



Nouvelles parutions en français

CAN/CSA-ISO 14971:01, 1^{re} édition
Dispositifs médicaux—Application de la gestion des risques aux dispositifs médicaux (norme ISO 14971:2000 adoptée, première édition, 2000-12-15) 95 \$

Cette norme spécifie une procédure pour permettre au fabricant d'identifier les phénomènes dangereux associés aux dispositifs médicaux et à leurs accessoires, y compris les dispositifs médicaux de diagnostic in vitro, d'estimer et d'évaluer les risques, de maîtriser ces risques et de surveiller l'efficacité de cette maîtrise.

Les exigences de cette norme sont applicables à tous les stades du cycle de vie d'un dispositif médical.

Cette norme ne spécifie pas les niveaux d'acceptabilité des risques.

Cette norme n'est pas applicable aux jugements cliniques relatifs à l'utilisation d'un dispositif médical.

Z412-00, 1^{re} édition
Guide sur l'ergonomie au bureau 150 \$

Ce document incorpore l'ergonomie à un processus de conception par étapes qui permet de créer un système bureautique des plus efficaces, ce qui inclut notamment la conception et l'organisation du travail, l'aménagement des bureaux, les conditions environnementales et la conception des postes de travail. Ce document s'adresse tout particulièrement aux employeurs et aux employés de bureau chargés d'administrer les programmes d'ergonomie et de santé et sécurité au travail de leur entreprise. Le document présente également un intérêt pour les concepteurs d'installations de travail, les acheteurs, les responsables de l'entretien des immeubles, les organismes de réglementation du secteur de la santé et de la sécurité au travail ainsi que les fabricants et les concepteurs qui doivent tenir compte des principes d'ergonomie au bureau.

L'objectif général de ce document est de favoriser la conception d'un système bureautique adapté aux utilisateurs. Pour ce faire, le document propose une démarche qui consiste à tenir compte des caractéristiques et des habiletés des éventuels utilisateurs dans l'organisation du travail et la conception des tâches, des écrans de visualisation, des dispositifs d'entrée ainsi que des aires et du milieu de travail.

Nouvelles parutions (suite)

La réalisation de cet objectif de la norme Z412 permet aux personnes travaillant dans un bureau :

- d'être en meilleure santé ;
- d'améliorer leur efficacité ;
- d'augmenter leur efficacité ;
- d'améliorer leur rendement ;
- de ne plus ressentir de malaises ;
- d'accroître leur sentiment de satisfaction.

Amendments

CAN/CSA-B620-98
Highway Tanks and Portable Tanks for the Transportation of Dangerous Goods

Revision of Table 8.1.

Modifications publiées en français

CAN/CSA-B620-98
Citernes routères et citernes amovibles pour le transport des marchandises dangereuses

Des modifications ont été apportées à la table des matières, aux articles 3.3, 5.2.1.10, 5.2.2.2, 5.3.2.1, 5.6.7.4, 5.6.8.1, 6.2.8.2, et 8.2.1, ainsi qu'au tableau 8.1. Les articles 5.1.6.4, 5.2.7, 5.3.2.5, 6.2.9.3, et 8.2.9 ainsi que les appendices C et D ont été ajoutés.

Proposed New Projects

For more information about the proposed development of the following new projects, contact Ron Meyers at 416-747-2687 or ron.meyers@csa.ca:

- **new standard [designation not assigned]**
Articulating (Knuckle) Boom Cranes
- **Z259.2.1, proposed amendments**
Fall-Arresting Devices and Vertical Lifelines
Proposed amendments to various clauses.
- **Z259.11, 2nd edition**
Shock Absorbers for Personal Fall Arrest Systems
- **Z888, 1st edition**
Lockout/Hazardous Energy Control



Proposed New Projects (cont'd)

For more information about the proposed development of the following new projects, contact Kevin Mackenzie at 416-747-4096 or kevin.mackenzie@csa.ca:

- **D250, 7th edition**
School Buses
- **Z614, 3rd edition**
Children's Playspaces and Equipment

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

- **Z11.1, 1st edition**
Portable Wooden Ladders
- **Z11.2, 1st edition**
Portable Metal Ladders
- **Z11.3, 1st edition**
Portable Reinforced Plastic Ladders
- **Z94.1, 5th edition**
Industrial Protective Headwear
- **Z94.3, 6th edition**
Industrial Eye and Face Protectors

Drafts

Please note: Public comments about draft standards and proposed amendments listed in this issue are due by April 15, 2002.

