BS EN ISO 15001:2011

BSI Standards Publication

Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2010)

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN ISO 15001:2011. It is identical to ISO 15001:2010. It supersedes BS EN ISO 15001:2010 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/6, Medical gas supply systems.

A list of organizations represented on this committee can be obtained on request to its secretary.

ISBN 978 0 580 76945 0

ICS 11.040.10

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2011.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15001

October 2011

ICS 11.040.40

Supersedes EN ISO 15001:2010

English Version

Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)

Matériel d'anesthésie et de réanimation respiratoire - Compatibilité avec l'oxygène (ISO 15001:2010)

Anästhesie- und Beatmungsgeräte - Verträglichkeit mit Sauerstoff (ISO 15001:2010)

This European Standard was approved by CEN on 20 September 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 15001:2011: E

Foreword

This document (EN ISO 15001:2011) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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

This document supersedes EN ISO 15001:2010.

This edition contains a revised Annex ZA.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15001:2010 has been approved by CEN as EN ISO 15001:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC Medical Devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
		This standard specifies minimum requirements for the oxygen compatibility of materials components and devices that can come into contact with oxygen in normal or single fault condition. All its requirements aim at minimising the risk of fire/oxidation and the consequences to the patients treated by devices connected to the concerned pipeline/devices system.
4, 5, 6	7.1 first indent	Risks other than risks to patients resulting from combustion/oxidation are not addressed.
4, 5, 6	7.3	Only for aspects of oxygen compatibility.
4, 5, 6	9.2 first indent	Only risks of injury linked with sudden increase of pressure, temperature due to fire are covered.
4, 5, 6	9.3	Only for aspects of oxygen compatibility.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword iv
Introduction v
1* **Scope** 1
2 **Normative references** 1
3 **Terms and definitions** 1
4 **Cleanliness** 2
5* **Resistance to ignition** 3
6 **Risk management** 3
Annex A (informative) **Examples of cleaning procedures** 4
Annex B (informative) **Typical methods for validation of cleaning procedures** 11
Annex C (informative) **Design considerations** 14
Annex D (informative) **Selection of materials** 19
Annex E (informative) **Recommended method for combustion and quantitative analysis of combustion products of non-metallic materials** 32
Annex F (informative) **Rationale** 37
Bibliography 38

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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*.

This second edition cancels and replaces the first edition (ISO 15001:2003), subclauses of which have been technically revised.

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 some non-metals (e.g. plastics, elastomers and lubricants) are toxic and thus patients remote from that equipment and 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, cleaning procedures and correct design and construction of equipment so that it is compatible with oxygen under the conditions of use.

This International Standard gives recommendations for the selection of materials and the cleaning of components made from them, 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 an asterisk (*) 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 and 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* Scope

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

Additionally, this International Standard gives general guidelines for the selection of materials and components based on available data on their oxygen compatibility, and for carrying out a risk analysis, including addressing the toxicity of products of combustion and/or decomposition.

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 at the design, manufacturing, maintenance and disposal stages.

This International Standard does not apply to biocompatibility.

This International Standard is applicable to anaesthetic and respiratory equipment that is 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.

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, *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 d

[ISO 10298:2010, definition 3.1]

3.4
oxygen index
minimum concentration of oxygen by volume percentage 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, definition 3.1]

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 reducing a risk is defective or a single abnormal condition is present

[IEC 60601-1:2009, definition 3.116]

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 according to the current knowledge

3.8
oxygen-enriched mixture
mixture that contains more than 23,5 % volume fraction of oxygen

4 Cleanliness

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

a)* 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 shall determine and ensure that the level of particle contamination is suitable for the intended application(s);

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

- not have a level of hydrocarbon contamination greater than 220 mg/m^2;

- not have particles of size greater than 100 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.

This International Standard does not specify quantifiable cleaning procedures or validation methods for them in relation to the values in a) and b) above. However, Annex A gives examples of known cleaning procedures and Annex B gives examples of methods for validation of cleaning procedures.

