Electrical safety and essential electrical systems in health care facilities

Legal Notice for Standards

Canadian Standards Association (CSA) standards are developed through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard. Although CSA administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.

Disclaimer and exclusion of liability

This document is provided without any representations, warranties, or conditions of any kind, express or implied, including, without limitation, implied warranties or conditions concerning this document's fitness for a particular purpose or use, its merchantability, or its non-infringement of any third party's intellectual property rights. CSA does not warrant the accuracy, completeness, or currency of any of the information published in this document. CSA makes no representations or warranties regarding this document's compliance with any applicable statute, rule, or regulation.

IN NO EVENT SHALL CSA, ITS VOLUNTEERS, MEMBERS, SUBSIDIARIES, OR AFFILIATED COMPANIES, OR THEIR EMPLOYEES, DIRECTORS, OR OFFICERS, BE LIABLE FOR ANY DIRECT, INDIRECT, OR INCIDENTAL DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES, HOWSOEVER CAUSED, INCLUDING BUT NOT LIMITED TO SPECIAL OR CONSEQUENTIAL DAMAGES, LOST REVENUE, BUSINESS INTERRUPTION, LOST OR DAMAGED DATA, OR ANY OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER THEORY OF LIABILITY, ARISING OUT OF OR RESULTING FROM ACCESS TO OR POSSESSION OR USE OF THIS DOCUMENT, EVEN IF CSA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES.

In publishing and making this document available, CSA is not undertaking to render professional or other services for or on behalf of any person or entity or to perform any duty owed by any person or entity to another person or entity. The information in this document is directed to those who have the appropriate degree of experience to use and apply its contents, and CSA accepts no responsibility whatsoever arising in any way from any and all use of or reliance on the information contained in this document.

CSA is a private not-for-profit company that publishes voluntary standards and related documents. CSA has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.

Intellectual property rights and ownership

As between CSA and the users of this document (whether it be in printed or electronic form), CSA is the owner of all works contained herein that are protected by copyright, all trade-marks (except as otherwise noted to the contrary), and all inventions and trade secrets that may be contained in this document, whether or not such inventions and trade secrets are protected by patents and applications for patents. The unauthorized use, modification, copying, or disclosure of this document may violate laws that protect CSA's intellectual property and may give rise to a right in CSA to seek legal redress for such use, modification, copying, or disclosure. CSA reserves all intellectual property rights in this document.

Authorized use of this document

This document is being provided by CSA for informational and non-commercial use only. The user of this document is authorized to do only the following:

If this document is in electronic form:

- load this document onto a computer for the sole purpose of reviewing it;
- search and browse this document; and
- print this document.

Limited copies of this document in print or paper form may be distributed only to persons who are authorized by CSA to have such copies, and only if this Legal Notice appears on each such copy.

In addition, users may not and may not permit others to

- alter this document in any way or remove this Legal Notice from the attached standard;
- sell this document without authorization from CSA; or
- make an electronic copy of this document.

If you do not agree with any of the terms and conditions contained in this Legal Notice, you may not load or use this document or make any copies of the contents hereof, and if you do make such copies, you are required to destroy them immediately. Use of this document constitutes your acceptance of the terms and conditions of this Legal Notice.



CSA Standards Update Service

Z32-04 September 2004

Title: Electrical safety and essential electrical systems in health care facilities

Pagination: 84 pages (ix preliminary and 75 text), each dated September 2004

Automatic notifications about any updates to this publication are available.

 To register for e-mail notifications, and/or to download any existing updates in PDF, enter the Online Store at www.ShopCSA.ca and click on My Account on the navigation bar.

The **List ID** for this document is **2016110**.

To receive printed updates, please complete and return the attached card.

Visit CSA's policy on privacy at www.csagroup.org/legal to find out how we protect your personal information.

<
Name
Organization
Address
City
Province/State
Country Postal/Zip Code
E-mail
I consent to CSA collecting and using the above information to send me updates relating to this publication.

