UL 61010-2-040

STANDARD FOR SAFETY

Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials

UL Standard for Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials, UL 61010-2-040

Third Edition, Dated February 17, 2021

Summary of Topics

Adoption of IEC 61010-2-040, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials, (third edition, issued by IEC May 2020) as a new IEC-based UL standard, UL 61010-2-040 with No US Differences.

The new requirements are substantially in accordance with Proposal(s) on this subject dated October 23, 2020.

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UL 61010-2-040

Standard for Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials

Second Edition – January, 2016

Third Edition

February 17, 2021

This ANSI/UL Standard for Safety consists of the Third Edition.

The most recent designation of ANSI/UL 61010-2-040 as an American National Standard (ANSI) occurred on February 17, 2021. ANSI approval for a standard does not include the Cover Page, Transmittal Pages, Title Page, Preface or the IEC Foreword.

Comments or proposals for revisions on any part of the Standard may be submitted to UL at any time. Proposals should be submitted via a Proposal Request in UL's On-Line Collaborative Standards Development System (CSDS) at https://csds.ul.com.

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Preface (UL)

This UL Standard is based on IEC Publication 61010-2-040: third edition Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials. IEC publication 61010-2-040 is copyrighted by the IEC.

Efforts have been made to synchronize the UL edition number with that of the corresponding IEC standard with which this standard is harmonized. As a result, one or more UL edition numbers have been skipped to match that of the IEC edition number.

This UL Standard 61010-2-040 Standard for Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials, is to be used in conjunction with the third edition of UL 61010-1. The safety requirements for electrical equipment intended for sterilization, washing, and disinfection of medical materials are contained in this Part 2 Standard and UL 61010-1.

Requirements of this Part 2 Standard, where stated, amend the requirements of UL 61010-1.

Where a particular subclause of UL 61010-1 is not mentioned in UL 61010-2-040, the UL 61010-1 subclause applies.

Note – Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.

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FOREWORD

INTERNATIONAL ELECTROTECHNICAL COMMISSION

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE – Part 2-040: Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

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

International Standard IEC 61010-2-040 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) it is established on the basis of the third edition (2010) of IEC 61010-1 and its Amendment 1 (2016);

b) added tolerance for stability of a.c. voltage test equipment to 6.8.3.1;

c) the status of a Group Safety Publication has been removed (this does not change the technical requirements in the document).

The text of this International Standard is based on the following documents:

CDV	Report on voting
66/699/CDV	66/716/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

The reader's attention is drawn to the fact that Annex G lists all of the "in-some-country" clauses on differing practices of a less permanent nature relating to the subject of this standard.

A list of all parts in the IEC 61010 series, published under the general title *Safety requirements for electrical equipment for measurement, control, and laboratory use*, can be found on the IEC website.

This Part 2-040 is to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) of IEC 61010-1 and its Amendment 1 (2016), hereinafter referred to as Part 1.

This Part 2-040 supplements or modifies the corresponding clauses in Part 1 so as to convert that publication into the IEC standard: *Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials*.

Where a particular subclause of Part 1 is not mentioned in this Part 2-040, that subclause applies as far as is reasonable. Where this Part 2-040 states "addition", "modification", "replacement", or "deletion", the relevant requirement, test specification or note in Part 1 shall be adapted accordingly.

In this standard:

1) the following print types are used:

– requirements: in roman type;

– NOTES: in small roman type;

– conformity and test: *in italic type*;

– terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.

2) subclauses, figures, and tables which are additional to those in Part 1 are numbered starting from 101; additional annexes are lettered starting from AA and additional list items are lettered from aa).

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore. iec. ch" in the data related to the specific document. At this date, the document will be

• reconfirmed,
• withdrawn,
• replaced by a revised edition, or
• amended.

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE – Part 2-040: Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Equipment included in scope

Replacement:

Replace the existing text with the following:

This part of IEC 61010 specifies safety requirements for electrical equipment intended for sterilization, washing, and disinfection of medical materials in the medical, veterinary, pharmaceutical and laboratory fields, when used under the environmental conditions of 1.4.

Examples of such equipment include the following:

a) STERILIZERS and disinfectors using steam and/or hot water as the sterilant;

b) STERILIZERS and disinfectors using toxic gas, toxic aerosol or toxic vapour as the sterilant;

c) STERILIZERS and disinfectors using hot air or hot inert gas as the sterilant; and

d) WASHER-DISINFECTORS.

1.1.2 Equipment excluded from scope

Addition:

Add the following note to item f):

NOTE IEC 60601-1:2005, 3.63, defines "medical electrical equipment" as follows (notes to entry are omitted):

Electrical equipment, having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

a) provided with not more than one connection to a particular supply MAINS; and

b) intended by its manufacturer to be used:

1) in the diagnosis, treatment, or monitoring of a patient; or

2) for compensation or alleviation of disease, injury or disability.

Addition:

Add the following new second paragraph after the lettered list:

This document does not apply to the following types of equipment:

aa) equipment for use in hazardous atmospheres (see IEC 60079); however this document does apply to an atmosphere created inside equipment by a flammable sterilizing agent (see 13.2.101 and 13.2.102);

bb) laboratory equipment for the heating of materials for purposes other than sterilization or disinfection (see IEC 61010-2-010);

cc) laundry equipment (see IEC 60335-2-4, IEC 60335-2-7, IEC 60335-2-11, and ISO 10472 (all parts)), unless designed for disinfecting medical materials;

dd) dishwashers (see IEC 60335-2-5 and IEC 60335-2-58).

1.2.1 Aspects included in scope

Replacement:

Replace item g) with the following new text:

g) liberated gases (including the non-intentional escape of toxic gas), pathogenic substances, explosion and implosion (see Clause 13).

1.2.2 Aspects excluded from scope

Addition:

Add the following two new items:

aa) special requirements for protection against chemical and high-risk micro-biological HAZARDS associated with the LOAD;

bb) general requirements for the design of calorifiers, shell boilers and PRESSURE VESSELS.

NOTE National and other regulations or codes apply for the safety of calorifiers, shell boilers and PRESSURE VESSELS (see 14.101).

