

INTERNATIONAL STANDARD



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

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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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INTERNATIONAL STANDARD



**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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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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

FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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 tests: *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.

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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; ~~and that makes physical or electrical contact with the patient or transfers energy to or from the patient or detects such energy transfer to or from the 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 ~~13.0~~ 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*

~~IEC 62471, *Photobiological safety of lamps and lamp systems*~~

~~IEC TR 62471-2, *Photobiological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety*~~

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:

Addition:

Add the following new terms and definitions:

3.2 Parts and accessories

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 ~~in place~~ when installed, a separate identical motor can be tested but it shall be tested in the same conditions that ~~meet or exceed the conditions within~~ 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 ~~at least~~ 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 ~~safety~~ 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 ~~may~~ 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

~~Replacement:~~

~~Replace the first paragraph by the following new paragraph:~~

~~Warning markings specified in 5.1.5.1, 5.1.5.2 c), 5.1.5.2 d), 5.1.8, 5.4.4 r), 6.1.2 b), 7.3.2, 7.102 b), 7.102 c), 9.1, 10.1, 13.2.2, and 14.103 shall meet the following requirements.~~

~~Warning and Caution symbols shall be at least 10 mm high.~~

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 two new items to the first new paragraph after item h) of the lettered list:~~

~~aa) attention is drawn to the existence of national and local regulations that can apply to the documentation,~~

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

~~Delete the second note.~~

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 2 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 ~~first paragraph~~ 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 second paragraph by the following new paragraph:*~~

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 ~~7.111~~ 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 ~~an~~ 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 ~~7.1.111~~ 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;
- a) 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 ~~7.1.114~~ 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.

~~NOTE—Expansion of flexible containers reduces the likelihood of bursting, and a temperature closer to boiling point is desirable because at 20 K below boiling point the outside surfaces of the container can be undesirably marked with water stains.~~

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 ~~one~~ 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 ~~packed~~ 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 ~~from~~ 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 ~~a personal~~ 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 ~~Mechanical resistance to shock and impact~~ 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 paragraphs 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 ~~subjects~~ 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), ~~11.105 g), and 13.2.102.1, to 13.101.6 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 ~~in NORMAL CONDITION~~ after a full OPERATING CYCLE, immediately before the door can be opened (in ~~connection~~ accordance with the requirement of 7.106 ~~a~~).
- bb) The temperature of fluid in sealed unvented containers shall be measured ~~in NORMAL CONDITION as soon as~~ at the end of one OPERATING CYCLE immediately before the door can be opened (in ~~connection~~ accordance with the requirement of 7.106 ~~b~~).
- cc) In case of doubt, the temperature of the CHAMBER wall shall be measured in NORMAL CONDITION and in SINGLE FAULT CONDITION ~~(in connection 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 ~~(in connection to verify conformity with the requirement of 10.5.101).~~
- ee) The temperature of parts of the equipment which ~~can be contacted by~~ come into contact with the sterilant shall be measured in NORMAL CONDITION and in SINGLE FAULT CONDITION ~~(in connection 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 ~~first paragraph~~ 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 ~~safety~~ protective device ~~(as specified in 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 ~~safety~~ 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 ~~safety~~ 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 ~~safety~~ protective device and the parts that it is intended to protect;
- f) if a ~~safety~~ protective valve is used as the ~~safety~~ 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 ~~safety~~ 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 ~~safety~~ protective device used and the manufacturer's data;
- 2) inspection of the ~~safety~~ 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-safety protection purposes, but shall be used in combination with an overpressure-safety protective valve to provide protection against leakage below the pressure at which the overpressure-safety 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-a));
- 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, ~~they~~ **safety-related 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 $(1\ 500^{\circ} \pm 15)$ 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:

~~Replacement:~~

~~Replace 12.3 by the following:~~

~~12.3 Optical radiation~~

~~Equipment with lamp and lamp systems emitting ultraviolet, visible, or infrared radiation, including light emitting diodes, shall not permit unintentional escape of radiation that could cause a HAZARD. The radiation sources shall be assessed in accordance with IEC 62471 except for sources considered to be safe (Table 101), or conditionally safe (Table 102). Lamp and lamp systems assessed to be in Risk Groups 1, 2 or 3 of IEC 62471 shall be labelled in accordance with IEC TR 62471-2. Protective measures, restrictions on use and operating instructions that may be necessary shall be provided, including the applicable conditions of use of Table 102.~~

~~NOTE—Attention is drawn to the possible existence of additional guidelines or requirements which may be specified by national authorities responsible for the health and safety of labour forces.~~

~~Conformity is checked by inspection, by review of the technical specifications of the lamp manufacturer, and if necessary by measurement of the optical radiation, followed by determination of the applicable Risk Groups according to IEC 62471.~~

~~Table 101 – Lamp or lamp systems considered photobiologically safe~~

Lamp or lamp system
Indicator LEDs
Personal digital device screens
LCD screens
Computer displays
Photographic flash lamps
Interactive whiteboard presentation equipment
Task lighting with tungsten filament lamps, compact fluorescent tubes, or fluorescent tubes with diffusers

~~Table 102 – Lamp or lamp systems considered photobiologically safe under certain conditions~~

Lamp or lamp system	Conditions of use
Fluorescent lighting without diffusers over the lamps	Safe at normal illumination levels (~600 lux)
Metal halide/high-pressure mercury flood lights	Safe if the front cover glass is intact and if the lamp is not in line of sight
Desktop projectors	Safe if the beam is not looked into
Low-pressure UVA black lights	Safe if not in line of sight and hands are not irradiated while holding the black light
Any Class 1 laser (according to IEC 60825-1)	Safe if covers intact. May be unsafe if covers removed.
Any 'Exempt Group' equipment (according to IEC 62471)	Safe if not in line of sight. May be unsafe if covers removed.

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 μ Pa 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

~~Replacement:~~

~~Replace the first paragraph by the following text:~~

~~Equipment shall not liberate dangerous amounts of hazardous substances in NORMAL CONDITION OF SINGLE FAULT CONDITION.~~

~~If potentially hazardous substances are liberated, the OPERATOR shall not be exposed to a quantity of the substance that could cause harm.~~

~~If NORMAL operation of the equipment requires the discharge of hazardous substances, and if that discharge is intended to be managed by the RESPONSIBLE BODY in accordance with the manufacturer's instructions, then such discharge is not considered to be liberation of hazardous substances.~~

Addition:

Add the following new note and new paragraphs after the ~~second paragraph~~ 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 ~~3 of Clause~~ 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 ~~should~~ 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 ~~must~~ 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 ~~must~~ 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 ~~be contacted by~~ 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.

13.101.2 Opening or disconnecting a sterilant supply system

If a HAZARD could arise during disconnection or opening of the sterilant supply system, means (for example, purging) shall be provided to prevent the HAZARD from arising.

Conformity is checked by inspection.

13.101.3 Gas blending

For STERILIZERS operating with a sterilant which is a mixture of gases blended at the point of use, means shall be provided to ensure that no toxic, fire, or explosion HAZARD can arise as a result of incorrect mixing in NORMAL CONDITION or in SINGLE FAULT CONDITION.