To receive copies of the following draft standard, or to offer comments, contact Ian Brodie at 416-747-2670 or ian.brodie@csa.ca:

- **B51, 16th edition**
Boiler, Pressure Vessel, and Pressure Piping Code

To receive copies of the following draft standard, or to offer comments, contact Totaram Tulshi at 416-747-2603 or totaram.tulshi@csa.ca:

- **Z98-01, Supplement No. 1**
Supplement No. 1 to Z98-01, Passenger Ropeways

Drafts (cont'd)

To receive copies of the following draft standards, or to offer comments, contact Jackie Halge at 416-747-2303 or jackie.halge@csa.ca:

- **B354.5, 1st edition**
Mast Climbers
- **Z259.13, 1st edition**
Horizontal Lifelines
- **Z275.4, 2nd edition**
Competency Standard for Diving Operations
- **Z314.10, 3rd edition**
Selection, Use, Maintenance, and Laundering of Reusable Textile Wrappers, Surgical Gowns, and Drapes for Health Care Facilities
- **Z314.15, 1st edition**
Warehousing, Storage and Transportation of Clean and Sterile Medical Devices
- **Z795, 2nd edition**
Code of Work Injury or Disease Information

Proposed Adoption of Standards

Note: Public comments about proposed adoptions listed in this issue are due by April 15, 2002.

For more information about the proposed adoption of the following IEC standard, contact Mike Dodd at 416-747-2322 or mike.dodd@csa.ca:

- **IEC 60601-2-12, 2nd edition**
Medical Electrical Equipment—Part 2-12: Particular Requirements for the Safety of Lung Ventilators—Critical Care Ventilators

Proposed Reaffirmation of Standards

For more information about the proposed reaffirmation of the following standard, contact Brian Weir at 416-747-4363 or brian.weir@csa.ca:

- **B167-96**
Safety Standard for Maintenance and Inspection of Overhead Cranes, Gantry Cranes, Monorails, Hoists, and Trolleys



Proposed Endorsement of Standards

Note: Public comments about proposed endorsements listed in this issue are due by April 15, 2002.

For more information about the proposed endorsement of the following ISO standards, contact George Schidowka at 416-747-2743 or george.schidowka@csa.ca:

- **ISO 3630-2:2000**
Dental Root Canal Instruments—Part 2: Enlargers
- **ISO 4049:2000**
Dentistry—Polymer-based Filling, Restorative and Luting Materials
- **ISO 4823:2000**
Dentistry—Elastomeric Impression Materials
- **ISO 6876:2001**
Dental Root Canal Sealing Materials (Available in English Only)
- **ISO 7490:2000**
Dental Gypsum-bonded Casting Investments
- **ISO 7491:2000**
Dental Materials—Determination of Colour Stability
- **ISO 7786:2001**
Dental Rotary Instruments—Laboratory Abrasive Instruments
- **ISO 7787-2:2000**
Dental Rotary Instruments—Cutters—Part 2: Carbide Laboratory Cutters
- **ISO 7885:2000**
Sterile Dental Injection Needles for Single Use
- **ISO 10271:2001**
Dental Metallic Materials—Corrosion Test Methods

Reaffirmed Standards

- B335-94 (R2001)**
Industrial Lift Truck Operator Training
- CAN3-B354.1-M82 (R2001)**
Elevating Rolling Work Platforms
- CAN/CSA-ISO 5840-98 (R2002)**
Cardiovascular Implants—Cardiac Valve
- CAN/CSA-ISO 7767-98 (R2002)**
Oxygen Monitors for Monitoring Patient Breathing Mixtures—Safety Requirements

Reaffirmed Standards (cont'd)