NOTE The values of 550 mg/m^2 and 220 mg/m^2 for hydrocarbon contamination are taken from ASTM G93-03[21] and the value of 3 000 kPa is taken from EIGA IGC 33/06/E[49].

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

4.3 Cleaning compounds and methods shall be compatible with the materials, components and devices to be cleaned.

Evidence of compliance shall be provided by the manufacturer upon request.

NOTE Regional or national regulations can require the provision of evidence to a notified body or competent authority upon request.

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

5* 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 × the nominal inlet pressure.

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

NOTE 1 Pneumatic impact test methods are given in ISO 10524-1[5], ISO 10524-2[6], ISO 10524-3[7], ISO 10297[3], ISO 21969[54] and ISO 7291[2] and can be used for similar devices where a device standard does not exist or does not include such a test.

NOTE 2 In the case of pure oxygen, the risk of ignition increases with the pressure. In the case of gas mixtures containing oxygen, the risk of ignition increases with the partial pressure of oxygen.

6 Risk management

6.1 The manufacturer of medical devices shall carry out a risk management process in accordance with ISO 14971. This should include oxygen fire hazards (see Annexes C and D), resistance to ignition (see Clause 5) and toxicity (see Annex E), cleaning procedures (see Annex A), design considerations (see Annex C) and selection of materials (see Annex D).

NOTE 1 ASTM G88-05[20] gives an example of oxygen fire hazard and risk analysis.

NOTE 2 Examples of oxygen fire hazards are given in ASTM G63-99[16] and ASTM G94-05[22].

NOTE 3 Typical “oxygen-compatible” lubricants can generate toxic products during combustion or decomposition.

NOTE 4 Annexes D and E contain information on toxicity.

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.

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 build-up, large quantities of oil, grease and 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 part to be cleaned;

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 to be cleaned;

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 should be tested to ensure that the solvent will not cause damage. If acidic or caustic chemical cleaners are used, it is essential that 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 in order 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 particles, e.g. airless abrasive blast blades or vane-type wheels, pressure blast nozzles or 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 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, all of which 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 contaminants 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 to aid 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 aid 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 systems 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 on to 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 re-used 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 ±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.

NOTE Chromic acid is classified as carcinogenic, mutagenic, very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment.

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 it 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 using 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 inhibitors to control corrosive reactions. The addition of inhibitors 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, pipeworks, etc.

A.3.4.9 Vapour degreasing

Vapour degreasing is the removal of soluble organic materials and subsequent washing 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 inflammable in air under certain conditions and have various degrees of toxicity; caution should therefore 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 water of suitable quality 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 dewpoint 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 a gas 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 the 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 is evaporated to dryness in a weighed vessel without overheating and the vessel is 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 of 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 a 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 of 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 increases the likelihood of 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 even at lower-than-atmospheric pressure, oxygen 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 inflammable, 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 inflammable 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:

$$T_\mathrm{f}/T_\mathrm{i} = (p_\mathrm{f}/p_\mathrm{i})^{(n-1)/n}$$

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 kPa	**Final temperature**[ab] °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 shut-down devices should be provided, where needed, for example on heaters, bearings and compressor heads.

The 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 could occur, 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 a sufficient amount of time, ignition and combustion can occur. The material's minimum ignition temperature and the energy sources that will produce an increase in the 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 inflammability characteristics. These differences in inflammability characteristics are listed in Table D.1.

Table D.1 — Comparison of inflammability 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 greater mass in the device	Low
Surface oxides	Can be protective	Not formed

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 a 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; oxygen dilution is therefore much less.

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, ignition and combustion can occur. Thus, the inflammability 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 here will assume the proper relative significance. To summarize, it depends on the application.

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

In some circumstances there may be no freedom to choose between metallic and non-metallic materials. For example, seal design for high-pressure service necessitates the use of non-metallic materials.

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 recognised 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).

However, it should be noted that sometimes in device design there may be no freedom to choose between metallic and non-metallic materials in certain functions (e.g. seal design for high-pressure service necessitates the use of non-metallic materials).