Conformity is checked by analysis and measurement of each gas in the mixture in NORMAL CONDITION and in SINGLE FAULT CONDITION (see 4.4.2.103).

13.101.4 Sterilant supply

If a HAZARD could arise from uncontrolled or incorrect supply of sterilant, additional controls or mechanisms shall be provided to interrupt the sterilant supply to the CHAMBER and prevent the HAZARD.

NOTE 1 In the case of toxic or flammable gases, ~~this~~ the interruption of the sterilant supply could be achieved by the use of a non-return valve and a flame arrester or heat-sensitive cut-off valve.

NOTE 2 National regulations can require automatic and manual valves on flammable gases.

Means shall be provided to dispense, connect and position containers of liquid sterilant without creating a HAZARD.

Conformity is checked by inspection, and by examination of data on RATED sterilants.

13.101.5 Supply from sterilant cartridges

If a HAZARD could arise, means shall be provided to prevent access to the sterilant cartridge during the OPERATING CYCLE.

NOTE A cartridge is a single-use container of sterilant.

Conformity is checked by inspection.

13.101.6 Isolation of any part of the sterilant supply system

When any part of the sterilant gas supply system can be isolated and its maximum working pressure could be exceeded in NORMAL CONDITION or in SINGLE FAULT CONDITION, it shall be protected by an overpressure safety device meeting the requirements of 11.7.4.

NOTE A HAZARD can arise in cases where the isolated length of pipe is full of liquid.

Conformity is checked by inspection and as specified in 11.7.4.

13.101.7 Failure of a sterilant supply control system

A failure which could cause a HAZARD shall be indicated by a visible alarm signal. It shall also cause the equipment to go to a safe state and it shall not be possible to initiate an OPERATING CYCLE while the failure exists.

Conformity is checked by inspection and test.

13.102 Chemical dosing systems

If a chemical dosing system is fitted, means shall be provided to replenish containers without creating a HAZARD.

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

14 Components and subassemblies

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new subclauses:

14.101 PRESSURE VESSELS and shell boilers

PRESSURE VESSELS and shell boilers shall comply with the pressure systems regulations, codes or standards applicable in the country of intended use (e.g. the applicable parts of EN 13445, EN 14222, and the applicable parts of EN 12953 in the European Union).

If no national regulations, codes or standards exist, the equipment shall comply with the requirements of 11.7.

Conformity is checked by inspection of the PRESSURE VESSEL or shell boiler and taking into consideration ~~of~~ the relevant national and local regulations and codes or as specified in 11.7.

14.102 Access ports

If an access port (for example, for injecting small quantities of chemicals into the CHAMBER) can be opened and closed by an OPERATOR without the use of a TOOL, means shall be provided to prevent opening if conditions inside the equipment could cause a HAZARD.

NOTE Means can include:

- a) interlocks (see Clause 15);
- b) ensuring inaccessibility during an OPERATING CYCLE;
- c) fitting an interlocked cover over the port (see Clause 15).

Conformity is checked by inspection and by examination of the design specification.

14.103 Control systems

If the setting of a control in NORMAL USE could cause a HAZARD, a warning marking (see 5.2) shall be provided.

To reduce the likelihood of the equipment being set in a way that could cause a HAZARD, access to the following functions (if provided), shall be limited by increasingly severe constraints. Examples of possible constraint levels are given in brackets.

- a) initiation of an OPERATING CYCLE [available to OPERATORS];
- b) selection of an OPERATING CYCLE [available to OPERATORS or supervisors, as appropriate];
- c) changing OPERATING CYCLE parameters [restricted to supervisors];
- d) manual advance through an OPERATING CYCLE [restricted to suitably trained technicians];
- e) maintenance [restricted to suitably trained service technicians];
- f) changing the OPERATING CYCLE programme [restricted to the manufacturer or manufacturer's agent].

Except for a) and b), the above functions shall require the use of different keys, codes or other equivalent means. Higher-level TOOLS, keys or codes can allow access to lower levels.

Termination of an OPERATING CYCLE shall not require the use of a special TOOL, key or code.

It shall not be possible to disable safety devices during NORMAL USE, or while gaining access to the LOAD. This applies both during manual advance of the OPERATING CYCLE and when under automatic control.

If operation can be either by manual advance or by an automatic controller, selection of the manual mode shall disable the automatic controller.

Automatic control is recommended for all equipment within the scope of this document, because a manual control system could present serious HAZARDS to the OPERATOR from chemicals, toxic gas, hot gases, steam, or hot water.

Conformity is checked by inspection and test by operating the equipment to confirm that the safety devices cannot be disabled.

14.104 Microprocessors

Failure of a safety-related microprocessor shall not cause a HAZARD.

NOTE 1 This requirement can be achieved by redundancy or diversity.

NOTE 2 Guidance on safety related control systems using microprocessors and other software controlled devices is given in IEC 61508-3, ISO 13849-2, IEC 62061 and IEC 62304.

If a battery is used to maintain a processor memory, no HAZARD shall arise as a result of loss of this power.

Conformity is checked by inspection, RISK analysis, function of the circuit under evaluation and, in case of doubt, by simulating a fault.

14.105 Asbestos

No parts made of asbestos shall be used.

Conformity is checked by examination of the manufacturer's data.

15 Protection by interlocks

15.1 General

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new text after the first sentence:

As an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements of 15.2 and 15.3 can be determined by applying, for example IEC 62061 (SIL) or ISO 13849 (PL) (all parts) or other solutions providing equivalent functional safety.

16 HAZARDS resulting from application

This clause of Part 1 is applicable.

17 Risk assessment

This clause of Part 1 is applicable except as follows:

Addition:

Add the following item to the list of standards in the note:

ISO 12100:2010,

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Annexes

The annexes of Part 1 are applicable, except as follows:

Annex G (informative)

Leakage and rupture from fluids under pressure

This annex of Part 1 is applicable except as follows:

Replace the first paragraph by the following new paragraph:

The requirements and tests of this annex are accepted in the USA, Canada, and in some other countries, as proof of conformity with national regulations relating to high pressures. However, they do not apply to shell boilers and PRESSURE VESSELS, for which there are separate and different national or local regulations.

