CANADIAN STANDARDS ASSOCIATION

Z314.3-09
(reaffirmed 2014)

Effective sterilization in health care facilities by the steam process

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CANADIAN STANDARDS ASSOCIATION

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The following revisions have been formally approved and are marked by the symbol delta (Δ) in the margin on the attached replacement pages:

Revised	Clauses 12.2.1(c), F.1, F.4, and F5
New	Table F.1
Deleted	None

- Update your copy by inserting these revised pages.
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depend on the type and quality of information that the health care facility requires in any given situation (see Annex E for more detailed information on chemical indicators). The six types of chemical indicators are the following:

(i) Class 1 (Process indicators) serve only to distinguish processed goods from items that have not been sterilized.
Note: *Sterilizer tape and indicator labels are examples of Class 1 indicators.*

(ii) Class 2 (Specific tests, e.g., Bowie-Dick) are employed in special applications such as the Bowie-Dick air removal test. They measure a specific attribute such as air removal or steam penetration.

(iii) Class 3 (Single variable indicators) respond to a single sterilization variable such as time or temperature. They provide limited information regarding the overall efficacy of a sterilization process.

(iv) Class 4 (Multi-variable indicators) respond to two or more of the critical variables of the sterilization process.

(v) Class 5 (Integrators) have stated values and respond to all critical sterilization variables over a stated range of sterilization cycles. Their response is correlated to that of the appropriate biological indicator test organism for that sterilization process and must maintain that correlation over a range of test conditions (e.g., for steam sterilization, a Class 5 chemical indicator must demonstrate correlation to the survival/kill curve of Geobacillus stearothermophilus at 121 °C, 135 °C, and one temperature in the middle of the range 121 to 135 °C).

(vi) Class 6 (Emulators) respond to all critical sterilization variables and provide stated values for each one. The stated values are specific to a particular sterilization process and are not necessarily correlated to the biological indicator test organism. In addition, Class 6 indicators are required to have stated values for only one specific set of sterilization conditions.

Δ (c) Biological indicators (BIs) consist of spores on a carrier. Self contained biological indicators also contain incubation medium. Once sterilized, BIs are incubated until it is determined whether or not the micro-organisms grow (i.e., they have survived the sterilization process). BIs provide a direct measure of the lethality of the sterilization process. When using BIs to monitor sterilizer efficacy, a BI control test shall be performed in accordance with the BI manufacturer's instructions. At least one BI control test shall be performed for each BI shipping container or lot, or both. The results of the BI test and the BI control test shall be documented.

12.2.2 Process challenge devices (PCDs)

During monitoring, a biological or chemical indicator is usually placed within a PCD, which presents a challenge to the process that is equal to or greater than the challenge posed by the most difficult item that is routinely sterilized. A biological test pack is an example of a PCD. A PCD can be commercially manufactured or prepared in-house.

12.2.3 Using sterilization indicators and PCDs

12.2.3.1

Sterilization indicators shall be used only for the sterilizer type and sterilization cycle for which they were designed and validated and shall be used in accordance with the indicator manufacturer's instructions.

12.2.3.2

Sterilization indicators shall be used and interpreted only by qualified personnel who have been trained in these functions.
Note: *This requirement includes the personnel who will interpret the indicators following sterilization and at point of use.*

12.2.3.3

Sterilization indicators shall be purchased in accordance with Clause 5.4.

12.2.3.4

PCDs, if prepared in-house, shall be assembled in accordance with Clause 12.12.

12.2.3.5
Sterilization indicators shall not be used beyond their expiration date and shall be stored in accordance with the manufacturer's instructions regarding environmental conditions.

12.2.3.6
Biological indicators that have a viable population (i.e., positive biological indicators) after incubation shall be disposed of according to health care facilities procedures.
Note: *Manufacturer's instructions should also be checked for disposal instructions.*

12.2.4 Changes to PCDs

12.2.4.1
When changing to a new brand or model of PCD, the facility should review product specifications or consult the manufacturer to determine equivalence to a reference PCD — either an in-house prepared PCD or a commercially-manufactured PCD that has been used successfully.
Note: *PCDs can differ significantly between brands, even when sold for the same purpose. The facility should request comparative data from the manufacturer of the new PCD to determine the range of conditions to which it responds (i.e., whether the response range is narrower or wider than the PCD currently being used and whether it responds at higher or lower points within the allowable range for its class).*

If a PCD with a narrow response range is replaced with one having a broader response range, changes in sterilizer performance could go unnoticed. Conversely, if an existing PCD is replaced with one having a narrower response range or a range that tends to be higher than the old PCD, the facility could see an increase in load failures. The purpose of the comparison is not necessarily to eliminate a PCD from consideration but to give the facility essential information that can help it to make a successful transition from the old to the new PCD.