Affranchir suffisamment

Place Stamp Here

ASSOCIATION CANADIENNE DE NORMALISATION

BUREAU CENTRAL DE L'INFORMATION 5060, SPECTRUM WAY, BUREAU 100 MISSISSAUGA ON L4W 5N6 CANADA

CANADIAN STANDARDS ASSOCIATION

CONSOLIDATED MAILING LIST 5060 SPECTRUM WAY, SUITE 100 MISSISSAUGA ON L4W 5N6 CANADA

CSA Standard

Z32-04

Electrical safety and essential electrical systems in health care facilities



®Registered trade-mark of Canadian Standards Association

Published in September 2004 by Canadian Standards Association
A not-for-profit private sector organization
5060 Spectrum Way, Suite 100, Mississauga, Ontario, Canada L4W 5N6
1-800-463-6727 • 416-747-4044

Visit our Online Store at www.ShopCSA.ca

ISBN 1-55436-863-4

Technical Editor: George Schidowka

© Canadian Standards Association — 2004

All rights reserved. No part of this publication may be reproduced in any form whatsoever without the prior permission of the publisher.

Contents

Technical Committee on Application of Electricity in Health Care vii

Subcommittee on Essential Electrical Systems viii

Preface ix

1 Scope <i>1</i>					
1.1	General 1				
1.1.1	Application 1				
1.1.2	Exclusions 1				
1.1.3	Relationship to the Canadian Electrical Code, Part I	1			
1.2	Electrical safety 1				
1.2.1	Areas 1				
1.2.2	Electrical equipment 1				
1.2.3	Aspects of electrical safety 2				
1.2.4	Medical risks or benefits 2				

1.3 Building electrical installations 2

- 1.4 Essential electrical systems 2
- 1.5 Terminology 2

2 Reference publications 2

3 Definitions 4

4	Electrical	safety	8
---	-------------------	--------	---

- 4.1 Safety philosophy 8
- 4.1.1 Underlying principle 8
- 4.1.2 Risks in patient procedures 8
- 4.1.3 Risks of medical devices 9
- 4.1.4 Risk management program 9
- 4.1.5 Procedure classification 9
- 4.1.6 Equipment and area classification 9
- 4.1.7 Management of safety factors 9
- 4.2 Electrical safety program 9
- 4.2.1 General 9
- 4.2.2 Responsibilities 9
- 4.2.3 Qualified personnel 9
- 4.2.4 Basic elements 10
- 4.2.5 Education 10
- 4.2.6 Patient care area classification 10
- 4.3 Electrical equipment control and use 11
- 4.3.1 General *11*
- 4.3.2 Medical electrical equipment 11
- 4.3.3 Safety requirements for medical electrical systems 12
- 4.3.4 Non-medical electrical equipment used in patient care areas 12
- 4.3.5 Patient-owned electrical devices 13
- 4.3.6 Specific equipment 13
- 4.3.7 Electromagnetic interference and electromagnetic compatibility 15
- 4.3.8 Line-borne electrical interference 16
- 4.4 Inspection, testing, acquisition, and maintenance of electrical equipment 16
- 4.4.1 General 16

- 4.4.2 Maintenance 16
- 4.4.3 Action criteria and maintenance log 16
- 4.4.4 Notification 17
- 4.4.5 Training *17*
- 4.4.6 Documentation 17
- 4.4.7 Acceptance tests 17
- 4.5 Maintenance of medical and non-medical electrical equipment 17
- 4.5.1 General 17
- 4.5.2 Verification criteria 17
- 4.5.3 Inspection and maintenance criteria 17