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Annex L
(informative)

Index of defined terms

Additional defined terms:

CHAMBER	3.2.101
LOAD	3.2.102
OPERATING CYCLE.....	3.2.105
PRESSURE VESSEL	3.2.104
STERILIZER.....	3.2.103
WASHER-DISINFECTOR.....	3.2.106

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Bibliography

Add the following publications:

~~IEC 60079 (all parts), Explosive atmospheres~~

IEC 60335-2-4, Household and similar electrical appliances – Safety – Part 2-4: Particular requirements for spin extractors

IEC 60335-2-5, Household and similar electrical appliances – Safety – Part 2-5: Particular requirements for dishwashers

IEC 60335-2-7, Household and similar electrical appliances – Safety – Part 2-7: Particular requirements for washing machines

IEC 60335-2-11, Household and similar electrical appliances – Safety – Part 2-11: Particular requirements for tumble dryers

IEC 60335-2-58, Household and similar electrical appliances – Safety – Part 2-58: Particular requirements for commercial electric dishwashing machines

IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

~~IEC 60825-1, Safety of laser products – Part 1: Equipment classification and requirements~~

IEC 61010-2-010, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials

~~IEC 61508 (all parts), Functional safety of electrical/electronic/programmable electronic safety-related systems~~

~~IEC 61672-1, Electroacoustics – Sound level meters – Part 1: Specifications~~

~~IEC 61672-2, Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests~~

IEC 62061, Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems

IEC 62304, Medical device software – Software life cycle processes

ISO 2901, ISO metric trapezoidal screw threads – Basic ~~profile and maximum material~~ and design profiles

ISO 2902, ISO metric trapezoidal screw threads – General plan

ISO 2903, ISO metric trapezoidal screw threads – Tolerances

ISO 2904, ISO metric trapezoidal screw threads – Basic dimensions

ISO 10472 (all parts), Safety requirements for industrial laundry machinery

ISO 12100:2010, Safety of machinery – General principles for design – Risk assessment and risk reduction

~~ISO 13849-2, Safety of machinery – Safety-related parts of control systems – Part 2: Validation~~

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

ISO 14971, *Medical devices – Application of risk management to medical devices*

ISO 15223-2, *Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 2: Symbol development, selection and validation*

EN 12953 (all parts), *Shell boilers*

EN 13445 (all parts), *Unfired pressure vessels*

EN 14222, *Stainless steel shell boilers*

EN 1837, *Safety of machinery. Integral lighting of machines*

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –

Partie 2-040: Exigences particulières pour stérilisateurs et laveurs désinfecteurs utilisés pour traiter le matériel médical

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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**

FOREWORD

- 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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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 tests: *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, safety-related 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 $(1\ 500 \pm 15)$ 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.

13.101.2 Opening or disconnecting a sterilant supply system

If a HAZARD could arise during disconnection or opening of the sterilant supply system, means (for example, purging) shall be provided to prevent the HAZARD from arising.

Conformity is checked by inspection.

13.101.3 Gas blending

For STERILIZERS operating with a sterilant which is a mixture of gases blended at the point of use, means shall be provided to ensure that no toxic, fire, or explosion HAZARD can arise as a result of incorrect mixing in NORMAL CONDITION or in SINGLE FAULT CONDITION.

Conformity is checked by analysis and measurement of each gas in the mixture in NORMAL CONDITION and in SINGLE FAULT CONDITION (see 4.4.2.103).

13.101.4 Sterilant supply

If a HAZARD could arise from uncontrolled or incorrect supply of sterilant, additional controls or mechanisms shall be provided to interrupt the sterilant supply to the CHAMBER and prevent the HAZARD.

NOTE 1 In the case of toxic or flammable gases, the interruption of the sterilant supply could be achieved by the use of a non-return valve and a flame arrester or heat-sensitive cut-off valve.

NOTE 2 National regulations can require automatic and manual valves on flammable gases.

Means shall be provided to dispense, connect and position containers of liquid sterilant without creating a HAZARD.

Conformity is checked by inspection, and by examination of data on RATED sterilants.

13.101.5 Supply from sterilant cartridges

If a HAZARD could arise, means shall be provided to prevent access to the sterilant cartridge during the OPERATING CYCLE.

NOTE A cartridge is a single-use container of sterilant.

Conformity is checked by inspection.

13.101.6 Isolation of any part of the sterilant supply system

When any part of the sterilant gas supply system can be isolated and its maximum working pressure could be exceeded in NORMAL CONDITION or in SINGLE FAULT CONDITION, it shall be protected by an overpressure safety device meeting the requirements of 11.7.4.

NOTE A HAZARD can arise in cases where the isolated length of pipe is full of liquid.

Conformity is checked by inspection and as specified in 11.7.4.

13.101.7 Failure of a sterilant supply control system

A failure which could cause a HAZARD shall be indicated by a visible alarm signal. It shall also cause the equipment to go to a safe state and it shall not be possible to initiate an OPERATING CYCLE while the failure exists.

Conformity is checked by inspection and test.

13.102 Chemical dosing systems

If a chemical dosing system is fitted, means shall be provided to replenish containers without creating a HAZARD.

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

14 Components and subassemblies

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new subclauses:

14.101 PRESSURE VESSELS and shell boilers

PRESSURE VESSELS and shell boilers shall comply with the pressure systems regulations, codes or standards applicable in the country of intended use (e.g. the applicable parts of EN 13445, EN 14222, and the applicable parts of EN 12953 in the European Union).

If no national regulations, codes or standards exist, the equipment shall comply with the requirements of 11.7.

Conformity is checked by inspection of the PRESSURE VESSEL or shell boiler and taking into consideration the relevant national and local regulations and codes or as specified in 11.7.

14.102 Access ports

If an access port (for example, for injecting small quantities of chemicals into the CHAMBER) can be opened and closed by an OPERATOR without the use of a TOOL, means shall be provided to prevent opening if conditions inside the equipment could cause a HAZARD.

NOTE Means can include:

- a) interlocks (see Clause 15);
- b) ensuring inaccessibility during an OPERATING CYCLE;
- c) fitting an interlocked cover over the port (see Clause 15).

Conformity is checked by inspection and by examination of the design specification.

14.103 Control systems

If the setting of a control in NORMAL USE could cause a HAZARD, a warning marking (see 5.2) shall be provided.

To reduce the likelihood of the equipment being set in a way that could cause a HAZARD, access to the following functions (if provided), shall be limited by increasingly severe constraints. Examples of possible constraint levels are given in brackets.

- a) initiation of an OPERATING CYCLE [available to OPERATORS];
- b) selection of an OPERATING CYCLE [available to OPERATORS or supervisors, as appropriate];
- c) changing OPERATING CYCLE parameters [restricted to supervisors];
- d) manual advance through an OPERATING CYCLE [restricted to suitably trained technicians];
- e) maintenance [restricted to suitably trained service technicians];
- f) changing the OPERATING CYCLE programme [restricted to the manufacturer or manufacturer's agent].

Except for a) and b), the above functions shall require the use of different keys, codes or other equivalent means. Higher-level TOOLS, keys or codes can allow access to lower levels.

Termination of an OPERATING CYCLE shall not require the use of a special TOOL, key or code.

It shall not be possible to disable safety devices during NORMAL USE, or while gaining access to the LOAD. This applies both during manual advance of the OPERATING CYCLE and when under automatic control.

If operation can be either by manual advance or by an automatic controller, selection of the manual mode shall disable the automatic controller.

Automatic control is recommended for all equipment within the scope of this document, because a manual control system could present serious HAZARDS to the OPERATOR from chemicals, toxic gas, hot gases, steam, or hot water.

Conformity is checked by inspection and test by operating the equipment to confirm that the safety devices cannot be disabled.

14.104 Microprocessors

Failure of a safety-related microprocessor shall not cause a HAZARD.