12.2.4.2
When changing to a new brand or model of PCD, staff shall be trained in the use of the new PCD, including differences in
(a) handling;
(b) placement;
(c) reading and interpreting;
(d) response ranges (breadth of response as well as response levels); and
(e) disposal.

12.3 Installation qualification
Installation qualification shall be performed by the sterilizer manufacturer (or designate) following installation of the sterilizer. The sterilizer manufacturer shall have written documentation outlining the health care facility's responsibilities and activities related to the installation qualification, including the management of documents and records relating to the purchase, installation, and commissioning of the equipment. These procedures shall describe the facility personnel who will be involved with the installation qualification of reprocessing equipment and their specific responsibilities with regards to the installation qualification and commissioning of the equipment. The installation qualification process shall be documented and a copy of the records retained by the health care facility.
Note: *Commissioning (which includes installation qualification and operational qualification) is the process of installing the sterilizer and assuring that the sterilizer operates with all its accessories according to the specified performance criteria. It includes the steps needed to confirm that the equipment meets the necessary requirements and that the utilities that are connected to the equipment meet the manufacturer's specifications. Commissioning can involve*
(a) checking steam and water capacities;
(b) checking sewer capacity and drain configuration;
(c) assuring that the installation location is straight, square, and level and meets architectural specifications;
(d) measuring clearance around the equipment and services;
(e) measuring water quality, water pressure, and volume of flow;
(f) evaluating steam quality;
(g) checking the installation against drawings, code requirements, and environmental specifications; and
(h) assuring that all environmental conditions are satisfied (i.e., lighting, HVAC, and physical facilities [flooring, ceiling, and walls] are correctly provided).

E.3.2

Chemical indicators are classified as follows:

(a) Class I indicators are process indicators (i.e., they are used to differentiate processed from non-processed goods). They are typically applied to the outside of packages. These indicators are designed to respond to one or more critical process variables and because of their exposed position will change well before sterilization conditions are reached. In a package that has been through a sterilizer, an unchanged Class 1 indicator would occur if, for example, the sterilizer was not turned on or if there was a gross malfunction, such as a power failure.

(b) Class II indicators are indicators that are designed for specific tests. In practice, most Class II indicators are for air-detection tests (Bowie and Dick tests). Within this group there is further distinction between the European and North American versions of the air-detection test.

(c) Class III indicators respond to a single critical process variable in the sterilization process (e.g., time or temperature) and is designed to indicate when a stated value (SV) of the chosen variable is reached. The SV is specified by the indicator manufacturer. Because they only respond to one variable, Class III indicators should be used with caution, as most sterilization processes have more than one critical variable that determines whether sterilization will not occur.

(d) Class IV indicators respond to two or more of the critical variables in the sterilization cycle. The manufacturer will state the conditions under which multi-variable chemical indicators will reach their endpoint. Class IV indicators typically provide more information than either process (Class I) or single parameter (Class III) indicators.

(e) Class V indicators are also referred to as integrating indicators because they are designed to respond to all critical variables. The SVs are generated to be equivalent to, or to exceed, the performance requirements of biological indicators, (i.e., they attempt to reproduce the response of a living micro-organism to the complex interrelationships of the critical sterilization process parameters). Class V indicators do not necessarily provide the same sort of biological integration of variables but they do provide information about the conditions necessary to destroy micro-organisms.

(f) Class VI indicators are also referred to as "emulating indicators." These indicators are designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process.

E.3.3

Chemical indicators provide information about sterilization conditions in the test location. The amount and quality of information depend on the design of the indicator. No chemical indicator can provide sterility assurance on its own. The overall sterility assurance program should include product identification and traceability of sterilized goods, sterilizer calibration, maintenance, and efficacy testing, as well as mechanical, chemical, and biological monitoring of sterilization cycles. See CAN/CSA-15882.