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references:

IEC 61770, *Electric appliances connected to the water mains – Avoidance of backsiphonage and failure of hose-sets*

ISO 3585, *Borosilicate glass 3.3 – Properties*

ISO 4126-1, *Safety devices for protection against excessive pressure – Part 1: Safety valves*

ISO 4126-2, *Safety devices for protection against excessive pressure – Part 2: Bursting disc safety devices*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.2 Parts and accessories

Addition:

Add the following new terms and definitions:

3.2.101
CHAMBER
part of the equipment which receives the LOAD

3.2.102
LOAD
equipment or materials put into a CHAMBER to be processed through an OPERATING CYCLE

3.2.103
STERILIZER
equipment designed to achieve sterilization which comprises a series of actions or operations needed to achieve the specified requirements for sterility

3.2.104
PRESSURE VESSEL
assembly comprising the CHAMBER, the jacket (if fitted), doors, and all other components in permanent open connection with the CHAMBER

Note 1 to entry: The PRESSURE VESSEL does not include parts from which it can be isolated, such as steam generators, pipework, and fittings.

3.2.105
OPERATING CYCLE
complete set of stages of the process that is carried out in a specified sequence

Note 1 to entry: Loading and unloading are not part of the OPERATING CYCLE.

3.2.106
WASHER-DISINFECTOR
equipment intended to clean and disinfect medical devices and other articles used in the context for example of medical, dental, pharmaceutical and veterinary practice

3.5 Safety terms

3.5.2
HAZARD

Addition:

Add the following new Note 1 to entry:

Note 1 to entry: In the context of this document, the term HAZARD relates only to potential sources of harm to the OPERATOR and surroundings (see 1.2.1), and does not include potential sources of harm related to the efficacy of the process.

3.5.11
OPERATOR

Addition:

Add the following Note 1 to entry:

Note 1 to entry: An OPERATOR includes persons installing, operating, adjusting, maintaining, cleaning, repairing or moving equipment.

4 Tests

This clause of Part 1 is applicable except as follows:

4.3.2.4 Covers and removable parts

Addition:

Add the following new second paragraph:

Covers including panels and control box ENCLOSURES which do not require the use of a TOOL for removal need not be removed if they have interlocks which meet the requirements of Clause 15, and which automatically de-activate all parts which would otherwise present a HAZARD when the cover is opened.

4.3.2.12 Duty cycle

Addition:

Add the following new second paragraph:

Equipment which can be operated continuously shall also be tested without any interval between consecutive OPERATING CYCLES.

Addition:

Add the following new subclause:

4.3.2.101 Non-electrical supplies and services

Non-electrical supplies and services shall be set to the least favourable RATED settings.

4.4.2.1 General

Replacement:

Replace the first sentence of the first paragraph with the following sentence:

Fault conditions shall include those specified in 4.4.2.2 to 4.4.2.14 and 4.4.2.101 to 4.4.2.103.

4.4.2.5 Motors

Addition:

Add the following new second paragraph:

If it is impracticable to test a motor when installed, a separate identical motor can be tested but it shall be tested in the same conditions that exist inside the equipment.

4.4.2.13 Interlocks

Addition:

Add the following new second paragraph:

If an interlock provides protection against accidental contact with a hazardous substance, the interlock is tested using a non-hazardous substance.

Addition:

Add the following three new subclauses:

4.4.2.101 Pressure controllers

Pressure controllers, except for overpressure safety devices meeting the requirements of 11.7.4, shall be overridden to supply the service continuously.

4.4.2.102 Failure, or partial failure, of the MAINS supply

The equipment shall be operated at 90 % and 110 % of the RATED voltage for one cycle. The voltage shall then be set to 90 % of the RATED voltage for 5 min. The voltage shall then be reduced gradually at a rate of approximately 10 V per min until the equipment fails to operate normally. The voltage shall then be reset to the RATED voltage with the equipment still switched on.

4.4.2.103 Failure, or partial failure, of other supplies and services

In turn, each non-electrical supply and service shall be interrupted, or partially interrupted, whichever is less favourable.

NOTE Examples include air, steam, feedwater, sterilant gas, detergent, disinfectant, and systems for drainage, exhaust, and ventilation.

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

5.1.2 Identification

Replacement:

Replace the existing text by the following:

The equipment shall as a minimum be marked with the following:

a) the name and address of the manufacturer;

b) any additional markings required by national and local regulations, including the name and address of the manufacturer's authorized representative in the country of intended use;

c) a marking that uniquely identifies the individual unit of manufacture such as a serial number;

d) year and place of manufacture, if different from manufacturer's address;

e) model identification;

f) designated purpose of the equipment.

Conformity is checked by inspection

Addition:

Add the following two new subclauses:

5.1.101 Overpressure protective device

The device (see 11.7.4) shall be marked with the name of the manufacturer of the device, the model number, and the pressure to which it is set. If a bursting disc is located between the CHAMBER and the overpressure safety device, the disc shall be marked with its specified bursting pressure and associated temperature.

NOTE National, local regulations and other codes can apply.

5.1.102 PRESSURE VESSELS and shell boilers

Attention is drawn to the existence of national and local regulations that can require additional markings.

5.2 Warning markings

Addition:

Add the following new second paragraph:

Warning and caution symbols shall be at least 10 mm high.

5.4.1 General

Replacement:

Replace the first paragraph (excluding lettered list) by the following new paragraph:

The following documentation necessary for safety purposes, as needed by the OPERATOR or RESPONSIBLE BODY, shall be marked with its date of issue or revision status and be provided with the equipment:

Add the following new paragraph after item h) of the lettered list:

If NORMAL USE involves the handling of a hazardous substance, documentation shall include information on constituents, correct storage, use, and safe disposal.

Replace Note 2 by the following new Note 2:

NOTE 2 Attention is drawn to the existence of national and local regulations that can apply to the documentation.

Add a new paragraph directly before the conformity statement:

Marking, information, and language shall:

1) comply with regulations applying in the country of intended use;

NOTE **3** ISO 15223-2 offers guidance for equipment classified as a medical device.

2) include instructions for the disposal of the equipment, its accessories and its packaging;

3) give due consideration to the technical knowledge, education and training of different OPERATOR categories;

4) not contradict information contained in documentation provided to describe the equipment.

5.4.2 Equipment RATINGS

Addition:

Add the following new item to the lettered list after item f):

aa) for each non-electrical service, if applicable, the RATED ranges of temperature, pressure and flow-rate.