NOTE 1 This requirement can be achieved by redundancy or diversity.

NOTE 2 Guidance on safety related control systems using microprocessors and other software controlled devices is given in IEC 61508-3, ISO 13849-2, IEC 62061 and IEC 62304.

If a battery is used to maintain a processor memory, no HAZARD shall arise as a result of loss of this power.

Conformity is checked by inspection, RISK analysis, function of the circuit under evaluation and, in case of doubt, by simulating a fault.

14.105 Asbestos

No parts made of asbestos shall be used.

Conformity is checked by examination of the manufacturer's data.

15 Protection by interlocks

15.1 General

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new text after the first sentence:

As an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements of 15.2 and 15.3 can be determined by applying, for example IEC 62061 (SIL) or ISO 13849 (PL) (all parts) or other solutions providing equivalent functional safety.

16 HAZARDS resulting from application

This clause of Part 1 is applicable.

17 Risk assessment

This clause of Part 1 is applicable except as follows:

Addition:

Add the following item to the list of standards in the note:

ISO 12100:2010,

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Annexes

The annexes of Part 1 are applicable, except as follows:

Annex G (informative)

Leakage and rupture from fluids under pressure

This annex of Part 1 is applicable except as follows:

Replace the first paragraph by the following new paragraph:

The requirements and tests of this annex are accepted in the USA, Canada, and in some other countries, as proof of conformity with national regulations relating to high pressures. However, they do not apply to shell boilers and PRESSURE VESSELS, for which there are separate and different national or local regulations.

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Annex L
(informative)

Index of defined terms

Additional defined terms:

CHAMBER	3.2.101
LOAD	3.2.102
OPERATING CYCLE.....	3.2.105
PRESSURE VESSEL	3.2.104
STERILIZER.....	3.2.103
WASHER-DISINFECTOR.....	3.2.106

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Bibliography

Add the following publications:

IEC 60335-2-4, *Household and similar electrical appliances – Safety – Part 2-4: Particular requirements for spin extractors*

IEC 60335-2-5, *Household and similar electrical appliances – Safety – Part 2-5: Particular requirements for dishwashers*

IEC 60335-2-7, *Household and similar electrical appliances – Safety – Part 2-7: Particular requirements for washing machines*

IEC 60335-2-11, *Household and similar electrical appliances – Safety – Part 2-11: Particular requirements for tumble dryers*

IEC 60335-2-58, *Household and similar electrical appliances – Safety – Part 2-58: Particular requirements for commercial electric dishwashing machines*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 61010-2-010, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials*

IEC 62061, *Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems*

IEC 62304, *Medical device software – Software life cycle processes*

ISO 2901, *ISO metric trapezoidal screw threads – Basic and design profiles*

ISO 2902, *ISO metric trapezoidal screw threads – General plan*

ISO 2903, *ISO metric trapezoidal screw threads – Tolerances*

ISO 2904, *ISO metric trapezoidal screw threads – Basic dimensions*

ISO 10472 (all parts), *Safety requirements for industrial laundry machinery*

ISO 12100:2010, *Safety of machinery – General principles for design – Risk assessment and risk reduction*

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

ISO 14971, *Medical devices – Application of risk management to medical devices*

ISO 15223-2, *Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 2: Symbol development, selection and validation*

EN 12953 (all parts), *Shell boilers*

EN 13445 (all parts), *Unfired pressure vessels*

EN 14222, *Stainless steel shell boilers*

EN 1837, *Safety of machinery. Integral lighting of machines*

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

**EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES
DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –****Partie 2-040: Exigences particulières pour STERILISATEURS
et LAVEURS DESINFECTEURS utilisés pour traiter le matériel médical**

AVANT-PROPOS

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Cette troisième édition annule et remplace la deuxième édition parue en 2015. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

- a) elle est établie sur la base de la troisième édition (2010) de l'IEC 61010-1 et son Amendement 1 (2016);
- b) tolérance ajoutée pour la stabilité des matériels d'essai sous tension alternative spécifiés en 6.8.3.1;

- c) le statut de publication groupée de sécurité a été supprimé (ce qui ne modifie pas les exigences techniques du document).

Le texte de cette Norme internationale est issu des documents suivants:

CDV	Rapport de vote
66/699/CDV	66/716/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

L'attention du lecteur est attirée sur le fait que l'Annexe G énumère tous les articles traitant des différences à caractère moins permanent inhérentes à certains pays, concernant le sujet de la présente norme.

Une liste de toutes les parties de la série IEC 61010, publiées sous le titre général *Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire*, peut être consultée sur le site web de l'IEC.

La présente Partie 2-040 doit être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010) de l'IEC 61010-1 et son Amendement 1 (2016), désignée ci-après comme la Partie 1.

La présente Partie 2-040 complète ou modifie les articles correspondants de la Partie 1 de façon à transformer cette publication en norme IEC: *Exigences particulières pour les STÉRILISATEURS et LAVEURS DESINFECTEURS utilisés pour traiter le matériel médical*.

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans cette Partie 2-040, ce paragraphe s'applique pour autant que cela soit raisonnable. Lorsque la présente Partie 2-040 spécifie "addition", "modification", "remplacement" ou "suppression", l'exigence, la modalité d'essai ou la note correspondant de la Partie 1 doit être adaptée en conséquence.

Dans la présente norme:

- 1) les caractères d'imprimerie suivants sont utilisés:

- exigences, caractères romains;
- NOTES: petits caractères romains;
- conformité et essais: *caractères italiques*;
- termes définis à l'Article 3 et utilisés dans cette norme: PETITES CAPITALES EN CARACTERES ROMAINS.
- les paragraphes, figures et tableaux qui sont ajoutés à ceux de la Partie 1 sont numérotés à partir de 101; les annexes complémentaires sont nommées à partir de AA et les listes de termes complémentaires à partir de aa).

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "<http://webstore.iec.ch>" dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

EXIGENCES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-040: Exigences particulières pour STERILISATEURS et LAVEURS DESINFECTEURS utilisés pour traiter le matériel médical

1 Domaine d'application et objet

Cet article de la Partie 1 s'applique, avec les exceptions suivantes:

1.1.1 Appareils inclus dans le domaine d'application

Remplacement:

Remplacer le texte par le nouveau texte suivant:

La présente partie de l'IEC 61010 définit les exigences de sécurité pour les appareils électriques destinés à la stérilisation, au lavage et à la désinfection du matériel médical dans les domaines médicaux, vétérinaires, pharmaceutiques et de laboratoire, lorsqu'ils sont utilisés dans les conditions d'environnement de 1.4.