E.4 Air-detection PCDs (bowie-dick test packs)

An air-detection PCD is a type of Class II chemical indicator used to determine whether a dynamic air removal-type sterilizer has properly evacuated the air from the load.

Annex F (informative)
Extended cycle times

Notes:
(1) *This Annex is not a mandatory part of this Standard.*
(2) *This text is adapted from a user alert that was developed by an ad hoc group of members from the Technical Committee on Sterilization and first published as Alfa (2006).*

Δ F.1

Prior to the purchase/trial of any new equipment, the health care facility should require from the medical device manufacturer detailed information on the cleaning procedures and steam sterilization cycles appropriate for use with the device. If the device requires a non-standard cycle (extended cycle) as part of the reprocessing protocol, the manufacturer should be asked if a protocol using the standard cycles is also available. If available, the alternative protocol should be received in writing from the manufacturer detailing the process. The health care facility should request information from the manufacturer as to the means whereby the extended processing cycle should be monitored in order to ensure that effective sterilization of the device is assured. This process should be implemented for all medical devices, regardless of whether the device is purchased, leased, or loaned. Product testing is performed to verify the extended timing recommended by the device or container manufacturer.

F.2

In the absence of appropriate biological and chemical indicators (PCDs, for existing sets, that have been validated for use with these prolonged sterilization cycles, the health care facility can do some limited testing to ensure that steam penetration is achieved by placing biological indicators in various locations within the instrument set (see Clauses 12.5.2.5 and 12.5.2.7). Regardless of the container design, the testing should include three biological indicators placed in each layer of the set. Once the case set has been wrapped and sterilized in the appropriate extended steam sterilization cycle, the biological indicators are removed and incubated as appropriate for that type of indicator and the tray is reprocessed. If any biological indicators fail (i.e., exhibit growth of the test organism), there is a high probability of inadequate steam penetration or poor heating since biological indicators should be completely killed within 3 to 4 min of exposure to saturated steam at 132 °C. If possible, breaking down the tray to smaller tray sets and then retesting should be done. If this is not possible or if failure still occurs, then the device is immediately removed from use and an incident report is sent to both the device manufacturer and Health Canada.

F.3

Once the cycle has been completed, the tray/container should be dismantled and the indicators tested. The loaded tray serves as the PCD. Although testing can be done for surgical sets, it is not possible to do this for individual devices where steam penetration is questionable (e.g., orthopedic devices or electrical equipment). Even if the test organisms in the biological indicator are killed, testing might not be a valid indication that the device has been adequately sterilized. Most biological indicators are typically inactivated within 3 to 4 min of steam exposure at 132 to 135 °C (with most prevacuum sterilizers, the spores are killed within the first 1 to 2 min of exposure). Another issue is that the growth media inside self-contained biological indicators might not function properly after processing through very long steam sterilization cycles. If the growth media is part of the PCD and if the growth-promoting ability of this media is detrimentally affected by the long exposure of the media to heat, the biological indicator might not perform properly. Therefore, it is imperative that the biological indicator manufacturer provide

validated data to confirm that the biological indicator functions appropriately and can be used in extended cycles. A PCD providing a challenge to the sterilization process equivalent to that presented by the actual device or load is required. This PCD could be provided either by the biological indicator manufacturer or the device manufacturer.

Δ F.4

The health care facility should be aware of the need for caution when a manufacturer or distributor claims their indicators are usable in extended or prion cycles. The following should be noted:

(a) whether the indicator device received clearance from the FDA (Food and Drug Administration) for use in extended cycles. If clearance has been given, a copy should be reviewed to verify that claim
(b) the cycle variables that the chemical and biological indicators monitor and the label claims that the indicator has.

Δ F.5

The health care facility needs to ensure that the medical device manufacturer's instructions are followed for extended cycle times unless the manufacturer provides written documentation that the device can be properly sterilized for 4 min at 132 °C or 3 min at 135 °C. Such an alternative might be available, for example, with devices from Europe that have a recommended 18 min sterilization cycle. This cycle is intended primarily for situations when prion contamination is a concern and the manufacturer might be able to offer a validated process with a shorter sterilization time if prion inactivation is not required. If no appropriate biological indicator or PCD exists for the extended cycle, the facility needs to require the device manufacturer to provide advice as to the appropriate biological indicator or PCD to use or perform testing themselves to ensure adequate sterilization conditions are realized. This is critical to ensure adequate patient safety. The user needs to ensure that packaging materials can withstand extended timings. See Table F.1 for standard extended steam sterilization cycle times and temperatures.