5.4.3 Equipment installation

Replacement:

Replace items a) to g) with the following:

a) location and mounting instructions;

b) space required for safe and efficient maintenance;

c) individual weights of principal heavy subassemblies;

d) overall weight and floor loading requirements;

e) unpacking and assembly instructions (see also 7.108);

f) MAINS supply requirements and connections, including the temperature rating of any cable required to meet the requirements in 5.1.8;

g) for PERMANENTLY CONNECTED EQUIPMENT:

1) supply wiring requirements;

2) requirements for any external switch or circuit-breaker (see 6.11.3.1) and external overcurrent protection devices (see 9.6.1) and a recommendation that the switch or circuit-breaker be near the equipment;

h) ventilation requirements (see 11.101, 13.1.103.1, and 13.1.101);

i) drainage requirements (see 11.101);

j) instructions for protective earthing;

k) instructions relating to sound level (see 12.5.1);

l) requirements for special services, for example air, feedwater, cooling liquid;

m) requirements related to hazardous gas atmospheres (see Clause 13);

n) instructions to position the equipment so that it is not difficult to operate the disconnecting device;

o) instructions relating to the handling and containment of hazardous substances, including any need for additional equipment that can be required to control emissions (see 13.1);

p) instructions relating to HAZARDS caused by liquids or hot items falling from the equipment (see 9.1);

q) requirements for material used in the installation of the equipment and which can come into contact with sterilant (see 13.1.103.4 and 13.2.101);

r) instructions for ambient illumination (see also 11.102);

NOTE ISO 12100 and EN 1837 give guidance on lighting.

s) instructions relating to heat emission.

Addition:

Add the following new subclause:

5.4.3.101 Special systems

Installation instructions shall include details of the following special systems, if needed to protect against possible HAZARDS:

a) non-recirculating ventilation system for the room in which the equipment is installed (also see 13.1.103.3);

Such a ventilation system shall normally give a minimum of 10 air changes per hour, but for large installations this may need to be increased.

b) for equipment using toxic sterilant, means to protect against HAZARDS arising from failure of the room ventilation system (see 13.1.103.3);

c) a non-recirculating local exhaust system to remove fugitive emissions (see 13.1.101.4);

d) a drainage system (see 13.1.101.3);

e) a venting system for the drain (see 13.1.101.3);

f) a CHAMBER exhaust system (see 13.1.101.2);

g) a system used to control escaping biological emissions (see 13.1.104);

h) any other supply, for example sterilant, steam, compressed air, hot or cold water (including instructions on the prevention of backsiphonage (see 11.104).

Conformity is checked by inspection.

5.4.4 Equipment operation

Replacement:

Replace items a) to j) with the following:

a) identification of operating controls and their use in all operating modes;

b) an instruction not to position the equipment so that it is difficult to operate the disconnecting device;

c) instructions for interconnection to accessories and other equipment, including details of suitable accessories, detachable parts and any special materials;

d) specification of limits for intermittent operation;

e) an explanation of symbols related to safety which are used on the equipment (see 5.2);

f) instructions for cleaning (see 11.2);

g) instructions for making the equipment safe after an incomplete OPERATING CYCLE;

h) instructions for the correct use of the lockable door closure prevention device (see 7.102 b));

i) instructions to the RESPONSIBLE BODY for safe access to the LOAD in the CHAMBER in the event of a fault (see 13.1.102);

j) instructions for action in case of a malfunction, including fault diagnosis;

NOTE 1 These instructions can include any special methods of interpreting data recorded or noted during the OPERATING CYCLE, to detect failure or trends that can lead to failure, for example the use of a temperature recorder.

k) loading procedure;

l) instructions for safe disposal of parts such as detergent containers, sterilant containers and parts contaminated by pathogenic material;

NOTE 2 Additional requirements on methods of disposal can be specified by national or local authorities.

m) instructions for testing the function of critical safety devices in a safe manner, for example overpressure safety devices (see 11.7.4);

n) if NORMAL USE involves the handling of substances, instructions on correct use and safety provisions. In addition, instructions shall be given on methods of safe handling before disposal, and recommendations on disposal (also see Note 2 above);

o) details of methods of reducing burn HAZARDS from surfaces permitted to exceed the temperature limits specified in Table 19;

p) guidelines to be followed in cases of emergency in which eye or skin contact or inhalation could occur, such as release of toxic material or pathogenic material, or leakage from a sterilizing agent container or disinfectant container or enzymatic, alkaline or acidic detergent container;

These guidelines shall also be prominently displayed on or near the equipment

q) instructions for safely replenishing containers of dosing chemicals (see 13.102);

r) if a HAZARD could result from the use of equipment with a type of LOAD other than those for which it is intended, there shall be an appropriate warning in the instructions, and a warning marking (see 5.2) shall state the types of LOAD which can be used. If small equipment has insufficient space for this warning marking, symbol 14 of Table 1 shall be marked;

s) instructions for inspection, replenishment, and storage of consumable materials which could cause a HAZARD, including details of HAZARDS which could arise from the introduction of incorrect quantities of recommended consumable materials, also procedures and details of the protection needed to minimize such HAZARDS;

t) identification of residual RISKS and instructions on necessary protective procedures (see Clause 17).

5.4.5 Equipment maintenance and service

Replacement:

Replace the existing text with the following new text:

Instructions shall be provided to the RESPONSIBLE BODY in sufficient detail to permit safe maintenance, inspection and testing of the equipment and to ensure continued safety of the equipment after the maintenance, inspection and test procedure.

Instructions shall include:

a) details of maintenance required on parts subject to wear and tear if failure could lead to a HAZARD;

b) inspection and replacement, if necessary, of any hoses/pipes or other parts containing fluids, if their failure could cause a HAZARD;

c) details of safety devices fitted together with their settings and replacement procedures;

d) procedures for making the equipment safe prior to maintenance;

e) maintenance schedules and repair procedures, including ambient lighting level (see 11.102) and any special precautions necessary to protect against HAZARDS during maintenance;

f) methods of safe handling for repair or disposal of any part containing or contaminated by toxic and/or pathogenic material;

NOTE 1 Requirements on methods of disposal can be specified by national or local authorities.

NOTE 2 Aspects of environmental impact are addressed in ISO 14971 and in applicable parts of IEC 61508.

g) battery types for equipment using replaceable batteries;

h) RATINGS and characteristics of replaceable fuses;

i) a list of parts (if any), restricted to examination and/or supply by the manufacturer or the manufacturer's agent;

j) residual RISKS (see Clause 17) and protective measures for these RISKS;

k) verification of the safe state of the equipment after repair.

Conformity is checked by inspection.