5 Building electrical system 18

- 5.1 General 18
- 5.2 Inspection and testing 18
- 5.2.1 Application 18
- 5.2.2 Measurement circuits 18
- 5.2.3 Design 18
- 5.2.4 Conditions for inspection and testing 18
- 5.2.5 Fault or substandard condition 18
- 5.3 Conductor insulation integrity test 19
- 5.3.1 General 19
- 5.3.2 Insulation resistance 19
- 5.3.3 Measurement 19
- 5.4 Branch circuits 19
- 5.4.1 General 19
- 5.4.2 Voltage drop requirements for grounded systems 19
- 5.4.3 Voltage drop test for grounded systems 19
- 5.5 Branch circuit breakers Mechanical operation test 20
- 5.6 Receptacles 20
- 5.6.1 General requirements 20
- 5.6.2 Connection 20
- 5.6.3 Isolated ground receptacles 21
- 5.6.4 Computerized equipment 21
- 5.6.5 Receptacle identification 21
- 5.6.6 Testing *21*
- 5.7 Panelboards 21
- 5.7.1 General *21*
- 5.7.2 Location 21
- 5.7.3 Identification 21
- 5.7.4 Load directory 22
- 5.7.5 Receptacle and load grouping 22
- 5.8 Bonding to ground 22
- 5.8.1 General 22
- 5.8.2 Exemptions *22*
- 5.9 Voltage difference between ground points 22
- 5.9.1 Voltage difference limits 22
- 5.9.2 Test method *22*
- 5.10 Ground return path voltage rise for grounded systems 22
- 5.10.1 General 22
- 5.10.2 Test method 23
- 5.11 Isolated power systems 23
- 5.11.1 General *23*
- 5.11.2 Test of impedance to ground (single-phase and three-phase isolated systems) and hazard index monitoring 23

- 5.12 Wiring accessories *25*
- 5.12.1 Power cord adapters 25
- 5.12.2 Ground fault circuit interrupters 25

6 Essential electrical systems 26

- 6.1 General 26
- 6.2 Installation 26
- 6.3 Transfer *26*
- 6.3.1 Vital and delayed vital branches 26
- 6.3.2 Conditional branch 26
- 6.4 Essential areas and functions 26
- 6.5 Maintenance or repair 26
- 6.6 Battery-operated emergency lighting 26
- 6.7 Emergency electrical power supply system 27
- 6.7.1 Working space *27*
- 6.7.2 Temperature *27*
- 6.7.3 Fuel system *27*
- 6.8 Normal supply and performance 27
- 6.8.1 General 27
- 6.8.2 Use of generator sets for peak shaving 28
- 6.9 Emergency supply and performance 28
- 6.9.1 General 28
- 6.9.2 Use of emergency supply 29
- 6.9.3 Control sequence 29
- 6.10 Emergency generating plants 30
- 6.10.1 Frequency *30*
- 6.10.2 Generator set location 30
- 6.10.3 Generators, exciters, and voltage regulators 30
- 6.10.4 Testing and commissioning of new and relocated auxiliary essential power generating sets 31
- 6.10.5 Voltage and frequency 31
- 6.10.6 Oil analysis 31
- 6.11 Transfer switches 31
- 6.11.1 Control device *31*
- 6.11.2 Bypass system *31*
- 6.11.3 Automatic transfer switch requirements 31
- 6.11.4 Manual (non-automatic) transfer switch 31
- 6.12 Operation and maintenance program 31
- 6.12.1 Tools 31
- 6.12.2 Operational tests 32
- 6.12.3 System operational test 32

Annexes

- A (informative) Electric shock 46
- **B** (informative) Risk management 49
- **ℂ** (informative) Electrical equipment in oxygen-enriched atmospheres 52
- **D** (informative) Certification programs 54
- **E** (informative) Electromagnetic interference and electromagnetic compatibility 55
- **F** (informative) Purchasing considerations for health care facility equipment 57
- **G** (informative) Test sheets 60
- **H** (informative) Building electrical systems 68
- I (informative) Precautions in transfer of loads 74
- J (informative) Equipment markings 75

Tables

- 1 Risk classes and applied part types associated with patient procedures 32
- 2 Allowable values of continuous leakage and patient auxiliary currents, mA 33
- **3** Risk current test limits 34
- **4** Leakage requirements for the safety of medical electrical systems 34
- **5** Approximate spacing for interference-free working with unfiltered equipment 35
- **6** Summary of testing for building electrical systems 36
- **7** Minimum number of receptacles required 37
- **8** Classification of loads and branches 38

Figures

- **1** Patient care environment 42
- **2** Voltage drop test for grounded systems 43
- **3** Standard load and measuring device 44
- **4** Ground return path voltage rise for grounded systems 45