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)
Aluminium	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	
	Grey 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 STP1197 – 1993[41], Table 2, p. 7.

D.4.1.3 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.4.1.4 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 be 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.4.1.5 Melting-point burn ratio

Since many metals have to be molten in order to burn, 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 the metal to its melting point and provide the latent heat of fusion. It is defined by:

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

where

H_{comb} is the heat of combustion;

$H_{\mathrm{rt\text{-}mp}}$ 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 G94-05-1990[22].

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

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 these 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 values (product of pressure and linear velocity) at ignition which 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 inflammability 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 highly inflammable 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 healthcare 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 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[9]. 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. Also, experience shows that some materials with low auto-ignition temperatures (e.g. polyamides) may perform nearly as well as higher rated materials in some applications. 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 did not occur.

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 risk of ignition. An example is a gasket protruding into the gas stream.

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]

NOTE 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.5.1.6 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 a result of local heating caused by adiabatic compression. Therefore, designers tend to choose materials with the highest possible auto-ignition temperatures in order to maximize the resistance to ignition (e.g. as measured by oxygen pressure shock testing of the assembled device). 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 can generate gaseous combustion products. Hydrocarbons that contain only C, H and O are likely to produce mainly CO_2 and H_2O during combustion in high concentrations of oxygen but incomplete combustion may yield CO. Polymers that also contain N or S 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 F and/or Cl) 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 on to other materials and then slowly released. The gases that 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 that 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). No validated data from the test procedure of Annex E are known to be available.

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 that 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.

Table D.7 — Toxicity data for potential products of combustion and/or decomposition of selected non-metallic materials

Materials	Potential combustion products[a]	LC_{50}[b]	TLV[c]	
		ml/m^3	ml/m^3	mg/m^3
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
Polyetheretherketone (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
Chloroprene rubber (NR, Neoprene)[j]				
Nitrile rubber (NBR, Buna N)[j]				
Flurocarbon rubber (FKM, Vinyledenefluoride hexafluoropropylene, Viton, Fluorel)[j]				

[a] Assumes complete combustion.

[b] Lethal concentration according to ISO 10298[4].

[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] The materials in this group contain 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.

[j] No data available.

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. Some of these requirements may lead to conflicting material selection options, resulting in significant residual risk, even after application of best practices. It is advisable to base material selection on more than one test method. Because the properties and test results of the material itself may not be the best predictors of performance in service, testing of the assembled device (where test procedures exist) should be an essential part of the material selection process.

If one or more potential ignition mechanisms have a relatively high probability of occurrence, only materials that have very high resistance to these mechanisms should be used. The higher the maximum operating pressure, the more critical the resistance to ignition. This may present a conflict with the need to minimize the toxicity of the products of combustion. It may not be possible to resolve this conflict with currently available data and test methods.

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.

Annex E
(informative)

Recommended method for combustion and quantitative analysis of combustion products of non-metallic materials

E.1 General

A method is described for the combustion of non-metallic materials under specified conditions and the analysis of the combustion products.

E.2 Principle

Combustion in pure oxygen is obtained by adiabatic compression at 24 000 kPa and 60 °C. If the nature of the material tested is unknown or imprecisely known, it is important that the material first be tested to determine the approximate amount of energy that is released during the adiabatic compression test. The hot wire test gives an estimate of this.

E.3 Hot wire test

The test apparatus is shown in Figure E.1.

Place 0,5 g of the material to be studied, divided into fine particles, in a sample holder and place it in an enclosure through which a stream of pressurized oxygen at ambient temperature flows at a rate of 6 l/min. Place a tungsten filament, which can be heated to three different temperatures (500 °C, 900 °C and 1 200 °C) in contact with the material.