Addition:

Add the following two new subclauses:

5.4.101 OPERATOR training

5.4.101.1 General

In order that OPERATORS be adequately trained in the safe use of the equipment, the manufacturer's instructions shall state that the RESPONSIBLE BODY should ensure:

a) that all personnel who operate or maintain the equipment are trained in its operation and in its safe use;

b) that, if exposure limits (i. e. short-term exposure limit (STEL) or long-term exposure limit (LTEL)) or permissible working environmental concentration limit (see the notes to 13.1) could be exceeded during NORMAL USE, personnel working with toxic chemicals, gases, and vapours are given comprehensive instructions in the process. These instructions include information on relevant health HAZARDS, national regulations, methods for safe use, and methods to detect escape of the agent;

c) that there is regular training of all personnel concerned with the operation and maintenance of the equipment, including emergency procedures for any toxic, flammable, explosive or pathogenic material released into the environment. Records of attendance at training are maintained, and evidence of understanding demonstrated.

Also see 7.3.2 b).

Conformity is checked by inspection.

5.4.101.2 Procedures for potentially hazardous actions

The manufacturer shall specify safety procedures for any potentially hazardous actions intended to be carried out by an OPERATOR, for example the replacement of parts or the adjustment of internal controls. The instructions shall specify that the RESPONSIBLE BODY must provide OPERATORS with training in these procedures.

Conformity is checked by inspection.

6 Protection against electric shock

This clause of Part 1 is applicable except as follows:

6.2.2 Examination

Addition:

Add the following new third paragraph after Figure 1:

FIXED EQUIPMENT, and equipment with a weight exceeding 80 kg, is not tilted or moved in order to check the bottom, but the test finger is applied to any part of the bottom that can be reached when the equipment is installed according to the manufacturer's instructions.

6.8.3.1 The a.c. voltage test

Replacement:

Replace the first sentence with the following sentence:

The voltage tester shall be capable of maintaining the test voltage throughout the test within ±5 % of the specified value.

6.9.2 Insulating materials

Addition:

Add the following new note at the end of the subclause, before the conformity statement:

NOTE Although ceramics can provide satisfactory electrical insulation at ambient temperature, attention is drawn to the possibility that some ceramics show reduced insulating properties at high temperatures. This is not only because they are susceptible to progressive mechanical deterioration, but also because they can become electrically conductive at high temperatures and in NORMAL USE can be contaminated by conductive material.

7 Protection against mechanical HAZARDS

This clause of Part 1 is applicable except as follows:

Replacement:

Replace the title with the following new title:

7 Protection against mechanical HAZARDS and against HAZARDS related to mechanical functions

7.1 General

Replacement:

Replace the conformity statement with the following new conformity statement:

Conformity is checked as specified in 7.2 to 7.7 and in 7.101 to 7.110.

7.4 Stability

Addition:

Add the following new item to the lettered list, after the note in item e):

aa) For equipment with a door which, when open, is horizontal or nearly horizontal, and which could be used to support the LOAD, a weight equal to 1,2 times the heaviest RATED LOAD (specified in the instruction manual) is applied to, or suspended from, the centre of the open door.

7.5 Provisions for lifting and carrying

Addition:

Add the following new subclause:

7.5.101 Transfer of LOADS into and out of the CHAMBER

Means shall be provided to protect the OPERATOR against mechanical HAZARDS that could arise during transfer of the LOAD into or out of the CHAMBER.

Means shall be provided to locate and retain the LOAD and its carrier (if any) in the correct position for transfer of the LOAD into or out of the CHAMBER.

If a sliding shelf within the CHAMBER has to be pulled out to accept the LOAD or permit its withdrawal, means shall be provided to prevent the shelf from tilting or becoming unintentionally disengaged when pulled out.

The force required by an OPERATOR to put the LOAD into the CHAMBER or to remove it from the CHAMBER shall not exceed 250 N.

Conformity is checked by inspection and test, using the least favourable LOAD specified by the manufacturer.

Addition:

Add the following new subclauses:

7.101 Doors, conveyors, etc

A HAZARD shall not be caused in NORMAL CONDITION or in SINGLE FAULT CONDITION by:

a) a mechanism used to open, close, or retain a door;

b) wear on threaded parts;

NOTE Threads meeting the requirements of ISO 2901, ISO 2902, ISO 2903 and ISO 2904 can be suitable.

c) residual movement caused by any of the following:

1) operation of an emergency shutdown device (see 7.110);

2) loss of power;

3) component failure;

4) removal of an obstruction;

d) a part which is powered or driven from stored energy.

Conformity with a) and b) is checked by inspection. Conformity with c) and d) is checked by measurement to confirm that any residual movement cannot cause a force of more than 150 N from any easily touched part.

7.102 Access to the CHAMBER

Access to the CHAMBER during an OPERATING CYCLE shall not be possible if this could cause a HAZARD.

Conformity is checked by inspection of the door design. In case of doubt a test is carried out simulating an attempt to open the door using reasonable force.

Means shall be provided to prevent:

a) starting of the OPERATING CYCLE while an OPERATOR is completely inside the CHAMBER;

b) a door (if fitted) closing while an OPERATOR is completely inside the CHAMBER.

The means shall be lockable by a dedicated key, TOOL, or other mechanism, and the manufacturer's instructions shall specify that the OPERATOR must retain the key or TOOL while inside the CHAMBER. A warning marking (see 5.2) on the equipment clearly visible to the OPERATOR shall instruct the OPERATOR to lock the means before entering the CHAMBER and to retain the locking key, or TOOL, at all times while in the CHAMBER.

Conformity is checked by inspection and test.

If in NORMAL CONDITION a HAZARD could arise from touching hot liquid remaining in the CHAMBER, there shall be a warning in the manufacturer's instructions and a warning marking (see 5.2) on the equipment.

In a SINGLE FAULT CONDITION, no HAZARD shall be caused by liquid and steam flowing out of the CHAMBER when the door is opened or when an attempt is made to open it.

Conformity is checked by inspection and test.

7.103 Prevention of entry of gases, steam or liquids

Interlocks shall be provided so that sterilant gas, carrier gas, steam, or other gases cannot enter or be generated in the CHAMBER until the door is closed and secured with all door pressure-retaining parts engaged to the extent specified by the manufacturer, in order to withstand the design pressure.

Conformity is checked by inspection and test.

7.104 Prevention of new OPERATING CYCLE

It shall not be possible to start a new OPERATING CYCLE if this could cause a HAZARD arising from a residual fault. Such faults include but are not limited to:

a) failure of a door operating system;

b) failure of the LOAD transport system;

c) failure of an exhaust system;

d) failure of any other device (for example a timer or sensor);

e) operation of the emergency shutdown device (see 7.110).

Conformity is checked by review of the manufacturer's inspection and by tests to show that a new OPERATING CYCLE cannot be started in any of the circumstances listed in a) to e) above.

7.105 Pressure-retaining parts of a door

Interlocks shall prevent the pressure-retaining parts of the door from being fully released until the CHAMBER has been vented to atmospheric pressure.

