New Standards & Editions

CAN/CSA-ISO 10993-1-01, 2nd edition
This standard describes the following:
- the general principles governing the biological evaluation of medical devices
- the categorization of devices based on the nature and duration of their contact with the body
- the selection of appropriate tests.

CAN/CSA-ISO 10993-5-01, 2nd edition
This standard describes test methods for assessing the in vitro cytotoxicity of medical devices. These methods specify the incubation of cultured cells (either directly or through diffusion) with extracts of a device and/or in contact with a device. The methods are designed to determine the biological response of mammalian cells in vitro using appropriate biological parameters.

CAN/CSA-M3776-00, 1st edition
This standard specifies requirements for: the location of the anchorages for pelvic restraint belts for operators of agricultural tractors fitted with a cab or frame; the force the anchorages must be subjected to.

CAN/CSA-Z8835-2-01, 1st edition
This standard specifies requirements for inhalational anaesthetic breathing systems for adults, which are supplied either assembled by the manufacturer or for assembly by the user. It also covers circle absorber assemblies, exhaust valves, and inspiratory and expiratory valves. In some designs, it also covers the parts of an anaesthetic breathing system that are incorporated in an anaesthetic workstation, including the expiratory gas pathway of an anaesthetic ventilator and any parts of a non-operator-detachable anaesthetic-gas scavenging system (AGSS).

CAN/CSA-Z8836-01, 2nd edition
This standard specifies requirements for plastic suction catheters for use in suction of the respiratory tract. It does not cover specialized suction catheters (such as those with more than one lumen). It does cover angled-tip suction catheters (such as Coudé catheters), which are not considered specialized.

The following six standards were developed by the International Electrotechnical Commission (IEC), and have been adopted by CSA International.

CAN/CSA-C22.2 No. 601.2.3A-01

CAN/CSA-C22.2 No. 601.2.17A-01 (bilingual)

CAN/CSA-C22.2 No. 601.2.19A-01 (bilingual)

CAN/CSA-C22.2 No. 601.2.20A-01 (bilingual)

CAN/CSA-C22.2 No. 601.2.21A-01 (bilingual)
Les quatre normes qui suivent ont été élaborées par la Commission Électrotechnique Internationale (CEI) et adoptées par CSA International.

**CAN/CSA-C22.2 n° 601.2.17A-01 (bilingue)**

**CAN/CSA-C22.2 n° 601.2.19A-01 (bilingue)**

**CAN/CSA-C22.2 n° 601.2.20A-01 (bilingue)**

**CAN/CSA-C22.2 n° 601.2.21A-01 (bilingue)**

**Drafts**

Please note: Public comments about draft standards and proposed amendments listed in this issue are due by April 26, 2001.

To receive copies of the following draft standard, or to offer comments, contact Nancy Bestic at 416-747-2710 or nancy.bestie@csa-international.org:

- **Z317.11, 2nd edition**
  *Area Measurement for Health Care Facilities*

To receive copies of the following draft standard, or to offer comments, contact Andre Wisaksana at 416-747-4242 or andre.wisaksana@csa-international.org:

- **Z317.1-99, proposed amendment**
  *Special Requirements for Plumbing*

  Proposed amendment to Clause 1.3.
Proposed New Projects

For more information about the proposed development of the following new publication, contact Ian Brodie at 416-747-2670 or ian.brodie@csa-international.org:

- PLUS 1159, 1st edition
  Customer Service Guide for Persons with Disabilities

For more information about the proposed development of the following new standard, contact Jeffrey Kraegel at 416-747-2249 or jeffrey.kraegel@csa-international.org:

- Z305.8, 1st edition
  Medical Supply Units

For more information about the proposed development of the following new handbook, contact Steve Paniri at 416-747-4118 or steve.paniri@csa-international.org:

- B44 Handbook, 1st edition

For more information about the proposed development of the following new editions, contact Dave Shanahan at 416-747-2586 or dave.shanahan@csa-international.org:

- Z275.1, 4th edition
  Hyperbaric Facilities

- Z275.2, 4th edition
  Occupational Safety Code for Diving Operations

- Z275.4, 2nd edition
  Competency Standard for Diving Operations

For more information about the proposed development of the following new edition, contact Andre Wisaksana at 416-747-4242 or andre.wisaksana@csa-international.org:

- Z318, 2nd edition
  Commissioning of Health Care Facilities

Reaffirmed Standards

CAN/CSA-B651-95 (R2001)
Barrier-Free Design

Certification Notices

Please note: Notices marked with an arrowhead are new in this issue.

<table>
<thead>
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<th>Effective Date</th>
<th>Subject</th>
<th>Title</th>
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</thead>
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<td>January 1, 2003</td>
<td>Publication of standards on Medical Electrical Equipment: CAN/CSA-C22.2 No. 601.1.3-98, No. 601.1.1SI-94, and No. 601.2.21, .23, .27, .31, .32, .33, and .34. (Products may be evaluated to these standards now.)</td>
<td>Health Care Equipment No. 11</td>
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