Δ

Table F.1
Standard extended steam sterilization cycle times and temperature
(See Clause F.5.)

Cycle type	Temperature	Time
Dynamic air removal	134°C	10 min
Dynamic air removal	132°C	20 min
Gravity displacement	121°C	40 min
Gravity displacement	121°C	60 min

Annex G (informative)
Specifications and calculations for the density of muslin textile packages

Notes:
(1) *This Annex is not a mandatory part of this Standard.*
(2) *The formula given is for muslin textiles only and should not be applied to other wrapping materials.*

G.1 Specifications

Muslin textile packages, used as reference PCDs for sterilization testing, have the following dimensions:
(a) dimensions of 305 × 305 × 508 mm;
(b) a mass of 5.45 kg; and
(c) a density of 115.3 kg/m^3.

G.2 Calculating density

G.2.1

The formula for calculating density of a textile package is

$$D = \frac{M}{V}$$

or

$$D = \frac{M}{L \times W \times H}$$

where
D = density, kg/m^3
M = mass, kg
V = volume, m^3
L = length, m
W = width, m
H = height, m

G.2.2

The following sample calculation for density is provided using the values given in Clause G.1:
(a) Volume of package:

Conversion factor 1 m^3 = 1 × 10^9 mm^3

Volume (m^3) = Dimensions of pack (mm^3) / 1 × 10^9 mm^3/m^3

305 × 305 × 508 mm/1 × 10^9 mm^3/m^3 = 47 256 700 mm^3/1 × 10^9 mm^3/m^3

= 4.726 × 10^{-2} m^3

(b) Density of package:

Density = 5.45 kg/4.726 × 10^{-2} m^3 = 115.3 kg/m^3

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Preface

This is the fifth edition of CSA Z314.3, *Effective sterilization in health care facilities by the steam process.* It supersedes the previous editions, published in 2001, 1991, 1985, and 1979. It is one of a series of CSA Standards dealing with the safe and effective sterilization of medical supplies and equipment.

This Standard is a procedural and equipment guide for health care facilities using steam sterilization and is based on the principle that steam sterilization should always be the preferred method of sterilization for medical devices. The aim of the Standard is to help health care facilities using steam sterilizers to achieve an adequate level of sterility assurance. The Standard emphasizes a systems approach, recognizing that sterility assurance is dependent not only on reliable sterilizer operation but also on proper pre- and post-sterilization practices.

CSA standards are reviewed at least every five years, and based on the Technical Committee's decision, a standard will be revised, reaffirmed, or withdrawn at that time. Users of this Standard are advised to ensure that they are working with the most recent published version.

This Standard was prepared by the Subcommittee on Moist Heat Sterilization under the jurisdiction of the Technical Committee on Sterilization and the Strategic Steering Committee on Health Care Technology. It has been formally approved by the Technical Committee, and will be submitted for approval as a National Standard of Canada by the Standards Council of Canada.

March 2009

Notes:

(1) *Use of the singular does not exclude the plural (and vice versa) when the sense allows.*

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

(3) *This publication was developed by consensus, which is defined by* CSA Policy governing standardization — Code of good practice for standardization *as "substantial agreement. Consensus implies much more than a simple majority, but not necessarily unanimity". It is consistent with this definition that a member may be included in the Technical Committee list and yet not be in full agreement with all clauses of this publication.*

(4) *CSA Standards are subject to periodic review, and suggestions for their improvement will be referred to the appropriate committee.*

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Requests for interpretation should

(a) define the problem, making reference to the specific clause, and, where appropriate, include an illustrative sketch;

(b) provide an explanation of circumstances surrounding the actual field condition; and

(c) be phrased where possible to permit a specific "yes" or "no" answer.

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Z314.3-09
Effective sterilization in health care facilities by the steam process

0 Introduction

This Standard is intended to form the basis of a quality system within a health care facility for the purpose of providing safe, reliable steam sterilization of reusable medical devices. It is one of a series of Standards dealing with specific aspects of medical device reprocessing.