Conformity is checked by operating the equipment through the OPERATING CYCLE that gives the maximum internal pressure, and confirming that the CHAMBER remains sealed while the pressure in the CHAMBER exceeds 0,2 bar (20 kPa) and that the door cannot open until the CHAMBER has vented to atmospheric pressure.

7.106 Doors of equipment for use with fluids in containers

It shall not be possible to open the door until the temperature of the entire LOAD, and of the fluid in the CHAMBER is below the boiling point of the fluid at ambient atmospheric pressure.

Conformity is checked by loading the CHAMBER with the maximum LOAD of the largest size container of fluid that the equipment is designed to process, ensuring the container is free to vent and, after a full OPERATING CYCLE, determining the highest temperature of the LOAD, and of the fluid in the CHAMBER, immediately before the door can be opened.

Equipment designed to process fluid in sealed unvented containers shall incorporate additional controls to ensure that it is not possible to open the door until the temperature of the fluid in the containers has fallen to a safe value.

The safe temperature for glass containers is 20 K below the boiling point of water at ambient atmospheric pressure, and for flexible containers (for example PVC bags), it is 10 K below the boiling point of water at ambient atmospheric pressure.

In order to compensate for the reduction in the boiling point at increased altitude, the manufacturer shall provide means for adjustment of the temperature below which a door will release.

Control by sensing the temperature of fluid in a container shall never be based on sensing a single container, which might break and lose its contents.

Conformity is checked by inspection and by loading the CHAMBER with the maximum RATED LOAD of each RATED type of container, filled with water. Sealed glass containers are of type 1 borosilicate glass in accordance with ISO 3585, filled to 90 % of their total volume. At the end of one OPERATING CYCLE, the temperature of the fluid in the containers is measured immediately before the door can be opened.

7.107 Double-ended equipment

It shall not be possible during NORMAL USE for an OPERATOR to open or close a door at the end of the CHAMBER remote from the OPERATOR.

Except for maintenance purposes, it shall not be possible for both doors to be open at the same time.

If a door at the end of the CHAMBER or remote from the OPERATOR or maintenance person can be opened and closed by an OPERATOR or maintenance person without the use of a TOOL, means shall be provided to prevent opening if conditions inside the equipment could cause a HAZARD.

Conformity is checked by inspection and by a test.

7.108 Transport and packaging

Where the weight, size or shape of the equipment or its component parts prevents movement by hand, they shall be fitted with, or accept attachments which can be easily connected to standard lifting equipment.

The equipment and/or its components shall be packaged in a manner such that when handled during transport and storage all parts of the equipment remain in position and stable and no HAZARD is caused.

The outside of packaging shall be clearly marked with instructions for handling, transport, storage, environment and unpacking.

Conformity is checked by inspection and, in case of doubt, by test for lifting and in accordance with established data for packaging.

7.109 Guards and panelling

Removal or opening of a guard or panel that provides personal protection shall require the use of a TOOL (see also 14.102).

If an access for persons is provided in a panel, this access shall be not less than 500 mm wide and 1 500 mm high, free from obstruction and require the use of a TOOL to open.

Fixings for attaching guards and panels shall remain attached to either the guard, or panel, or to the structure of the equipment.

Conformity is checked by inspection.

7.110 Emergency shutdown device

If a HAZARD could arise from the function of the equipment, or be caused by an OPERATOR error or a single fault, there shall be an easily reached and prominently placed push-button or other actuator at one or more appropriate locations to operate an emergency shutdown device.

The shutdown device shall:

a) not disconnect auxiliary circuits (such as cooling) which are necessary to protect against HAZARD;

b) disconnect accessories necessary for the correct function of the equipment and which if disconnected separately could cause a HAZARD.

Installation instructions shall specify to the RESPONSIBLE BODY requirements for the interconnection of accessories necessary for the correct function of the equipment.

If a mechanical HAZARD could occur, there shall be an actuator within 1 m of the hazardous moving part. This actuator shall be designed to withstand a force of 250 N sustained for a minimum period of 0,75 s.

If the power supply to any door or conveyor is interrupted during operation, the shutdown device shall operate automatically if a HAZARD could arise.

While an emergency shutdown device is in operation:

1) residual movement of any powered part such as a door or conveyor shall not create a HAZARD;

2) potentially hazardous parts of the equipment shall return to a state in which a HAZARD cannot occur. In addition to mechanical devices, such parts include valves, seals and other components which are used to control compressed air, steam, liquids and contaminated materials.

Unless an interlock system prevents restoration of normal operation until the hazardous conditions are eliminated, a key, code or other equivalent means shall be required to reset the shutdown device.

NOTE In some cases, the MAINS switch can meet the requirements of a shutdown device.

Conformity is checked by inspection, and by:

• *operating and resetting each shutdown actuator in turn;*

• *interrupting the power supply to each door or conveyor in turn during an OPERATING CYCLE, then restoring the supply, to confirm that no HAZARD arises.*

8 Resistance to mechanical stresses

This clause of Part 1 is applicable.

9 Protection against the spread of fire

9.1 General

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new paragraph and conformity statement after Note 2:

If a HAZARD could be caused by hot items falling from the equipment or by fire from a flammable substance in the CHAMBER, for example when a door is opened, there shall be a warning in the instructions and a warning marking on the equipment stating that the equipment should not be located where hot items could fall on surfaces that could present a fire or fume HAZARD.

Conformity is checked by inspection.

9.5 Requirements for equipment containing or using flammable liquids

Addition:

Add the following new subclause:

9.5.101 Requirements for equipment containing or using flammable gases

For requirements relating to fire, see 11.7.4 d), 11.104 g), and 13.2.102.

Conformity is checked as specified in the applicable clauses.

10 Equipment temperature limits and resistance to heat

This clause of Part 1 is applicable except as follows:

10.1 Surface temperature limits for protection against burns

Replacement

Replace the third paragraph by the following two new paragraphs:

Also see 9.1 relating to possible HAZARDS from hot items falling out of equipment.

If easily touched heated surfaces are necessary for functional reasons, whether because they are intended to deliver heat or are hot because of proximity to heated parts, they are permitted to exceed the values of Table 19 in NORMAL CONDITION and to exceed 105 °C in SINGLE FAULT CONDITION, provided that they are recognizable as such by appearance or function or are marked with symbol 13 of Table 1 (see 5.2).