Examine the nature of the reaction with the material, according to the following decreasing order of reaction:

a) explosion;

b) strong combustion;

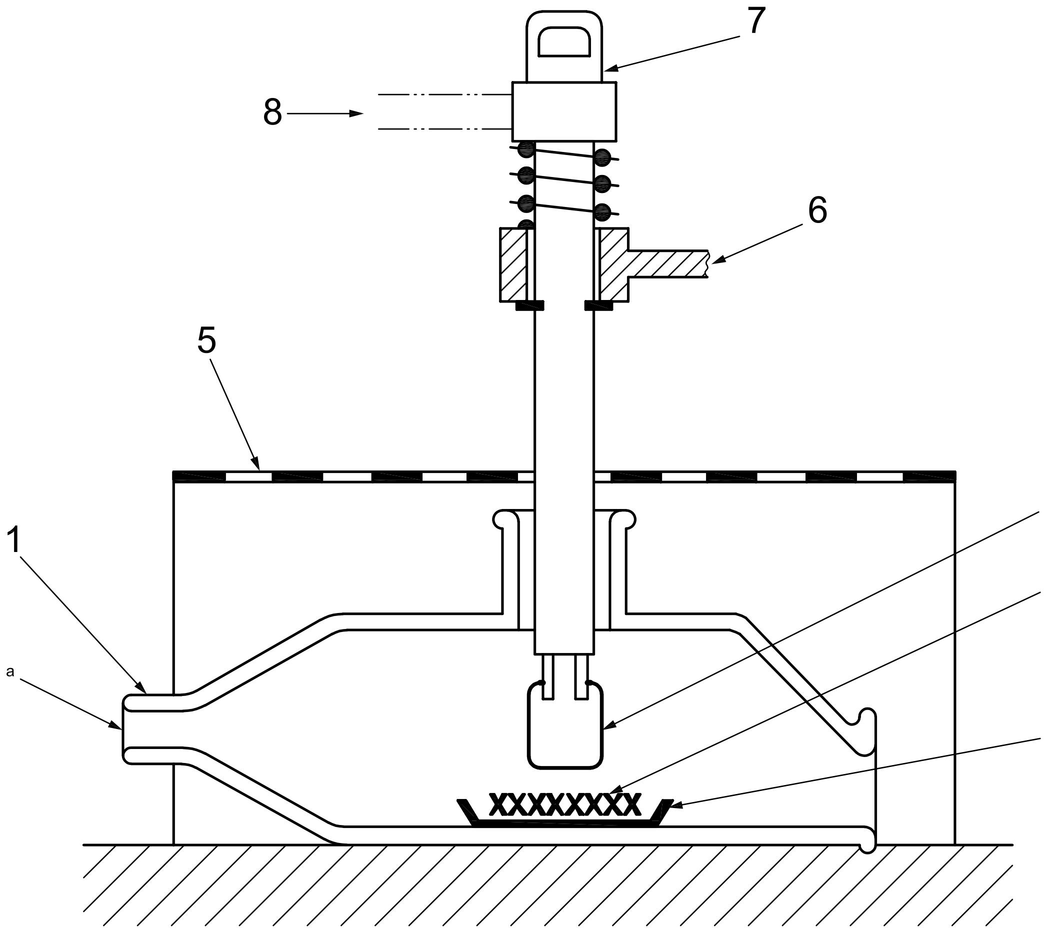
c) combustion;

d) difficult combustion;

e) slow combustion;

f) no combustion.

Record the reaction type for each temperature.



Key

1	glass enclosure	5	protection grid
2	sample container	6	fixed threaded support
3	test sample	7	handle
4	hot wire (tungsten filament)	8	rheostat

[a] Oxygen supply.

Figure E.1 — Apparatus for hot wire test

E.4 Adiabatic compression test

WARNING — The adiabatic compression test of a material at 24 000 kPa **and** 60 °C **can release considerable energy, depending on the type of material tested, and therefore there is a risk of explosion, fire or destruction of the test equipment.**