Technical Committee on Application of Electricity in Health Care

A.M. Dolan Institute of Biomedical Engineering, Chair

University of Toronto, Toronto, Ontario

M. Bourassa Standards Council of Canada, Associate

Ottawa, Ontario

B. Buckler ASCO Power Technologies Canada,

Brantford, Ontario

J.G. Cayouette Horizon Medical Services Ltd., Associate

Toronto, Ontario

K. Cheong Stantec Consulting Ltd.,

Vancouver, British Columbia

P. Dvorak Health and Welfare Canada,

Ottawa, Ontario

P. Fabry CSA,

Toronto, Ontario

J. Gams Medtronic of Canada Limited,

Mississauga, Ontario

P.M. Gelinas Hôpital du Sacré-Cœur de Montréal,

Montréal, Québec

P.E. Paasche University of New Brunswick,

Fredericton, New Brunswick

M.B. Raber Winnipeg, Manitoba

J.-L. Robert Régie du bâtiment du Québec,

Québec, Québec

D. Roberts Schneider Canada Inc.,

Mississauga, Ontario

J.M. Smith Hospital for Sick Children,

Toronto, Ontario

R. Stevenson Queen's University,

Kingston, Ontario

J. Thompson Toronto, Ontario

A. Tsisserev City of Vancouver,

Vancouver, British Columbia

G. Schidowka CSA.

Mississauga, Ontario

Project Manager

Licensed to/Autorisé à David Christansen, Northern Alberta Institute of Technology, on/le 3/18/2005. Single user license only. Storage, distribution or use on network prohibited /Permis d'utilisateur simple seulement. Le stockage, la distribution ou l'utilisation sur le réseau est intendit

Subcommittee on Essential Electrical Systems

A.M. Dolan Institute of Biomedical Engineering, Chair

University of Toronto, Toronto, Ontario

G.R. Beer Jay Electric Ltd.,

Brampton, Ontario

B. Buckler ASCO Power Technologies Canada,

Brantford, Ontario

K. Cheong Stantec Consulting Ltd.,

Vancouver, British Columbia

P. Fabry CSA,

Toronto, Ontario

T. Olechna Electrical Safety Authority,

Mississauga, Ontario

P.E. Paasche University of New Brunswick,

Fredericton, New Brunswick

M.R. Ramirez Hospital for Sick Children,

Toronto, Ontario

J.-L. Robert Régie du bâtiment du Québec,

Québec, Québec

D. Roberts Schneider Canada Inc.,

Mississauga, Ontario

J.A. Stedman Care Technology,

Spruce Grove, Alberta

R. Stevenson Queen's University,

Kingston, Ontario

J. Thompson Toronto, Ontario

A. Tsisserev City of Vancouver,

Vancouver, British Columbia

B. Van Skiver University of Alberta Hospital,

Edmonton, Alberta

W. Woodley Humber River Regional Hospital,

Toronto, Ontario

T. Woolhouse Ellard-Willson Engineering Limited,

Markham, Ontario

G. Schidowka CSA,

Mississauga, Ontario

Project Manager

Preface

This is the second edition of CSA Z32, *Electrical safety and essential electrical systems in health care facilities*. It supersedes the first edition, published in 1999, and is harmonized with CSA C22.1-02, the *Canadian Electrical Code*, *Part I*, and CAN/CSA-C282-00, *Emergency Electrical Power Supply for Buildings*.

This Standard was prepared by the Subcommittee on Essential Electrical Systems, under the jurisdiction of the Technical Committee on Application of Electricity in Health Care and the Strategic Steering Committee on Health Care Technology, and has been formally approved by the Technical Committee. It will be submitted to the Standards Council of Canada for approval as a National Standard of Canada.

September 2004

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.
- (5) All enquiries regarding this Standard, including requests for interpretation, should be addressed to Canadian Standards Association, 5060 Spectrum Way, Suite 100, Mississauga, Ontario, Canada L4W 5N6.

 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.

Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization and are published in CSA's periodical Info Update, which is available on the CSA Web site at www.csa.ca.