Exemples de ce type d'appareils:

- a) les STERILISATEURS et désinfecteurs utilisant la vapeur et/ou l'eau chaude comme agent stérilisant;
- b) les STERILISATEURS et désinfecteurs utilisant le gaz toxique, l'aérosol toxique, ou la vapeur toxique comme agent stérilisant;
- c) les STERILISATEURS et désinfecteurs utilisant de l'air chaud ou du gaz inerte chaud comme agent stérilisant; et
- d) les LAVEURS DESINFECTEURS.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter la note suivante au point f):

NOTE L'IEC 60601-1:2005, 3.63, définit les appareils électromédicaux comme suit (sans les notes à l'article):

appareil électrique qui possède une partie appliquée ou qui transfère de l'énergie vers le patient ou à partir de celui-ci ou qui détecte un tel transfert d'énergie vers le patient ou à partir de celui-ci et qui est:

- a) équipé au plus d'un moyen de raccordement à un RESEAU d'alimentation donné; et
- b) destiné par son fabricant à être utilisé:
 - 1) pour le diagnostic, le traitement ou la surveillance d'un patient ou
 - 2) pour la compensation ou l'atténuation d'une maladie, d'une blessure ou d'une incapacité

Addition:

Ajouter le nouveau second alinéa suivant après la liste:

Le présent document ne s'applique pas aux types d'appareils suivants:

- aa) appareils destinés à être utilisés dans des atmosphères dangereuses (voir l'IEC 60079), mais il s'applique toutefois à une atmosphère créée à l'intérieur de l'appareil par un agent stérilisant inflammable (voir 13.2.101 et 13.2.102);

- bb) équipements de laboratoire pour le chauffage des matériaux pour d'autres usages que la stérilisation ou la désinfection (voir l'IEC 61010-2-010);
- cc) équipement de blanchisserie (voir l'IEC 60335-2-4, l'IEC 60335-2-7, l'IEC 60335-2-11, et l'ISO 10472 (toutes les parties)), sauf s'il est conçu pour la désinfection des matériels médicaux;
- dd) lave-vaisselle (voir l'IEC 60335-2-5 et l'IEC 60335-2-58).

1.2.1 Aspects inclus dans le domaine d'application

Remplacement:

Remplacer le point g) par le nouveau texte suivant:

- g) les émissions de gaz (y compris l'échappement involontaire de gaz toxiques), les substances pathogènes, les explosions et les implosions (voir l'Article 13).

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter les deux nouveaux points suivants:

- aa) les exigences particulières pour la protection contre les DANGERS chimiques et microbiologiques à haut risque associés à la CHARGE.
- bb) les exigences générales pour la conception des calorifères, chaudières à tubes de fumée et RESERVOIRS SOUS PRESSION.

NOTE Les règlements ou codes nationaux et autres règlements ou codes s'appliquent pour la sécurité des calorifères, chaudières à tubes de fumée et RESERVOIRS SOUS PRESSION (voir 14.101).

2 Références normatives

Cet article de la Partie 1 s'applique, avec l'exception suivante:

Addition:

Ajouter les nouvelles références suivantes:

IEC 61770, *Appareils électriques raccordés au réseau d'alimentation en eau – Exigences pour éviter le retour d'eau par siphonnage et la défaillance des ensembles de raccordement*

ISO 3585, *Verre borosilicaté 3.3 – Propriétés*

ISO 4126-1, *Dispositifs de sécurité pour protection contre les pressions excessives – Partie 1: Soupapes de sûreté*

ISO 4126-2, *Dispositifs de sécurité pour protection contre les pressions excessives – Partie 2: Dispositifs de sûreté à disque de rupture*

3 Termes et définitions

Cet article de la Partie 1 s'applique, avec les exceptions suivantes:

3.2 Parties et accessoires

Addition:

Ajouter les nouveaux termes et définitions suivants:

3.2.101**CHAMBRE**

partie de l'appareil qui reçoit la CHARGE

3.2.102**CHARGE**

appareils ou matériaux mis dans une CHAMBRE pour être traités pendant un CYCLE DE FONCTIONNEMENT

3.2.103**STERILISATEUR**

appareil conçu pour réaliser la stérilisation qui comprend une série d'actions ou d'opérations nécessaires pour satisfaire aux exigences spécifiées pour l'asepsie

3.2.104**RESERVOIR SOUS PRESSION**

ensemble comprenant la CHAMBRE, l'enveloppe (si prévue), les portes, et tous les autres composants en connexion ouverte en permanence avec la CHAMBRE

Note 1 à l'article: Le RESERVOIR SOUS PRESSION n'inclut pas les parties desquelles il peut être isolé, comme les générateurs de vapeur, les tuyauteries et les accessoires.

3.2.105**CYCLE DE FONCTIONNEMENT**

ensemble complet d'étapes du processus exécuté, dans un ordre indiqué

Note 1 à l'article: Le chargement et le déchargement ne font pas partie du CYCLE DE FONCTIONNEMENT.

3.2.106**LAVEUR DESINFECTEUR**

appareil destiné à nettoyer et désinfecter les dispositifs médicaux et d'autres articles utilisés dans le contexte de la pratique médicale, dentaire, pharmaceutique et vétérinaire, par exemple

3.5 Termes de sécurité**3.5.2****DANGER**

Addition:

Ajouter la nouvelle Note 1 à l'article suivante:

Note 1 à l'article: Dans le cadre du présent document, le terme DANGER est uniquement lié aux sources potentielles de dommage affectant l'OPERATEUR et l'environnement (voir 1.2.1), et n'inclut pas les sources potentielles de dommage liées à l'efficacité du processus.

3.5.11**OPERATEUR**

Addition:

Ajouter la Note 1 à l'article suivante:

Note 1 à l'article: Le terme OPERATEUR inclut les personnes qui installent, font fonctionner, règlent, entretiennent, nettoient, réparent ou déplacent des appareils.

4 Essais

Cet article de la Partie 1 s'applique, avec les exceptions suivantes:

4.3.2.4 Couvertres et éléments amovibles

Addition:

Ajouter le nouveau second alinéa suivant:

Il n'est pas nécessaire d'enlever les couvercles, dont les panneaux et les enveloppes des boîtiers de commande, qui n'exigent pas l'utilisation d'un OUTIL pour le retrait, s'ils ont des systèmes de verrouillage qui satisfont aux exigences de l'Article 15, et qui désactivent automatiquement toutes les parties qui présenteraient autrement un DANGER quand le couvercle est ouvert.

4.3.2.12 Cycle de service

Addition:

Ajouter le nouveau second alinéa suivant:

Les appareils qui peuvent fonctionner de manière continue doivent également être soumis à l'essai sans aucun intervalle entre les CYCLES de FONCTIONNEMENT consécutifs.

Addition:

Ajouter le nouveau paragraphe suivant:

4.3.2.101 Alimentations et services non électriques

Ces alimentations et services doivent être placés sur les réglages ASSIGNÉS les moins favorables.

4.4.2.1 Généralités

Remplacement:

Remplacer la première phrase du premier alinéa par la phrase suivante:

Les conditions de défaut doivent inclure les conditions spécifiées de 4.4.2.2 à 4.4.2.14 et 4.4.2.101 à 4.4.2.103.

4.4.2.5 Moteurs

Addition:

Ajouter le nouveau second alinéa suivant:

S'il est impossible de soumettre à l'essai un moteur installé, un moteur identique séparé peut être soumis à l'essai, mais il doit l'être dans les mêmes conditions que celles à l'intérieur de l'appareil.