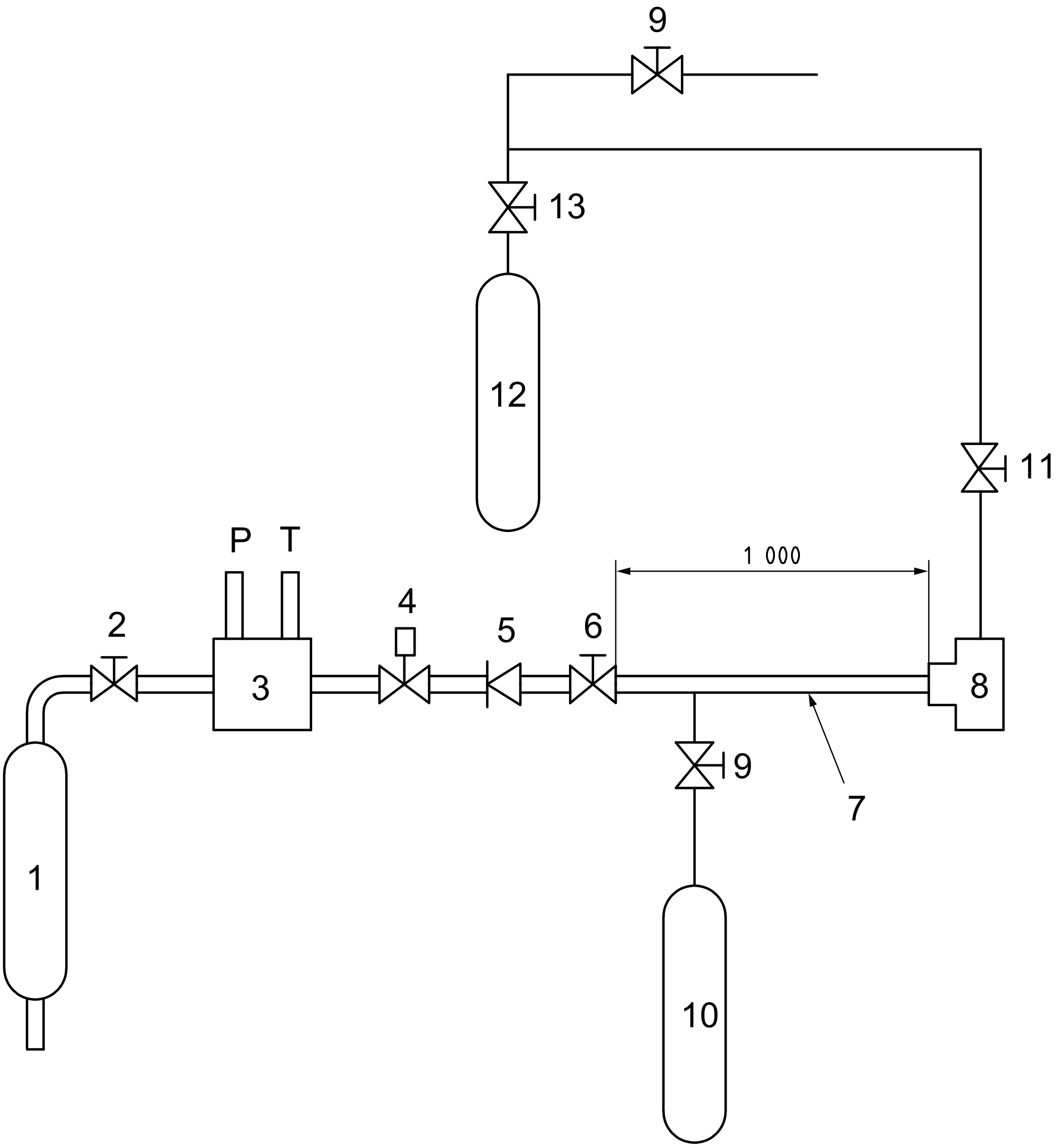
E.4.1 Test apparatus

The test apparatus is shown in Figure E.2.

The test apparatus consists of an oxygen supply (1) connected, via an inlet valve (2), to a vessel equipped with a preheating device (3) which heats the oxygen to 60 °C.

Oxygen at 60 °C is brought into contact with the material to be tested via a 5 mm diameter, 1 000 mm long copper connection tube (7), which is opened and closed by a quick-opening valve (4).