September 2004

Z32-04

Electrical safety and essential electrical systems in health care facilities

1 Scope

1.1 General

1.1.1 Application

This Standard deals with the following subjects:

- (a) electrical safety associated with health care provision;
- (b) electrical installations for health care facilities; and
- (c) essential electrical systems for health care facilities.

Note: See Clause 3 for the definition of "health care facility".

1.1.2 Exclusions

1.1.2.1

This Standard is not intended to apply to veterinary facilities, although its electrical safety principles could prove useful in the design, construction, and operation of such facilities.

1.1.2.2

Uninterruptible power supplies, which can be essential for specific critical applications (e.g., critical care equipment and computer equipment), are not covered by this Standard.

1.1.3 Relationship to the Canadian Electrical Code, Part I

The installation requirements specified in this Standard supplement the installation requirements specified in Sections 24 and 52 of the Canadian Electrical Code, Part I.

1.2 Electrical safety

1.2.1 Areas

This Standard applies to

- (a) patient care areas of health care facilities; and
- (b) areas outside health care facilities that are intended for patient diagnosis, treatment, or care involving intentional electrical contact of any kind between patients and medical electrical equipment.

1.2.2 Electrical equipment

This Standard applies to

- (a) medical electrical equipment;
- (b) health-care-facility-owned non-medical electrical equipment;
- (c) patient-owned electrical devices; and
- (d) the use and management of the equipment and installations in patient care areas.

The electrical equipment described in Items (a) to (c) can be portable or permanently connected.

1.2.3 Aspects of electrical safety

This Standard deals principally with safety from the hazards of electric shock (see Annex A). Other aspects of electrical safety, such as fires and interference with proper operation, are also addressed.

Note: The Canadian Electrical Code specifies the minimum requirements for a safe building electrical installation for supplying utilization equipment in patient care areas, but does not specify requirements for the number, arrangement, and circuit loading of branch circuits and receptacles required for the procedures to be performed. Neither does it state requirements for the use and maintenance of such installations. This Standard builds on the requirements of the Canadian Electrical Code and provides this additional information.

1.2.4 Medical risks or benefits

The medical purposes, risks, or benefits of procedures or equipment are the professional responsibility of health care practitioners and therefore are beyond the scope of this Standard, which provides general quidelines to ensure the safe use of electrically operated equipment.

1.3 Building electrical installations

This Standard applies to electrical installations in patient care areas of health care facilities.

1.4 Essential electrical systems

Clause 6 of this Standard applies to the design, installation, operation, and maintenance of the emergency supply required to provide electrical power to those portions of a health care facility's electrical system in which the interruption of the normal supply can jeopardize effective and safe patient care, the safety of health care facility staff, and public safety.

For aspects of emergency electrical power supply systems not covered by Clause 6 of this Standard, the requirements specified in CAN/CSA-C282 should be followed. However, when the requirements specified in CAN/CSA-C282 and in this Standard conflict, the requirements of this Standard should be followed.

1.5 Terminology

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. Legends to equations and figures are considered 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 all amendments published thereto.

CSA (Canadian Standards Association)

C22.1-02

Canadian Electrical Code, Part I

C22.2 No. 21-95

Cord Sets and Power Supply Cords

C22.2 No. 42-99

General Receptacles, Attachment Plugs, and Similar Wiring Devices

CAN/CSA-C22.2 No. 114-M90 (R2000)

Diagnostic Imaging and Radiation Therapy Equipment

C22.2 No. 125-M1984 (R1999)

Electromedical Equipment

C22.2 No. 141-02

Unit Equipment for Emergency Lighting

CAN/CSA-C22.2 No. 144-M91 (R2001)

Ground Fault Circuit Interrupters

C22.2 No. 178-1978 (R2001)

Automatic Transfer Switches

C22.2 No. 60601 series of Standards

Medical Electrical Equipment

CAN/CSA-C22.2 No. 601.1-M90 (R2001)