4.4.2.13 Verrouillage

Addition:

Ajouter le nouveau second alinéa suivant:

Si un système de verrouillage fournit la protection contre le contact accidentel avec une substance dangereuse, il est soumis à l'essai en utilisant une substance non dangereuse.

Addition:

Ajouter les trois nouveaux paragraphes suivants:

4.4.2.101 Régulateurs de pression

Les régulateurs de pression, sauf pour les dispositifs de sécurité de surpression satisfaisant aux exigences de 11.7.4, doivent être neutralisés pour fournir le service sans interruption.

4.4.2.102 Défaillance, ou défaillance partielle, de l'alimentation RÉSEAU

L'appareil doit fonctionner à 90 % et 110 % de la tension ASSIGNEE pour un cycle. La tension doit ensuite être placée à 90 % de la tension ASSIGNEE pendant 5 min. La tension doit ensuite être réduite progressivement à un taux d'approximativement 10 V par min jusqu'à ce que l'appareil ne fonctionne plus normalement. La tension doit ensuite être ramenée à la tension ASSIGNEE avec l'appareil toujours alimenté.

4.4.2.103 Défaillance, ou défaillance partielle, d'autres alimentations et services

Tour à tour, chaque alimentation et chaque service non électriques doivent être interrompus, ou partiellement interrompus, selon la condition la moins favorable.

NOTE Les exemples incluent l'air, la vapeur, l'eau d'alimentation, le gaz stérilisant, le détergent, le désinfectant et les systèmes pour la purge, l'échappement et la ventilation.

5 Marquage et documentation

Cet article de la Partie 1 s'applique, avec les exceptions suivantes:

5.1.2 Identification

Remplacement:

Remplacer le texte existant par le nouveau texte suivant:

L'appareil doit être marqué au moins de ce qui suit:

- a) le nom et l'adresse du fabricant;
- b) tout marquage supplémentaire exigé par les règlements nationaux et locaux, y compris le nom et l'adresse du représentant autorisé du fabricant dans le pays d'utilisation prévue;
- c) un marquage qui identifie de manière unique un seul appareil fabriqué, comme un numéro de série;
- d) l'année et le lieu de fabrication, s'ils diffèrent de l'adresse du fabricant;
- e) l'identification du modèle;
- f) la désignation de la fonction de l'appareil.

La vérification est effectuée par inspection.

Addition:

Ajouter les deux nouveaux paragraphes suivants:

5.1.101 Dispositif de protection contre la surpression

Le dispositif (voir 11.7.4) doit être marqué du nom du fabricant du dispositif, du numéro du modèle et de la pression à laquelle il est réglé. Si un disque de rupture est situé entre la CHAMBRE et le dispositif de sécurité de surpression, il doit être identifié par sa pression de rupture spécifiée et la température associée.

NOTE Des règlements nationaux ou locaux ou autres codes peuvent s'appliquer.

5.1.102 RÉSERVOIRS SOUS PRESSION et chaudières à tubes de fumée

L'attention est attirée sur l'existence de règlements nationaux et locaux qui peuvent exiger des marquages complémentaires.

5.2 Marquages des avertissements

Addition:

Ajouter le nouveau second alinéa suivant:

Les symboles des marquages Avertissement et Attention doivent avoir une hauteur d'au moins 10 mm.

5.4.1 Généralités

Remplacement:

Remplacer le premier alinéa (à l'exclusion de la liste) par le nouvel alinéa suivant:

Pour les besoins des OPERATEURS ou de l'AUTORITE RESPONSABLE, la documentation suivante, nécessaire pour des raisons de sécurité, doit être marquée de sa date d'édition ou de son statut de révision et être fournie avec l'appareil:

Ajouter le nouvel alinéa suivant après le point h) de la liste:

Si l'UTILISATION NORMALE comporte la manipulation d'une substance dangereuse, la documentation doit inclure des informations sur les constituants, le stockage correct, l'utilisation et l'élimination en toute sécurité.

Remplacer la Note 2 par la nouvelle Note 2 suivante:

NOTE 2 L'attention est attirée sur l'existence de règlements nationaux et locaux qui peuvent s'appliquer à la documentation.

Ajouter un nouvel alinéa juste avant l'énoncé de conformité:

Le marquage, les informations et la langue doivent:

- 1) être conformes aux règlements qui s'appliquent dans le pays de l'utilisation prévue;

NOTE 3 L'ISO 15223-2 fournit des recommandations concernant les appareils classés comme dispositifs médicaux.

- 2) comporter des instructions sur l'élimination de l'appareil, ses accessoires et son conditionnement;

- 3) prendre dûment en considération les connaissances techniques, l'éducation et la formation des différentes catégories d'OPERATEURS;
- 4) ne pas être en contradiction avec les informations figurant dans la documentation fournie pour décrire l'appareil.

5.4.2 Caractéristiques assignées des appareils

Addition:

Ajouter le nouveau point suivant à la liste, après le point f):

- aa) pour chaque service non électrique, le cas échéant, les plages ASSIGNEES de température, de pression et de débit.

5.4.3 Installation des appareils

Remplacement:

Remplacer les points a) à g) par ce qui suit:

- a) les instructions d'emplacement et de montage;
- b) l'espace exigé pour l'entretien sûr et efficace;
- c) les différents poids des principaux sous-ensembles lourds;
- d) les exigences relatives au poids global et aux charges au sol;
- e) les instructions de déballage et d'assemblage (voir aussi 7.108);
- f) les exigences et connexions relatives à l'alimentation RESEAU, y compris les caractéristiques assignées de la température de tout câble dont il faut qu'elles satisfassent aux exigences de 5.1.8;
- g) pour les APPAREILS BRANCHES EN PERMANENCE:
 - 1) les exigences relatives au câblage d'alimentation;
 - 2) les exigences pour tout interrupteur ou tout disjoncteur extérieur (voir 6.11.3.1) et pour les dispositifs extérieurs de protection contre les surintensités (voir 9.6.1), ainsi qu'une recommandation stipulant que l'interrupteur ou le disjoncteur soit placé à côté de l'appareil;
- h) les exigences relatives à la ventilation (voir 11.101, 13.1.103.1 et 13.1.101);
- i) les exigences relatives à la purge (voir 11.101);
- j) les instructions pour la mise à la terre de protection;
- k) les instructions relatives au niveau acoustique (voir 12.5.1);
- l) les exigences relatives aux services particuliers, par exemple air, eau d'alimentation, liquide de refroidissement;
- m) les exigences relatives aux atmosphères de gaz dangereuses (voir l'Article 13);
- n) les instructions pour placer l'appareil de sorte qu'il ne soit pas difficile de déclencher le dispositif de sectionnement;
- o) les instructions concernant la manipulation et le confinement de substances dangereuses, y compris tout besoin de matériel supplémentaire qui peut être exigé pour contrôler des émissions (voir 13.1);
- p) les instructions concernant les DANGERS provoqués par des liquides ou éléments chauds tombant de l'appareil (voir 9.1);
- q) les exigences relatives aux matériaux utilisés dans l'installation de l'appareil et qui peuvent entrer en contact avec l'agent stérilisant (voir 13.1.103.4 et 13.2.101);
- r) les instructions pour l'éclairage ambiant (voir aussi 11.102);

NOTE L'ISO 12100 et l'EN 1837 fournissent des recommandations concernant l'éclairage.

s) les instructions relatives à l'émission de chaleur.