Dimensions in millimetres



Key

1	oxygen supply	9	purging valve
2	inlet valve	10	purging cylinder
3	vessel with preheating device	11	shut-off valve
4	quick-opening valve	12	sampling cylinder
5	check valve	13	cylinder valve
6	shut-off valve	P	pressure transducer
7	connection tube	T	thermometer
8	sample holder (see Figure E.3)		

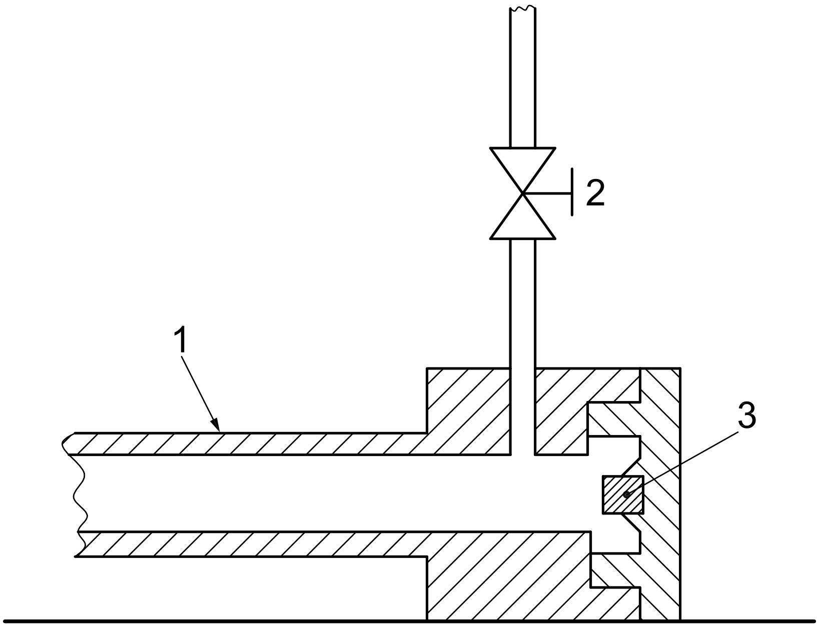
Figure E.2 — Test apparatus for combustion by adiabatic compression

A check valve (5) and a shut-off valve (6) are provided to isolate the test sample and the combustion products released.

The sample holder (8) enables the sampling of the solid or liquid residues, with no risk of loss and as few angles or recesses as possible, to ensure that adiabatic compression has a direct impact on the sample. A section of a typical sample holder is shown in Figure E.3.

A purging assembly (9 and 10) is used to purge the connection tube, the sample holder and combustion products sampling line with oxygen before beginning the adiabatic compression test.

During adiabatic compression, the sample holder is isolated downstream by a shut-off valve (11). After the adiabatic compression, this valve is opened to allow the combustion products to flow into the sampling system. The sampling system can vary, depending upon the method of analysis.



Key

1 connection tube
2 shut-off valve
3 test sample

Figure E.3 — Section of a typical sample holder

E.4.2 Test procedure

E.4.2.1 Test sample

Prepare the requisite number of test samples (at least three) to achieve acceptable reproducibility of combustion product analyses. Unless otherwise indicated by the results of the hot wire test, use samples of mass (0,5 ± 0,05) g. If the hot wire test indicates that too much energy is released by 0,5 g of sample, reduce the mass of the samples accordingly. Do not divide the samples.

Place the sample to be tested in the sample holder (8). Position the sample so that it does not block or hinder the flow of the purging gases to the sampling line. It is important to ensure that any material used to seal the sample holder (e.g. PTFE tape) is not ignited during the adiabatic compression.

E.4.2.2 Combustion test

Purge the test and sampling systems with oxygen.

Close the shut-off valve (11) downstream of the sample holder.

Heat the oxygen to (60 ± 3) °C in the oxygen-preheating device. Open the quick-opening valve (4) to subject the test sample to an increase in pressure from atmospheric pressure to maximum test pressure (24 000 kPa) in a time of $(20_{-5}^{\ 0})$ ms. After the adiabatic compression, close the shut-off valve (6) to prevent any leakage of the combustion products.

