result of local heating caused by adiabatic compression. Therefore, designers tend to choose materials with the highest possible auto-ignition temperatures. Polymers containing fluorine and/or chlorine, e.g. polytetrafluoroethylene (PTFE) and polychlorotrifluoroethylene (PCTFE), typically have high auto-ignition temperatures (see Table D.5).

In medical devices used with oxygen, the toxicity of the products of combustion also needs to be considered.

All polymers can burn in oxygen, especially at high oxygen pressures, and generate gaseous combustion products. The majority of polymers contain carbon and hydrogen and their complete combustion yields carbon dioxide and water. Polymers that also contain nitrogen or sulfur can also yield a range of simple acidic inorganic and neutral organic gases. Combustion of polymers with high auto-ignition temperatures (e.g. those containing fluorine and/or chlorine) can yield complex mixtures of gaseous products. Table D.7 contains a list of selected polymers and the potential products of their combustion, together with relevant toxicity and human exposure data.

Combustion of all or part of a non-metallic component in medical devices might not be immediately apparent and the products of combustion might be completely contained within the equipment. In this case these toxic products might either be delivered as a bolus of high concentration or adsorbed onto other materials and then

slowly released. The gases which are produced during combustion depend not only upon the chemical composition of the polymer, but also upon the conditions of combustion, particularly temperature, pressure and oxygen concentration.

A list of possible combustion products of several non-metallic materials together with their threshold limit values (TLV) and lethal concentration (LC_{50}) values is given in Table D.7. The list is not exhaustive but includes known major toxic products which could be produced during combustion. LC_{50} is a measure of toxicity and a lower numerical value indicates higher toxicity. TLV is a numerical indicator of the concentration of a substance to which nearly all healthy workers can be repeatedly exposed without adverse health effects and lower numerical values indicate that a given substance is potentially more harmful.

A recommended test procedure for the combustion of non-metallic materials is given in Annex E. This procedure is intended to simulate combustion conditions in a high-pressure oxygen circuit. A method is also recommended for quantitative analysis of the combustion products (see Annex E).

Table D.7 — Some potential products of combustion of selected non-metallic materials

Materials	Potential combustion products [a]	LC_{50} [b] ml/m³	TLV [c] ml/m³	TLV [c] mg/m³
Polytetrafluoroethylene (PTFE) [d] Polychlorotrifluoroethylene (PCTFE) Polyvinylchloride (PVC)	$C_2Cl_4O_2$ diphosgene	2		
	$COCl_2$ phosgene	5	0,05	0,2
	F_2O oxygen difluoride	2,6	0,05	0,1
	F_2 fluorine	185	1	2
	Cl_2 chlorine	293	1	3
	COF_2 carbonyl fluoride	360		
	HF hydrogen fluoride	966	3	2,5
	HCl hydrogen chloride	3 120	5	7,5
	ClF_5 chlorine pentafluoride	122		
	ClF_3 chlorine trifluoride	299	0,1	0,4
Polyamide (PA) [e] Polyurethane (PU)	NO nitric oxide	115	25	30
	NO_2 nitrogen dioxide	115	5	9
	N_2O_3 nitrogen trioxide	57		
	HCN hydrogen cyanide	140	10	10
	$(CN)_2$ cyanogen	350	10	
Polyethylene (PE) [f]	CO carbon monoxide [g]	3 760	50	55
Polypropylene sulfide (PPS) [h]	H_2S hydrogen sulfide	712	10	15
	CH_3SH methyl mercaptan	1 350		
	COS carbonyl sulfide	1 700		
	SO_2 sulfur dioxide	2 520	5	13
Polyetherether ketone (PEEK) [f]	CO carbon monoxide [g]	3 760	50	55
Ethylene-propylene (EPDM) [f]	CO carbon monoxide [g]	3 760	50	55
	SO_2 sulfur dioxide [i]	2 520	5	13

[a] Assumes complete combustion.
[b] Lethal concentration according to ISO 10298.
[c] Threshold limit value.
[d] The materials in this group contain: carbon, oxygen, hydrogen, chlorine and fluorine.
[e] The materials in this group contain carbon, oxygen, hydrogen and nitrogen.
[f] Contains carbon, oxygen and hydrogen.
[g] Normally transformed into CO_2 because of excess of oxygen.
[h] Contains carbon, oxygen, hydrogen and sulfur.
[i] Possibility of sulfur traces, depending on the manufacturing process.

D.5.1.7 Thermal conductivity

The thermal conductivities of non-metals are typically much lower than those of metals. Dissipation of heat from non-metallic components can be facilitated by close contact with metallic components and by limiting the mass of non-metallic components.

D.5.1.8 Degradation

Non-metals in contact with gases, particularly oxygen, can undergo chemical changes which affect their mechanical properties. Maintenance schedules should take such changes into account.

D.5.1.9 Mechanical impact

Few reactions should occur when tested by mechanical impact.

D.5.1.10 Flame temperature

A material with a low flame temperature is preferred.

D.5.1.11 Flame propagation rate

A material with a low flame-propagation rate is preferred.

D.5.2 Non-metals selection method

D.5.2.1 Selection

To select a material for an application, the application should first be reviewed to determine the probability that the chosen material will be exposed to significant ignition phenomena in service. The material's susceptibility to ignition, and its destructive potential or capacity to involve other materials once ignited, should then be considered together with the potential effects of an ignition on the system environment. Finally, the demands of the application and the level of performance expected from the material should be compared in the context of the necessity to avoid ignition.

D.5.2.2 Principles

The least reactive material available consistent with sound engineering and economic practice should be used. The auto-ignition temperature, oxygen index, mechanical impact ignition and gaseous impact pressure threshold should be maximized. The heat of combustion, total heat release and the toxicity of the products of combustion should be minimized. Not every test need be conducted for every application, but it is advisable to base material selection on more than one test method.

If one or more potential ignition mechanisms have a relatively high probability of occurrence, only materials which have very high resistance to these mechanisms should be used. The higher the maximum operating pressure, the more critical the resistance to ignition.

Low heats of combustion are preferred; heats of combustion of 41 000 J/g or higher are unsuitable for all but the mildest applications.

Materials with high oxygen indices are preferable to materials with low oxygen indices. The use of materials with intermediate oxygen indices is a matter of judgement involving consideration of all significant factors in the particular application.

Experience with a given material in a similar application or with a similar material in the same application frequently forms a sound basis for material selection. However, discretion should be used in the extrapolation of conditions.

Because some materials vary from batch to batch, it may be necessary to test each batch for some applications.

For these reasons medical devices used in oxygen-enriched atmospheres should be designed in such a way that the use of non-metallic materials is minimized.