Medical devices are used in nearly every medical procedure. Patients and health care professionals expect these devices to be as safe as possible in terms of design, manufacture, and maintenance. The safety of medical devices begins with the manufacturer and is supported and maintained by a system of national standards and government regulations that includes device licensing, construction and performance standards, and problem reporting systems.

Within this structure, a health care facility that reprocesses reusable devices plays an essential role and, at the same time, faces unique challenges. Unlike a medical device manufacturer, health care facilities work with a wide array of items made by different companies and these devices arrive in the sterile processing department in varying states of cleanliness and repair. It is up to the department to clean and decontaminate each device, assess its condition, perform necessary maintenance, and sterilize it, using tested and validated methods. The ultimate goal is to be able to provide reprocessed medical devices, having confidence that they will do what they were originally manufactured to do and are safe to use on patients.

Health Canada requires the manufacturers of the more critical classes of reusable medical devices to establish and maintain quality systems in accordance with international standards. Under these quality systems, manufacturers must validate their recommended reprocessing instructions through the use of extensive testing. Health care facilities do not have the resources or expertise to do this type of validation in their own sterilizers, and therefore must instead develop procedures whereby they can verify they are correctly performing the validated processes recommended by the manufacturer.

This Standard sets out the requirements for health care facilities to establish, document, and maintain their own policies and procedures for the reprocessing of medical devices to form a unique internal quality system. These policies and procedures are based on several inputs, including government regulation, national standards, and the specific requirements that make up the quality system of the individual organization.

Quality systems in health care are intended to ensure that services and products will meet established standards and will result in appropriate clinical outcomes; in other words, to meet the expectations of those using the product or receiving the service. In reprocessing, a quality system helps to ensure that reusable medical devices are free of contamination and will work as intended.

1 Scope

1.1

This Standard specifies essential elements in implementing a program for using steam to sterilize medical devices in health care facilities, with the object of achieving an adequate level of sterility assurance and minimizing the risk of injury to health care facility personnel and patients.

Notes:

(1) *The term "health care facility" includes, but is not limited to, hospitals, nursing homes, extended-care facilities, clinics, medical and dental offices, and health units in industry.*

(2) *Comprehensive guidance for small, office-based facilities can be found in CSA PLUS 1112.*

1.2

This Standard includes requirements for

(a) policies, procedures, and documentation;
(b) personnel qualifications and training;
(c) quality system;
(d) evaluation and purchase of reusable medical devices;
(e) work areas and equipment;
(f) preparation and packaging of medical devices requiring sterilization;
(g) sterilizer loading and operation;
(h) storage of sterilized medical devices;
(i) sterility assurance, including process challenge device (PCD) construction and use;
(j) maintenance and sterilizer quality assurance; and
(k) flash sterilization.

Notes:

(1) *Flash sterilization (also known as emergency sterilization) is usually performed outside of the sterile processing area.*

(2) *PCD has replaced the term "test pack".*

1.3

This Standard does not apply to

(a) manufacturers' requirements for construction and performance of steam sterilizers;
Note: *See CAN/CSA-Z314.7.*
(b) washer/sterilizers;
(c) decontamination of reusable medical devices prior to sterilization;
Note: *See CSA Z314.8.*
(d) single-use/disposable medical devices; or
Note: *Information concerning safety, technology, cost/benefit, and legal issues involving the reuse of such devices is found in such publications as the Canadian Healthcare Association (1996) and ECRI Institute (1997).*
(e) medical devices that have been used with patients who are known or suspected to have Creutzfeldt-Jakob Disease (CJD) or prion-related diseases.
Note: *See Health Canada (2007).*

1.4

In CSA Standards, "shall" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard; "should" is used to express a recommendation or that which is advised but not required; "may" is used to express an option or that which is permissible within the limits of the standard; and "can" is used to express possibility or capability. Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material. Notes to tables and figures are considered part of the table or figure and may be written as requirements. Annexes are designated normative (mandatory) or informative (non-mandatory) to define their application.

2 Reference publications

This Standard refers to the following publications, and where such reference is made, it shall be to the edition listed below, including amendments published thereto.

CSA (Canadian Standards Association)

CAN/CSA-C22.2 No. 1010.2.041-96 (R2004)
Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes