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,

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.

Annex L
(informative)

Index of defined terms

Additional defined terms:

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*