- CAN/CSA-ISO 10993-5-97 (R2002)**
Biological Evaluation of Medical Devices—Part 5: Tests for Cytotoxicity: in vitro Methods
- CAN/CSA-ISO 10993.7-98 (R2002)**
Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals
- CAN/CSA-ISO 10993-10-98 (R2002)**
Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Sensitization
- CAN/CSA-ISO 10993-11-98 (R2002)**
Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity
- CAN/CSA-ISO 10993-12-98 (R2002)**
Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials
- CAN/CSA-ISO 11134-98 (R2002)**
Sterilization of Health Care Products—Requirements for Validation and Routine Control—Industrial Moist Heat Sterilization
- CAN/CSA-ISO 11135-98 (R2002)**
Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization
- CAN/CSA-ISO 11137-98 (R2002)**
Sterilization of Health Care Products—Requirements for Validation and Routine Control of Radiation Sterilization
- CAN/CSA-ISO 11196-98 (R2002)**
Anaesthetic Gas Monitors
- CAN/CSA-ISO-13485-98 (R2001)**
Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9001
- CAN/CSA-ISO-13488-98 (R2001)**
Quality Systems—Medical Devices—Particular Requirements for the Application of ISO 9002
- CAN/CSA-M3767-2-97 (R2002)**
Tractors, Machinery for Agriculture and Forestry, Powered Lawn and Garden Equipment—Symbols for Operator Controls and Other Displays—Part 2: Symbols for Agricultural Tractors and Machinery
- CAN3-Z11-M81 (R2001)**
Portable Ladders
- Z62.1-95 (R2001)**
Chain Saws
- CAN/CSA-Z91-M90 (R2001)**
Safety Code for Window Cleaning Operation



Reaffirmed Standards (cont'd)

- CAN/CSA-Z142-M90 (R2001)
Code for Punch Press and Brake Press Operation: Health, Safety, and Guarding Requirements
- Z168.3-97 (R2001)
Anaesthetic Machines for Medical Use
- Z168.5.1-97 (R2001)
Anaesthesia Ventilators
- Z168.5.3-97 (R2001)
Neonatal Ventilators
- Z168.5.6-96 (R2001)
Expired Air Pulmonary Resuscitators
- Z168.11-94 (R2001)
Vacuum Devices Used for Suction and Drainage
- Z168.13-97 (R2001)
Gas-Specific Connections: Ancillary Devices for Medical Air
- Z248-1975 (R2001)
Code for Tower Cranes
- CAN/CSA-Z305.1-92 (R2001)
Non-flammable Medical Gas Piping Systems
- CAN/CSA-Z305.2-M88 (R2001)
Low-pressure Connecting Assemblies for Medical Gas Systems
- CAN/CSA-Z305.6-92 (R2001)
Medical Oxygen Concentrator Central Supply Systems for Use With Nonflammable Medical Gas Piping Systems
- CAN/CSA-Z314.10-97 (R2002)
Selection, Use, Maintenance, and Laundering of Reusable Textile Wrappers, Surgical Gowns, and Drapes for Health Facilities
- Z316.3-95 (R2002)
Biological Containment Cabinets (Class I and II) Installation and Field Testing
- Z316.5-94 (R2002)
Fume Hoods and Associated Exhaust Systems
- Z316.6-95 (R2002)
Evaluation of Single Use Medical Sharps Containers for Biohazardous and Cytotoxic Waste
- Z364.2.2-94 (R2001)
Water Treatment Equipment and Water Quality Requirements for Haemodialysis

Reaffirmed Standards (cont'd)

- Z604-95 (R2002)
Transportable Mobility Aids
- Z605-95 (R2002)
Mobility Aid Securement and Occupant Restraint (MASOR) Systems for Motor Vehicles
- CAN/CSA-Z795-96 (R2001)
Coding of Work Injury or Disease Information
- CAN/CSA-Z5361-94 (R2001)
Tracheal Tubes