Medical Electrical Equipment, Part 1: General Requirements for Safety

CAN/CSA-C22.2 No. 60601-1-1:02

Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems

CAN/CSA-C22.2 No. 60601-1-2:03

Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests

CAN/CSA-C282-00

Emergency Electrical Power Supply for Buildings

CAN/CSA-Z305.8-03

Medical Supply Units

CAN/CSA-Z317.5-98

Illumination Systems in Health Care Facilities

CAN/CSA-CEI/IEC 1288-1-98 (R2002)

Cardiac defibrillators — Cardiac defibrillators-monitors — Part 1: Operation

CAN/CSA-CEI/IEC 1288-2-98 (R2002)

Cardiac defibrillators — Cardiac defibrillators-monitors — Part 2: Maintenance

CAN/CSA-CEI/IEC 1289-1-98 (R2002)

High frequency surgical equipment — Part 1: Operation

CAN/CSA-CEI/IEC 1289-2-98 (R2002)

High frequency surgical equipment — Part 2: Maintenance

IEC (International Electrotechnical Commission)

60601 series of Standards

Medical electrical equipment

IEEE (Institute of Electrical and Electronics Engineers)

C37.90.1-2002

IEEE Standard for Surge Withstand Capabilities (SWC) Tests for Relays and Relay Systems Associated with Electric Power Apparatus

C63.18-1997

Recommended Practice for an On-Site, Ad-Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio Frequency Transmitters

Industry Canada

ICES-001, issue 3 (March 1998)

Industrial, Scientific and Medical Radio Frequency Generators

ISO (International Organization for Standardization)

14971:2000

Medical devices — Application of risk management to medical devices

Ministry of Health (United Kingdom)

Abatement of Electrical Interference (London, July 1965)

National Research Council Canada

National Building Code of Canada, 1995

Ontario Hydro

Standard Specification A-28-82 Oscillatory Transient Interference Immunity Test

Other publications

Freund, A. 1998 (March). Nonlinear Loads Mean Trouble. Electrical Construction and Maintenance, 83–90.

3 Definitions

The following definitions apply in this Standard:

Administrator — the person responsible for operating the health care facility (or his or her designee). **Note:** The term "administrator" is used in this Standard to denote the authority representing the health care facility and charged with responsibilities specified in this Standard. The administrator may (and usually does) delegate these responsibilities to appropriately qualified individuals.

Applied part(s) — the part or parts of medical electrical equipment, including the patient leads, that are intentionally placed in contact with the patient to be examined or treated.

Type B applied part — an applied part that complies with the requirements specified in CAN/CSA-C22.2 No. 601.1 for providing protection against electric shock, (particularly regarding allowable leakage current) and is marked with symbol 1 in Table DII of Appendix D of CAN/CSA-C22.2 No. 601.1.

Type BF applied part — a Type F applied part that complies with the requirements specified in CAN/CSA-C22.2 No. 601.1 for providing a higher degree of protection against electric shock than is provided by Type B applied parts and is marked with symbol 2 in Table DII of Appendix D of CAN/CSA-C22.2 No. 601.1.

Type CF applied part — a Type F applied part that complies with the requirements specified in CAN/CSA-C22.2 No. 601.1 for providing a higher degree of protection against electric shock than is provided by Type BF applied parts and is marked with symbol 3 in Table DII of Appendix D of CAN/CSA-C22.2 No. 601.1.

Type F applied part — an applied part isolated from other parts of the equipment to such an extent that no current higher than the patient leakage current allowable in single-fault condition flows if an unintended voltage originating from an external source is connected to the patient and is thereby applied between the applied part and ground.

Approved (as applied to electrical equipment) —

- (a) a certification organization accredited by the Standards Council of Canada has certified such equipment in accordance with the requirements of
 - (i) CSA Standards; or
 - (ii) other recognized documents, where such CSA Standards do not exist or are not applicable; or
- (b) such equipment conforms to the requirements of the regulatory authority.

Note: This definition is taken (with minor editorial changes) from Section 0 of the Canadian Electrical Code, Part I.

Basic care area — a patient care area where body contact between a patient and medical electrical equipment is neither frequent nor usual.