Open the shut-off valve (11) to fill the sampling cylinder (12) and flush the gaseous combustion products from the connection tube and sample holder (8) into the sampling cylinder (12).

Close the shut-off valve (11) to isolate the sampling system.

Disassemble the sample holder (8), rinse it with an appropriate solvent and collect the solid and liquid residues for analysis.

Dry the sample holder (8), insert the second sample and connect it to the apparatus.

Re-open the shut-off valve (6), purge the system, replace the sampling cylinder and repeat the test procedure.

E.4.2.3 Quantitative analysis

Quantitative analysis of combustion products should be performed. ISO 19701[52] provides guidance for quantifying the concentration in the gas sampled.

All quantification (mass balances) should be on the basis of material masses in the product which could actually combust.

Annex F
(informative)

Rationale

The following corresponds to the clauses and subclauses in this International Standard marked with an asterisk. The numbering is, therefore, not consecutive.

F.1 The value of 50 kPa is based upon the practical experience that components of breathing systems do not create a fire hazard under normal or single fault conditions. For components of medical electrical equipment operating at pressures below 50 kPa, fire prevention is covered by particular standards.

F.4.1 Several values of cleanliness level are given in ASTM G93-03[21], ranging from 11 mg/m^2 to 550 mg/m^2 of hydrocarbons. However, experience has shown that for applications covered by this International Standard, the values given in this subclause from the “General upper limit case” in ASTM G93-03 are satisfactory and are equivalent to those in guidelines for industrial practice (see, for example, EIGA IGC 33/06/E[49]).

F.4.1 a) Within the pressure range of 50 kPa to 3 000 kPa, the presence of particles is not believed to be an ignition hazard, but other problems such as leaks past seals may require control of particle contamination.

F.4.1 b) Control of particulate contamination is important to reduce the risk of ignition at pressures greater than 3 000 kPa.

F.5 Devices (e.g. line pressure regulators for medical gas pipeline systems) can normally be supplied with gas at inlet pressures up to 1 500 kPa. In the single fault condition, pressures up to 3 000 kPa may be supplied to the devices. However, only a small rise in temperature can be expected due to such an increase in pressure. Therefore, devices designed for use at pressures less than 3 000 kPa do not need to have pneumatic impact testing.

Bibliography

[1] ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

[2] ISO 7291, *Gas welding equipment — Pressure regulators for manifold systems used in welding, cutting and allied processes up to 30 MPa (300 bar)*

[3] ISO 10297, *Transportable gas cylinders — Cylinder valves — Specification and type testing*

[4] ISO 10298:2010, *Determination of toxicity of a gas or gas mixture*

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

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

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

[8] ISO 11114-1, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 1: Metallic materials*

[9] ISO 11114-3, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere*

[10] ISO 4589-1, *Plastics — Determination of burning behaviour by oxygen index — Part 1: Guidance*

[11] ISO 4589-2:1996, *Plastics — Determination of burning behaviour by oxygen index — Part 2: Ambient-temperature test*

[12] ISO 4589-3, *Plastics — Determination of burning behaviour by oxygen index — Part 3: Elevated-temperature test*

[13] EN 13348, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

[14] ASTM B819-00, *Standard Specification for Seamless Copper Tube for Medical Gas Systems*

[15] ASTM D2863-00, *Standard Test Method for Measuring the Minimum Oxygen Concentration to Support Candle-Like Combustion of Plastics (Oxygen Index)*

[16] ASTM G63-99, *Standard Guide for Evaluating Nonmetallic Materials for Oxygen Service*

[17] ASTM G72-01, *Standard Test Method for Autogenous Ignition Temperature of Liquids and Solids in a High-Pressure Oxygen-Enriched Environment*

[18] ASTM G74-08, *Standard Test Method for Ignition Sensitivity of Materials to Gaseous Fluid Impact*

[19] ASTM G86-98a, *Standard Test Method for Determining Ignition Sensitivity of Materials to Mechanical Impact in Ambient Liquid Oxygen and Pressurized Liquid and Gaseous Oxygen Environments*