Withdrawn Standards

- CAN/CSA-Z323.4.2-M86 (R1998)
Wheelchairs—Determination of Overall Dimensions, Mass and Turning Space
- CAN/CSA-Z323.4.3-M89 (R1998)
Wheelchairs—Determination of Static Stability
- CAN/CSA-Z323.4.4-M89 (R1998)
Wheelchairs—Determination of Break Effectiveness
- CAN/CSA-Z323.4.6-M89 (R1998)
Wheelchairs—Determination of Maximum Speed, Acceleration and Retardation of Electric Wheelchairs
- CAN/CSA-Z323.4.7-M89 (R1998)
Wheelchairs—Determination of Obstacle Climbing Ability of Electric Wheelchairs
- CAN/CSA-Z323.4.8-94 (R1998)
Wheelchairs—Part 8: Test Dummies
- CAN/CSA-Z323.4.9-94 (R1998)
Wheelchairs—Part 9: Determination of Coefficient of Friction of Test Surfaces
- CAN/CSA-Z323.4.10-94 (R1995)
Wheelchairs—Part 10: Determination of Efficiency of Brakes
- CAN/CSA-Z323.4.11-94 (R1998)
Wheelchairs—Part 11: Determination of Dynamic Stability of Electric Wheelchairs
- CAN/CSA-Z323.4.12-94 (R2000)
Wheelchairs—Part 12: Climatic Tests for Electric Wheelchairs



Certification Notices

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

Effective Date	Subject	Title
February 21, 2003	Publication of Technical Information Letter (TIL) No. MHC-08, covering interim certification requirements for electromechanical lifting devices for persons.	Health Care Equipment No. 12

Status of CSA Standards Projects

TYPE: ns *new standard*; ne *new edition*; spec *special publication*; p *preliminary standard*.

STATUS: 1 *The project is under initial evaluation.*

2 *The technical content is being drafted.*

3 *The draft is undergoing an internal quality audit by CSA.*

4 *The publication is being processed for formal letter-ballot approval.*

5 *The approved publication will be for sale within 2–3 months.*

H *The publication is on hold.*

C *The publication has been cancelled. It will be removed from the next status report.*

SUBJECT	NUMBER	TYPE	STATUS
Health Care Technology			
Medical Electrical Equipment—Part 1: General Requirements for Safety— 1. Collateral Standard: Safety Requirements for Medical Electrical Systems	C22.2 No. 60601-1-1	ne	5
Medical Electrical Equipment—Part 1-4: General Requirements for Safety— Collateral Standard: Programmable Electrical Medical Systems	C22.2 No. 60601-1-4	ns	5
Medical Electrical Equipment—Part 2-5: Particular Requirements for the Safety of Ultrasonic Physiotherapy Equipment	C22.2 No. 60601-2-5	ne	5
Application of Auditory and Visual Medical Devices	ISO 9703-3	ns	2
Biological Evaluation of Medical Devices—Part 15: Identification and Quantification of Degradation Products from Metals and Alloys	ISO 10993-15	ns	3
Medical Devices—Symbols to Be Used with Medical Device Labels, Labelling and Information to Be Supplied	ISO 15223	ns	C
Metered Dose Inhaler Spacer Device	Z264.1	ns	3
Medical Electrical Equipment—Particular Requirements for Safety of Medical Supply Units	Z305.8	ns	3
Selection, Use, Maintenance, and Laundering of Reusable Textile Wrappers, Surgical Gowns, and Drapes for Health Facilities	Z314.10	ne	3
Selection and Use of Rigid Sterilization Containers	Z314.14	ne	2
Area Measurement for Health Care Facilities	Z317.11	ne	5
Water Treatment Equipment and Water Quality Requirements for Haemodialysis	Z364.2.2	ne	2
Transportable Mobility Aids	Z604	ne	5
Mobility Aid Securement and Occupant Restraint Systems	Z605	ne	5
Safety of Tissues and Organs for Transplantation	Z900.1	ns	2
Safety of Tissues for Assisted Reproduction	Z900.2.1	ns	2
Safety of Tissues for Transplantation	Z900.2.2	ns	2
Safety of Perfusable Organs for Transplantation	Z900.2.3	ns	2
Safety of Ocular Tissues for Transplantation	Z900.2.4	ns	2
Safety of Hematopoietic Cells for Transplantation	Z900.2.5	ns	2



Status of CSA Standards Projects (cont'd)