10.3 Other temperature measurements

Addition:

Add the following new items to the existing list:

aa) The temperature of the LOAD and of the fluid in the CHAMBER shall be measured after a full OPERATING CYCLE, immediately before the door can be opened (in accordance with the requirement of 7.106).

bb) The temperature of fluid in sealed unvented containers shall be measured at the end of one OPERATING CYCLE immediately before the door can be opened (in accordance with the requirement of 7.106).

cc) In case of doubt, the temperature of the CHAMBER wall shall be measured in NORMAL CONDITION and in SINGLE FAULT CONDITION to verify conformity with the requirement of 10.5.101.

dd) In case of doubt, the temperature of a material shall be measured in NORMAL CONDITION and in SINGLE FAULT CONDITION to verify conformity with the requirement of 10.5.101.

ee) The temperature of parts of the equipment which can come into contact with the sterilant shall be measured in NORMAL CONDITION and in SINGLE FAULT CONDITION to verify conformity with the requirement of paragraph three of 13.2.102.2.

10.5 Resistance to heat

Addition:

Add the following new subclause:

10.5.101 Other materials

A material shall not exceed a temperature that could result in a deterioration in its performance to an extent which could cause a HAZARD in NORMAL CONDITION or in SINGLE FAULT CONDITION.

NOTE An example is that the strength of some materials, particularly some aluminium alloys, deteriorates rapidly at temperatures slightly above the maximum normal working temperature of some of the equipment covered by this document.

Conformity is checked by examination of the manufacturer's data and in case of doubt by temperature measurement as specified in 10.3 cc) and 10.3 dd).

11 Protection against HAZARDS from fluids and solid foreign objects

This clause of Part 1 is applicable except as follows:

11.1 General

Addition:

Add the following new paragraph after the second paragraph, before Note 2:

Also see 13.1.104 relating to pathogenic substances and 13.102 relating to chemical dosing systems.

11.7.2 Leakage and rupture at high pressure

Addition:

Add the following new paragraph after the lettered list:

PRESSURE VESSELS and shell boilers meeting the requirements of 14.101 are considered to meet the requirements of this Subclause 11.7.2.

11.7.4 Overpressure safety device

Replacement:

Replace the title and the text by the following new title and text:

11.7.4 Overpressure protective device

If it is possible that the maximum working pressure of a CHAMBER or PRESSURE VESSEL or its associated pipe work will be exceeded, an overpressure protection device according to ISO 4126-1 shall be fitted. This device shall be set to operate at a pressure not greater than the maximum working pressure and shall ensure that pressure does not exceed 110 % of the maximum working pressure.

An overpressure protective device shall not operate in NORMAL USE and it shall fulfill all of the following requirements:

a) it shall be connected as close as possible to the fluid-containing parts of the system that it is intended to protect;

b) it shall be installed according to the instructions given by the overpressure protective device manufacturer, and provide easy access for inspection, maintenance and repair;

c) it shall not be capable of being adjusted without the use of a TOOL;

d) it shall have its discharge opening so located, connected and directed that any discharge of hot, toxic, flammable or pathogenic material will not cause a HAZARD;

e) there shall be no shut-off valve or other obstructing device such as a filter between an overpressure protective device and the parts that it is intended to protect;

f) if a protective valve is used as the protective device, precautions shall be taken to ensure that fluid is unlikely to accumulate on the seating of the valve;

NOTE This is to avoid the likelihood of deterioration due to the deposition of scale from salts in the water which could ultimately block the device.

g) unless equivalent other provisions for draining are provided, the discharge from the protective device shall have a drain connection at its lowest point. The discharge from this point shall not cause a HAZARD;

h) the device shall be constructed from materials that will not be degraded in conditions of NORMAL USE to an extent that could cause a HAZARD;

i) it shall have the markings as specified in 5.1.101.

Conformity is checked by:

1) inspection of the type of protective device used and the manufacturer's data;

2) inspection of the protective device as fitted;

3) a test to confirm that the device is not used to discharge excess pressure during the OPERATING CYCLE in NORMAL USE;

4) a test to demonstrate that the pressure in any PRESSURE VESSEL will not exceed 110 % of the maximum RATED working pressure of the PRESSURE VESSEL when supplied at the maximum source pressure and flow rate specified by the manufacturer of the equipment.

A bursting disc shall not be used alone for overpressure protection purposes, but shall be used in combination with an overpressure protective valve to provide protection against leakage below the pressure at which the overpressure protective valve is set to operate. A bursting disc shall conform to ISO 4126-2.

Conformity is checked by inspection of the types of valve and bursting disc used, and of the manufacturer's data.

NOTE National, local regulations and other codes can apply.

Addition:

Add the following four new subclauses:

11.101 Discharge to atmosphere

Discharges from pressure-venting valves and pipes, or from ventilation systems, shall not cause a HAZARD.

A pipe discharging to atmosphere shall have a continuous fall from its source to its outlet unless an automatic drain is provided at every point where liquid could collect. If the pipe is to be provided as part of the building installation, the manufacturer's instructions shall specify this (see also 11.7.4 g)).

If a discharge is released inside the equipment, it shall be vented so that build-up of pressure cannot occur. The discharge into the equipment and the vent from it shall be located so that no HAZARD can occur.

Conformity is checked by inspection.

11.102 Instruments and indicating devices

If necessary to protect against HAZARDS, equipment shall have devices as applicable to indicate the following:

a) CHAMBER pressure;

b) jacket pressure;

c) OPERATING CYCLE count;

d) the current stage in the OPERATING CYCLE;

e) failure or partial failure of any safety-related MAINS supply;

f) line pressure for any pressurized sterilant or chemical (except for cartridge containment systems);

g) detection of leaks (see 13.1.103.1);

h) water pump pressure;

i) vapour condenser temperature;

j) operating temperature.

Redundancy shall be provided to ensure that the OPERATOR receives sufficient information to avoid a HAZARD, even in SINGLE FAULT CONDITIONS.

Conformity is checked by analysis and inspection.

Where operation by a maintenance person is undertaken in a plant room, provision shall be made to repeat safety-related data. Except in the case of OPERATING CYCLE counters, safetyrelated data shall be readable (by normal or corrected vision) from a distance of 1 m at any external illumination level in the range of (215 ± 15) lx to (1 500 ± 15) lx.

Conformity is checked by inspection and by examination under specified conditions.

11.103 Protection of hot and cold water services

Backsiphonage from the equipment to the water services shall be prevented by means meeting the relevant requirements of IEC 61770. Attention is drawn to the existence of national and local regulations. If the means are to be provided by the RESPONSIBLE BODY, this shall be stated in the manufacturer's installation instructions.

Conformity is checked by inspection and by examination of the manufacturer's instructions.