[20] ASTM G88-05, *Standard Guide for Designing Systems for Oxygen Service*

[21] ASTM G93-03, *Standard Practice for Cleaning Methods and Cleanliness Levels for Materials and Equipment Used in Oxygen-Enriched Environments*

[22] ASTM G94-05, *Standard Guide for Evaluating Metals for Oxygen Service*

[23] ASTM G114-07, *Standard Practices for Evaluating the Age Resistance of Polymeric Materials Used in Oxygen Service*

[24] ASTM G120-01, *Standard Practice for Determination of Soluble Residual Contamination by Soxhlet Extraction*

[25] ASTM G122-96, *Standard Test Method for Evaluating the Effectiveness of Cleaning Agents*

[26] ASTM G124-95, *Standard Test Method for Determining the Combustion Behavior of Metallic Materials in Oxygen-Enriched Atmospheres*

[27] ASTM G125-00, *Standard Test Method for Measuring Liquid and Solid Material Fire Limits in Gaseous Oxidants*

[28] ASTM G126-00, *Standard Terminology Relating to the Compatibility and Sensitivity of Materials in Oxygen Enriched Atmospheres*

[29] ASTM G127-95, *Standard Guide for the Selection of Cleaning Agents for Oxygen Systems*

[30] ASTM G128-02, *Standard Guide for Control of Hazards and Risks in Oxygen Enriched Systems*

[31] ASTM G131-96, *Standard Practice for Cleaning of Materials and Components by Ultrasonic Techniques*

[32] ASTM G144-01, *Standard Test Method for Determination of Residual Contamination of Materials and Components by Total Carbon Analysis Using a High Temperature Combustion Analyzer*

[33] ASTM G145-08, *Standard Guide for Studying Fire Incidents in Oxygen Systems*

[34] ASTM Manual Series: MNL 36, 2nd ed. *Safe Use of Oxygen and Oxygen Systems: Guidelines for Oxygen System Design, Materials Selection, Operations, Storage, and Transportation*

[35] ASTM G175-03, *Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications*

[36] ASTM STP812, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* First Volume: 1983

[37] ASTM STP910, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* Second Volume: 1986

[38] ASTM STP986, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* Third Volume: 1988

[39] ASTM STP1040, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* Fourth Volume: 1989

[40] ASTM STP1111, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* Fifth Volume: 1991

[41] ASTM STP1197, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* Sixth Volume: 1993

[42] ASTM STP1267, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* Seventh Volume: 1995

[43] ASTM STP1319, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres.* Eighth Volume: 1997

[44] ASTM STP1395, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres,* Ninth Volume, 2000

[45] ASTM STP1454, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres,* Tenth Volume, 2003

[46] ASTM STP1479, *Flammability and Sensitivity of Materials in Oxygen-Enriched Atmospheres,* Eleventh Volume, 2006

[47] BS 6869:1987, *Code of practice for procedures for ensuring the cleanliness of industrial-process measurement and control equipment in oxygen service*

[48] CGA V-9:2009, *Compressed Gas Association Standard for Compressed Gas Cylinder Valves*

[49] EIGA IGC 33/06/E, *Cleaning of equipment for oxygen service — Guideline*

[50] NFPA 53, *Recommended practice on materials, equipment, and systems used in oxygen-enriched atmospheres*, 2004

[51] Proceedings of ASTM G4: *Toxicity of Fluorinated and Chlorinated Polymers Used in Breathing Gas Service*, Pittsburgh, PA, March 12, 2002

[52] ISO 19701, *Methods for sampling and analysis of fire effluents*

[53] IEC 60601-1:2009, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

[54] ISO 21969, *High-pressure flexible connections for use with medical gas systems*

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards-based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

All the data, software and documentation set out in all British Standards and other BSI publications are the property of and copyrighted by BSI, or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means – electronic, photocopying, recording or otherwise – without prior written permission from BSI. Details and advice can be obtained from the Copyright & Licensing Department.

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

...making excellence a habit.™