Addition:

Ajouter le nouveau paragraphe suivant:

5.4.3.101 Systèmes spéciaux

Les instructions d'installation doivent inclure les informations détaillées des systèmes spéciaux suivants, si nécessaires pour assurer une protection contre des DANGERS possibles:

a) un système de ventilation sans remise en circulation pour le local dans lequel l'appareil est installé (voir aussi 13.1.103.3);

Un tel système de ventilation doit normalement fournir 10 renouvellements d'air à l'heure au minimum, mais, pour de grandes installations, il peut être nécessaire d'augmenter ce débit.

b) pour les appareils utilisant un agent stérilisant toxique, les moyens de protection contre des DANGERS résultant de la défaillance du système de ventilation du local (voir 13.1.103.3);

c) un système d'évacuation local sans remise en circulation pour enlever les émissions transitoires (voir 13.1.101.4);

d) un système de purge (voir 13.1.101.3);

e) un système de ventilation pour la purge (voir 13.1.101.3);

f) un système d'évacuation de CHAMBRE (voir 13.1.101.2);

g) un système utilisé pour contrôler les émissions biologiques échappantes (voir 13.1.104);

h) toute autre alimentation, par exemple agent stérilisant, vapeur, air comprimé, eau chaude ou froide (y compris les instructions sur la prévention du retour d'eau par siphonnement (voir 11.104).

La vérification est effectuée par inspection.

5.4.4 Fonctionnement de l'appareil

Remplacement:

Remplacer les points a) à j) par ce qui suit:

a) l'identification des dispositifs de commande et leur utilisation dans tous les modes de fonctionnement;

b) une instruction de ne pas positionner l'appareil de manière à rendre difficile la manœuvre du dispositif de sectionnement;

c) les instructions pour l'interconnexion aux accessoires et tout autre appareil, y compris les informations détaillées des accessoires appropriés, pièces amovibles et tous matériaux spéciaux;

d) la spécification des limites de fonctionnement intermittent;

e) une explication des symboles relatifs à la sécurité utilisés sur l'appareil (voir 5.2);

f) les instructions relatives au nettoyage (voir 11.2);

g) les instructions pour rendre les appareils sûrs après un CYCLE DE FONCTIONNEMENT incomplet;

h) les instructions pour l'utilisation correcte du dispositif de prévention de fermeture de la porte verrouillable (voir 7.102 b));

i) les instructions destinées à l'AUTORITE RESPONSABLE pour l'accès sûr à la CHARGE dans la CHAMBRE en cas de défaut (voir 13.1.102);

j) les instructions pour l'action en cas de dysfonctionnement, y compris le diagnostic de panne;

NOTE 1 Ces instructions peuvent inclure toutes les méthodes spéciales d'interprétation des données enregistrées ou notées pendant le CYCLE DE FONCTIONNEMENT, pour détecter les défaillances ou les tendances qui peuvent mener à la défaillance, par exemple l'utilisation d'un enregistreur de température.

- k) la procédure de charge;
- l) les instructions pour l'élimination en toute sécurité des parties telles que les récipients de détergent, les récipients d'agent stérilisant et les parties contaminées par une matière pathogène;

NOTE 2 Les exigences complémentaires sur les méthodes d'élimination peuvent être spécifiées par les autorités nationales ou locales.

- m) les instructions pour vérifier par essai la fonction des dispositifs de sécurité critiques de manière sûre, par exemple les dispositifs de sécurité de surpression (voir 11.7.4);
- n) si l'UTILISATION NORMALE comporte la manipulation de substances, des instructions sur l'utilisation correcte et des dispositions de sécurité. En complément, des instructions doivent être fournies sur les méthodes de manipulation en toute sécurité avant l'élimination, et les recommandations d'élimination (voir aussi la Note 2 ci-dessus);
- o) les informations détaillées concernant les méthodes de réduction des DANGERS de brûlures provoqués par des surfaces qui peuvent dépasser les limites de température spécifiées dans le Tableau 19;
- p) les lignes directrices à suivre en cas d'urgence impliquant un risque de contact oculaire ou cutané ou d'inhalation, tel que le dégagement d'une matière toxique ou d'une matière pathogène, ou la fuite d'un récipient d'agent stérilisant ou d'agent désinfectant ou la fuite d'un récipient de détergent enzymatique, alcalin ou acide;
Ces lignes directrices doivent également être indiquées de façon lisible sur ou à proximité de l'appareil.
- q) les instructions de remplissage en toute sécurité des récipients de dosage de produits chimiques (voir 13.102);
- r) en cas de DANGER résultant de l'utilisation de l'appareil avec un type de CHARGE autre que les types pour lesquels il est prévu, les instructions doivent comporter un avertissement approprié et un marquage d'avertissement (voir 5.2) doit énoncer les types de CHARGES qui peuvent être employés. Si un appareil de petite taille ne dispose pas d'un espace suffisant pour ce marquage d'avertissement, le symbole 14 du Tableau 1 doit être marqué;
- s) les instructions pour l'inspection, le remplissage et le stockage des matières consommables susceptibles de provoquer un DANGER, y compris des informations détaillées concernant les DANGERS susceptibles de résulter de l'introduction de quantités incorrectes de matières consommables recommandées, ainsi que les procédures et informations détaillées de la protection nécessaire pour réduire le plus possible de tels DANGERS;
- t) l'identification des RISQUES résiduels et des instructions sur les mesures de protection nécessaires (voir l'Article 17).

5.4.5 Entretien de l'appareil et service

Remplacement:

Remplacer le texte existant par le nouveau texte suivant:

Les instructions doivent être fournies à l'attention de l'AUTORITE RESPONSABLE de façon suffisamment détaillée pour permettre l'entretien, l'inspection et l'essai de l'appareil en toute sécurité, et pour assurer la sécurité permanente de l'appareil après les procédures d'entretien, d'inspection et d'essai.

Les instructions doivent inclure:

- a) les informations détaillées de l'entretien exigé des parties soumises à l'usure si une défaillance peut donner lieu à un DANGER;
- b) l'inspection et le remplacement, si nécessaire, de tous les flexibles/tuyaux ou autres parties contenant des fluides, si leur défaillance peut provoquer un DANGER;

- c) les informations détaillées des dispositifs de sécurité installés, ainsi que leurs réglages et procédures de remplacement;
- d) les procédures pour assurer la sécurité des appareils avant entretien;
- e) les programmes d'entretien et les procédures de réparation, y compris le niveau d'éclairage ambiant (voir 11.102) et toutes les précautions particulières nécessaires pour la protection contre les DANGERS pendant l'entretien;
- f) les méthodes de manipulation en toute sécurité, pour la réparation ou l'élimination, de toute partie contenant des matières toxiques et/ou pathogènes ou contaminée par elles;

NOTE 1 Des exigences concernant les méthodes d'élimination peuvent être spécifiées par les autorités nationales ou locales.