11.104 Equipment with inflatable or pressure-activated seals

No HAZARD shall arise if the door seal pressure of a CHAMBER sealed by an inflatable or pressure activated seal falls below the minimum pressure specified by the manufacturer or exceeds its maximum working pressure (see 11.7.4). Means to ensure this shall include the following, as applicable:

a) the OPERATING CYCLE stops;

b) an audible or visible alarm signal, or both, indicates the fault condition;

c) the door(s) remain closed;

d) there is no supply of sterilizing or disinfecting agent, steam, water or air into the CHAMBER;

e) local exhaust ventilation;

f) the source of sterilant gas is isolated by an automatically operated valve and the complete system from the isolation valve at the source of the sterilant gas supply through to and including the CHAMBER, is evacuated to the discharge pipe;

g) if the sterilant is flammable, the complete system (see f) above) is purged using air or inert gas.

Conformity is checked by inspection, by examination of the documentation, and by simulating failure of the door seal so as to cause the pressure to fall.

12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure

This clause of Part 1 is applicable except as follows:

12.5 Sonic and ultrasonic pressure

12.5.1 Sound level

Replacement:

Replace the existing text by the following new text:

If equipment produces noise at a level which could cause a HAZARD, the manufacturer shall measure the maximum sound pressure level which the equipment can produce (except for sound from alarms and sound from parts remote from the equipment).

The instructions for use shall state potentially hazardous sound pressure levels both at the OPERATOR'S position in NORMAL USE and at a point 1 m from the ENCLOSURE of the equipment which has the highest sound pressure level.

Conformity is checked by inspection and by measuring the maximum A-weighted sound pressure level at the OPERATOR'S position and at bystander positions.

During the measurement the following conditions shall apply:

a) Any part necessary for the correct operation of the equipment and supplied by the manufacturer as an integral part of such equipment, for example, a pump, is fitted and operated as in NORMAL USE;

b) Sound level meters used in the measurement conform either to type 1 of IEC 61672-1 or, in the case of an integrating sound level meter, to type 1 of IEC 61672-2;

c) The test room is semi-reverberant, with a hard reflecting floor. The distance between any wall or any other object and the surface of the equipment is not less than 3 m;

d) The equipment is tested with the combination of LOAD *and other operating conditions (for example, pressure, flow, temperature) which creates the maximum sound pressure level.*

Installation instructions shall specify how the RESPONSIBLE BODY can ensure that the sound pressure level from equipment, at its point of use after installation, will not reach a value that could cause a HAZARD. These instructions shall:

1) identify readily available and practicable protective materials or measures which can be used, including the fitting of noise-reducing baffles or hoods;

2) recommend that the sound pressure level be measured in NORMAL USE at the OPERATOR'S position and at a point 1 m from the ENCLOSURE in a location that has the highest sound pressure level.

NOTE A sound pressure level of 80 dB above a reference sound pressure of 20 µPa is at present regarded by many authorities as the threshold at which a HAZARD can be caused. Special means, such as the use of protective earpieces, can make a higher level non-hazardous to an OPERATOR.

Conformity is checked by inspection.

13 Protection against liberated gases, substances, explosion and implosion

This clause of Part 1 is applicable except as follows:

13.1 Poisonous and injurious gases and substances

Addition:

Add the following new note and new paragraphs after the existing note. Number the existing note to NOTE 1:

NOTE 2 A HAZARD is considered to occur if toxic emissions can exceed the short-term exposure limit (STEL) or the long-term exposure limit (LTEL) for the gas under consideration. Toxic emissions include all sterilizing and disinfecting agents that have defined STEL or LTEL values.

For equipment using highly toxic, flammable, or explosive chemicals such as pure ethylene oxide, the RISK assessment shall be carried out for both NORMAL CONDITION and SINGLE FAULT CONDITION to determine if leakage could cause a toxic or explosive atmosphere.

See also 7.102 a) relating to access to the CHAMBER during an OPERATING CYCLE, 7.104 relating to preventing the start of a new OPERATING CYCLE, and the paragraph added in 9.1 relating to a possible fire HAZARD from hot items falling out of equipment.

Addition:

Add the following new subclauses:

13.1.101 CHAMBER discharge systems

13.1.101.1 Discharge from the CHAMBER

Discharge from the CHAMBER shall not cause a HAZARD.

Conformity is checked by inspection and by examination of the installation instructions.

13.1.101.2 Failure of a CHAMBER exhaust system

If a HAZARD could arise from a failure of a CHAMBER exhaust system, audible and visible alarm signals, independent from the supply MAINS, shall warn of failure of any system that is designed to remove a discharge of sterilant gas from the CHAMBER. Examples of such failure are malfunction of an extractor fan, obstruction of a flow duct, and failure of the power supply.

If a HAZARD could arise from a failure of MAINS supply, the exhaust system shall be supplied by an emergency power system.

During a failure of a CHAMBER exhaust system, it shall not be possible to initiate an OPERATING CYCLE. If an OPERATING CYCLE is already in progress and at a stage where sterilant gas has been admitted to the CHAMBER, access to the LOAD shall be prevented until the exhaust system is again operational and a flushing stage has been completed.

Conformity is checked by provoking all possible single faults in turn, and confirming that:

a) the alarm signals operate even with the supply MAINS disconnected;

b) the OPERATING CYCLE cannot be started;

c) access to the LOAD is prevented.

13.1.101.3 Protection from gases liberated from a drain

Discharge from the CHAMBER into the part of a drainage system which forms part of the equipment and its connection to the building drainage system shall not cause a HAZARD. Installation instructions shall state that any venting of the drain shall be to a safe place.

NOTE National and local regulations and other codes can specify additional requirements for drainage systems.

Conformity is checked by:

a) inspecting the drainage system and its venting;

b) connecting the equipment to a drain that complies with the manufacturer's specification;

c) measuring the concentration of sterilant gas at the connection to the drain, to check that STEL and LTEL values are not exceeded.

13.1.101.4 Local exhaust ventilation

If a HAZARD could arise from fugitive emissions, the equipment shall be provided with means to connect a local exhaust ventilation system to remove them.

The manufacturer's installation instructions shall warn the RESPONSIBLE BODY that:

a) additional local exhaust ventilation can also be required in storage areas for sterilant gas;

b) the discharge from a local exhaust ventilation system is located so as not to cause a HAZARD.

NOTE This local exhaust ventilation system can also be designed to be activated if the STEL value of the sterilant is exceeded.

Conformity is checked by inspection.