SUBJECT	NUMBER	TYPE	STATUS
Health Care Technology (cont'd)			
Nonflammable Medical Gas Pipeline Systems—Part 1: Pipelines for Compressed Medical Gases and Vacuum	Z7396.1	ns	2
Nonflammable Medical Gas Pipeline Systems—Part 2: Pipelines for Anaesthetic Gas Scavenging Disposal Systems	Z7396.2	ns	5
Pressure Regulators and Pressure Regulators with Flow-Metering Devices for Medical Gas Systems	Z10524	ns	5
Flow-Metering Devices for Connection to Terminal Units of Medical Gas Pipeline Systems	Z15002	ns	5
Mechanical Industrial Equipment			
Elevator and Escalator Electrical Equipment	B44.1	ne	4
Safety Code for Manlifts	B311	ne	5
Cylinders, Spheres and Tubes for the Transportation of Dangerous Goods	B339	ne	5
Selection and Use of Cylinders, Spheres, Tubes, and Other Containers for the Transportation of Dangerous Goods, Class 2	B340	ne	5
Selection and Use of Highway Tanks, Portable Tanks, Cargo Compartments and Containers for the Transportation of Dangerous Goods, Classes 3, 4, 5, 6, 8, and 9	B621	ne	3
Selection and Use of Highway Tanks, Multi-Unit Tank Car Tanks, and Portable Tanks for the Transportation of Dangerous Goods, Class 2	B622	ne	3
Community and Personal Issues			
Customer Service Guide for Persons with Disabilities	B480	ns	3
Barrier-Free Design	B651	ne	1
Design for Aging	B659	ns	5
Motor Vehicles for the Transportation of Physically Disabled Persons	D409	ne	5
Transit Vehicles for the Transportation of Persons with Physical Disabilities	D435	ns	4
Over-the-road Buses for the Transportation of Persons with Physical Disabilities	D436	ns	4
Dimensions for Facially-Featured Headforms	Z262.6	ns	5
Racquet Sports Eye Protection	Z400	ns	1
Children's Playspaces and Equipment	Z614	ne	2
Occupational Health and Safety			
Industrial Lift Truck Operator Training	B335	ne	3
Elevating Rolling Work Platforms	B354.1	ne	2
Boom-Type Elevating Work Platforms	B354.4	ne	5
Mast Climbers	B354.5	ns	2
Lighting and Marking of Agricultural Field Equipment on Highways	M669	ne	5
Agricultural Tractors—Operator's Seating Accommodation—Dimensions	M4253	ns	H
Portable Wooden Ladders	Z11.1	ns	1
Portable Metal Ladders	Z11.2	ns	1
Portable Reinforced Plastic Ladders	Z11.3	ns	1
Chain Saws	Z62.1	ne	2
Health and Safety Code for Suspended Equipment Operations	Z91	ne	4
Hearing Protection	Z94.2	ne	5
Eyewear User Guide	Z94.3.1	spec	5
Selection, Use, and Care of Respirators	Z94.4	ne	4
High-Visibility Safety Apparel	Z96	ns	2



Status of CSA Standards Projects (cont'd)

SUBJECT	NUMBER	TYPE	STATUS
Occupational Health and Safety (cont'd)			
Code for Punch Press and Brake Press Operation: Health, Safety, and Guarding Requirements	Z142	ne	4
Protective Footwear	Z195	ne	5
Footwear User Guide	Z195.1	spec	5
Design of Double Girder Electric Overhead Travelling Cranes	Z202	ns	H
Code for Tower Cranes	Z248	ne	4
Flexible Horizontal Lifelines	Z259.13	ns	2
Anchorage Connectors	Z259.15	ns	2
Fall Protection Systems Design Code	Z259.16	ns	2
Hyperbaric Facilities	Z275.1	ne	2
Safety Code for Diving Operations	Z275.2	ne	2
Competency Standard for Diving Operations	Z275.4	ne	3
Safeguarding of Machinery	Z432	ne	2
Industrial Robots and Robot Systems—General Safety Requirements	Z434	ne	3
Riot Helmets and Faceshields	Z611	ne	2
Scaffolding Guidelines	Z797	ns	2