NOTE 2 Les aspects relatifs à l'impact sur l'environnement sont traités dans l'ISO 14971 et dans les parties applicables de l'IEC 61508.

- g) les types de batteries pour les appareils utilisant des batteries remplaçables;
- h) les valeurs assignées et caractéristiques des fusibles remplaçables.
- i) une liste des parties (le cas échéant), limitée à l'examen et/ou la fourniture par le fabricant ou par son représentant;
- j) les RISQUES résiduels (voir l'Article 17) et les mesures de protection pour ces RISQUES;
- k) la vérification que l'appareil est dans un état sûr après la réparation.

La vérification est effectuée par inspection.

Addition:

Ajouter les deux nouveaux paragraphes suivants:

5.4.101 Formation de l'OPÉRATEUR

5.4.101.1 Généralités

Pour que les OPERATEURS soient correctement formés à l'utilisation en toute sécurité de l'appareil, les instructions du fabricant doivent indiquer qu'il convient que l'AUTORITE RESPONSABLE vérifie:

- a) que tout le personnel qui fait fonctionner ou entretient l'appareil est formé à son fonctionnement et à son utilisation en toute sécurité;
- b) que, si des limites d'exposition (c'est-à-dire limite d'exposition à court terme (STEL – *short-term exposure limit*) ou limite d'exposition à long terme (LTEL – *long-term exposure limit*)) ou la limite de concentration environnementale de fonctionnement admissible (voir les notes de 13.1) peuvent être dépassées pendant l'UTILISATION NORMALE, le personnel qui travaille avec des produits chimiques, gaz et vapeurs toxiques a reçu des instructions complètes dans le processus. Ces instructions incluent l'information concernant les DANGERS pour la santé concernés, des règlements nationaux, des méthodes pour l'utilisation en toute sécurité et des méthodes pour détecter la fuite de l'agent stérilisant;
- c) qu'il existe une formation régulière de tout le personnel concerné par le fonctionnement et l'entretien de l'appareil, y compris des procédures de secours pour toute matière toxique, inflammable, explosive ou pathogène déchargée dans l'environnement. Les enregistrements de la présence à la formation sont tenus à jour, et la preuve de la compréhension est démontrée.

Voir aussi 7.3.2 b).

La vérification est effectuée par inspection.

5.4.101.2 Procédures pour les actions potentiellement dangereuses

Le fabricant doit indiquer les procédures de sécurité pour toutes les actions potentiellement dangereuses destinées à être effectuées par un OPERATEUR, par exemple le remplacement des pièces ou l'ajustement des commandes internes. Les instructions doivent indiquer qu'il faut que l'AUTORITE RESPONSABLE fournisse AUX OPERATEURS la formation nécessaire à ces procédures.

La vérification est effectuée par inspection.

6 Protection contre les chocs électriques

Cet article de la Partie 1 s'applique, avec les exceptions suivantes:

6.2.2 Examen

Addition:

Ajouter le nouveau troisième alinéa suivant après la Figure 1:

Les APPAREILS FIXES et les appareils avec un poids dépassant 80 kg ne sont pas inclinés ou déplacés afin de vérifier le fond, mais le doigt d'épreuve est appliqué sur toute partie du fond qui peut être atteinte quand l'appareil est installé selon les instructions du fabricant.

6.8.3.1 Essai en tension alternative

Remplacement:

Remplacer la première phrase par la phrase suivante:

Le testeur de tension doit être capable de maintenir la tension d'essai tout au long de l'essai à $\pm 5\%$ de la valeur spécifiée.

6.9.2 Matériaux isolants

Addition:

Ajouter la nouvelle note suivante à la fin du paragraphe, avant l'énoncé de conformité:

NOTE Bien que la céramique puisse fournir une isolation électrique satisfaisante à la température ambiante, l'attention est attirée sur le fait que certaines céramiques peuvent présenter des propriétés isolantes réduites à des températures élevées. Ce phénomène s'explique non seulement parce que ces céramiques sont susceptibles de détérioration mécanique progressive, mais également parce qu'elles peuvent devenir électriquement conductrices à des températures élevées et peuvent, en UTILISATION NORMALE, être contaminées par le matériau conducteur.

7 Protection contre les DANGERS mécaniques

Cet article de la Partie 1 s'applique, avec les exceptions suivantes:

Remplacement:

Remplacer le titre par le nouveau titre suivant:

7 Protection contre les DANGERS mécaniques et les DANGERS liés aux fonctions mécaniques

7.1 Généralités

Remplacement:

Remplacer l'énoncé de conformité par le nouvel énoncé de conformité suivant:

La vérification est effectuée comme cela est spécifié de 7.2 à 7.7 et de 7.101 à 7.110.

7.4 Stabilité

Addition:

Ajouter le nouveau point suivant à la liste, après la note du point e):

- aa) *pour les appareils avec une porte qui, lorsqu'elle est ouverte, est horizontale ou quasi horizontale, et qui peut être utilisée pour soutenir la CHARGE, un poids égal à 1,2 fois la CHARGE ASSIGNEE la plus élevée (spécifiée dans le manuel d'utilisation) est appliqué au centre de la porte ouverte, ou suspendu audit centre.*

7.5 Moyens de levage et de transport

Addition:

Ajouter le nouveau paragraphe suivant:

7.5.101 Transfert des CHARGES dans et hors de la CHAMBRE

Des moyens doivent être prévus pour protéger l'OPERATEUR contre les DANGERS mécaniques qui peuvent survenir pendant le transfert de la CHARGE dans ou hors de la CHAMBRE.

Des moyens doivent être prévus pour localiser et maintenir la CHARGE et son support (lorsqu'il existe) dans la position correcte pour le transfert de la CHARGE dans ou hors de la CHAMBRE.

Si une étagère coulissante dans la CHAMBRE doit être retirée pour accepter la CHARGE ou permettre son retrait, des moyens doivent être prévus pour empêcher d'incliner l'étagère ou pour éviter de la dégager involontairement en la retirant.

La force exigée par un OPERATEUR pour mettre la CHARGE dans la CHAMBRE ou pour l'enlever de la CHAMBRE ne doit pas dépasser 250 N.

La vérification est effectuée par inspection et par essai, en utilisant la CHARGE la moins favorable spécifiée par le fabricant.

Addition:

Ajouter les nouveaux paragraphes suivants:

7.101 Portes, convoyeurs, etc.

Un DANGER ne doit pas être provoqué en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAULT par:

- a) un mécanisme utilisé pour ouvrir, fermer, ou retenir une porte;
- b) l'usure des pièces filetées;

NOTE Les filetages satisfaisant aux exigences de l'ISO 2901, l'ISO 2902, l'ISO 2903 et l'ISO 2904 peuvent être adaptés.