13.1.102 LOAD access after a fault

The manufacturer shall provide instructions to ensure safe access to the LOAD if a fault occurs during an OPERATING CYCLE.

Conformity is checked by analysis of the control system and by inspection.

13.1.103 HAZARDS arising from the use of toxic sterilant

13.1.103.1 CHAMBER leakage

If leakage from the CHAMBER could cause a HAZARD, each OPERATING CYCLE shall include a check, before sterilant gas is admitted to the CHAMBER, to detect any potentially hazardous leakage. Detection of leakage that could cause a HAZARD shall cause the equipment to revert to a safe condition.

NOTE The relevant values specified for leakage rates will depend on a number of factors, for example the volume of the CHAMBER, the OPERATING CYCLE, and the nature of the sterilant gas, including its STEL and LTEL values.

Conformity is checked by analysis of the OPERATING CYCLE and by testing all means provided for leak detection.

Equipment operating above atmospheric pressure shall have a means, such as a non-return valve in the air inlet pipe, to prevent the escape of toxic sterilant gas from the CHAMBER.

Conformity is checked by inspection.

13.1.103.2 Protection against gases liberated from the LOAD

It shall not be possible to open the door until the sterilant concentration has been reduced to a level where the LOAD will not present a HAZARD to the OPERATOR when the STERILIZER is unloaded.

The manufacturer shall advise the RESPONSIBLE BODY of any change required to take account of the very different gas absorption characteristics of materials processed.

NOTE One method of ensuring this is for the sterilant removal stage to be followed by a stage during which further sterilant is removed by flushing with filtered air or inert gas. The air or gas can either be passed continuously through the CHAMBER or there can be multiple admissions, each followed by evacuation.

Conformity is checked by inspection and by analysis of the OPERATING CYCLE and by measurement of the sterilant concentration at 170 cm from the floor and 1 m directly in front of the middle of the door at the least favourable time after releasing a seal or opening the door.

13.1.103.3 Failure of room ventilation system

If room ventilation is required to prevent a HAZARD, means shall be provided so that in the event of its failure:

a) the equipment will go to a safe state;

b) a new OPERATING CYCLE cannot be started while the failure continues to exist;

c) this is indicated by both audible and visible alarm signals.

NOTE Measurement of air flow can be used to identify a failure.

Conformity is checked by inspection, and by simulating failure of the room ventilation system.

13.1.103.4 Materials in contact with sterilant

Material used in the construction of the STERILIZER which can come into contact with sterilant shall not react with sterilant or carrier gas to an extent that material deterioration could lead to leakage in sufficient quantity to cause STEL or LTEL values to be exceeded.

The manufacturer's instructions shall state that material used in the installation of the STERILIZER which can come into contact with sterilant shall not react with sterilant or carrier gas to an extent that material deterioration could lead to leakage in sufficient quantity to cause STEL or LTEL values to be exceeded.

Conformity is checked by inspection, including inspection of the manufacturer's installation instructions and by examination of data accumulated by the manufacturer during failure-mode analysis and during tests, to demonstrate that the materials used are compatible with sterilant and carrier gases.

13.1.104 Pathogenic substances

In NORMAL CONDITION or in SINGLE FAULT CONDITION, emission of aerosols or fluids from equipment shall not cause a HAZARD. If additional means are required to control emissions, they shall be specified in the manufacturer's installation instructions.

NOTE For some applications, visual examination for aerosols and fluids can be sufficient.

Conformity is checked by inspection and test, and by examination of the manufacturer's instructions.

13.2 Explosion and implosion

Addition:

Add the following subclauses:

13.2.101 Materials in contact with sterilant

The equipment shall be made of materials which, in NORMAL USE, will not react with sterilant or carrier gases in a manner and to an extent that could lead to a change in pressure (either by ignition or exothermic reaction) that could result in explosion or implosion.

The manufacturer's instructions shall state that materials used in the installation of the STERILIZER which can come into contact with sterilant shall not react with sterilant or carrier gas to an extent that material deterioration could result in explosion or implosion.

For the selection of materials for pressure-retaining parts and their integral attachments, attention shall be paid to the effects of galvanic attack and different rates of expansion when dissimilar metals are in contact.

Copper or copper alloys containing more than 65 % mass fraction of copper are not suitable if the sterilant gas contains acetylene.

Conformity is checked by inspection, and by examination of data accumulated by the manufacturer during failure-mode analysis and during tests, to demonstrate that the materials used are compatible with sterilant and carrier gases.

13.2.102 Explosion, implosion and fire of toxic gas STERILIZERS

13.2.102.1 Flammable sterilants

Equipment intended for use with flammable sterilants shall have no source of ignition within the CHAMBER, its sterilant connections, or its exhaust piping.

If during a process the mixture of air with the flammable sterilant could lead to fire or explosion in NORMAL CONDITION or in SINGLE FAULT CONDITION, the sterilant concentration shall be reduced to below the flammable limit before air is admitted at the end of the OPERATING CYCLE. The OPERATING CYCLE shall also ensure that progress to the next stage of the sterilization cycle cannot occur if there is a possibility of a fire or explosion HAZARD.

Conformity is checked by examination of the interior of the CHAMBER and its sterilant and exhaust connections, by analysis of the OPERATING CYCLE, and by calculating the sterilant concentration at the time the air is admitted.

If a fire or explosion HAZARD could arise from a failure of the CHAMBER exhaust system, the requirements of 13.1.101.2 apply.

Conformity is checked as specified in 13.1.101.2.

13.2.102.2 Heating of flammable liquid sterilant

Sterilant containers shall not be subjected to direct heating which could cause a HAZARD.

If a HAZARD could arise, flammable or explosive liquids, such as ethylene oxide, shall not be heated by an electrical heating element in direct contact with the liquid.

In NORMAL CONDITION or in SINGLE FAULT CONDITION, parts of the equipment which could come into contact with the sterilant shall not reach a temperature at which fire, explosion, or other HAZARD could be caused.

NOTE This temperature will depend on the type of sterilant. For example, the temperature limit for ethylene oxide is normally 70 °C to prevent polymerization or catalytic reaction.

Conformity is checked by inspection and examination of sterilant safety data and, in case of doubt, by temperature measurement as specified in 10.3 ee).

Addition:

Add the following new subclauses:

13.101 Other HAZARDS arising from the use of toxic sterilants

13.101.1 General

NOTE A toxic HAZARD is considered to occur if toxic sterilant emissions can exceed STEL or LTEL for the gas under consideration. Toxic sterilants include all sterilizing and disinfecting agents that have defined STEL or LTEL limits.