Note: *See Clause 4.2.6.1.*

Body contact — an intentional contact at the skin surface or internally, but not directly with the heart.

Branch (in the context of essential electrical systems) —

Note: This definition is adapted from that in the Canadian Electrical Code, Part I.

Branch circuit — that portion of the wiring installation between the outlet(s) and the final overcurrent device protecting the circuit.

Conditional branch — that portion of an essential electrical system in which the circuits require power restoration by emergency service within 24 h.

Delayed vital branch — that portion of an essential electrical system in which the circuits require power restoration within 2 min.

Vital branch — that portion of an essential electrical system in which the circuits require power restoration within 10 s.

Cardiac contact — an intentional contact directly with the heart by means of an invasive procedure.

Casual contact — contact by voluntary action with a device that does not have applied parts and is not intended to be connected to a patient.

Critical care area — a patient care area where the induction and maintenance of general anaesthesia routinely occurs in connection with the examination or treatment of patients, or where cardiac contact between a patient and medical electrical equipment is frequent or normal.

Notes:

- (1) This definition is adapted from that in the Canadian Electrical Code, Part I.
- (2) See Clause 4.2.6.1.

Emergency electrical power supply system — one or more in-house electrical generator sets intended to be available if all other supplies fail, and capable of supplying all of the essential loads.

Enclosure leakage current — current that

- (a) flows from the enclosure or parts of the enclosure, excluding applied parts; and
- (b) is accessible to the operator or patient during normal use through an external conductive connection (other than the bonding conductor) to ground or to another part of the enclosure.

Essential electrical system — an electrical system that has the capability of restoring and sustaining a supply of electrical energy to specified loads if the normal supply of energy is lost.

Extra-low-voltage Class 2 circuit — any circuit operating at a voltage of up to and including 30 V rms, 42.4 V peak, or 30 V dc, and whose current is limited as follows:

- (a) 0 to 20 V: a circuit in which the open-circuit voltage does not exceed 20 V and overcurrent protection is rated at not more than 5 A, except that overcurrent protection is not required where the current is supplied by
 - (i) primary batteries that under short-circuit will not supply a current exceeding 7.5 A after 1 min;

- (ii) a Class 2 circuit transformer; or
- (iii) a device that will limit the current under normal operating conditions or under fault conditions to 5 A or less.
- (b) Over 20 V but not exceeding 30 V: a circuit in which the open-circuit voltage exceeds 20 V but does not exceed 30 V and the overcurrent protection rating does not exceed 100/V A, where V is the open-circuit voltage, except that the overcurrent protection is not required where the current is supplied by
 - (i) primary batteries that under short-circuit will not supply a current exceeding 5 A after 1 min;
 - (ii) a Class 2 circuit transformer; or
 - (iii) a device that will limit the current under normal operating conditions or under fault conditions to 100/V A, where V is the open-circuit voltage.

Generator set — the combination of an electrical generator or alternator, driven by a prime mover, and any required ancillary and control equipment.

Harm — physical injury and/or damage to health or property.

Note: This definition is identical to that in ISO 14971.

Hazard — a potential source of harm.

Note: This definition is identical to that in ISO 14971.

Hazard index — for a given set of conditions in an isolated power system, the current, expressed in milliamperes and consisting of resistive and capacitive leakage and fault currents, that would flow through a low impedance if the low impedance were to be connected between either isolated conductor and ground.

Note: The hazard index with one isolated conductor connected to ground is not necessarily the same as the hazard index with the other isolated conductor connected to ground; of the two, the higher hazard index governs.

Maximum hazard index — the hazard index of an isolated system with all permanently connected equipment switched on, as read on the line isolation monitor.

System hazard index — the hazard index of an isolated system with all permanently connected equipment switched off and the line isolation monitor and all cord-connected equipment disconnected.

Total hazard index — the hazard index of an isolated system with all appliances connected, including the line isolation monitor.

Health care facility — a set of physical infrastructure elements that are intended to support the delivery of specific health-related services.

Health care facility, Class A — a facility, designated as a hospital by the government of Canada or the government of a Canadian province or territory, where patients are accommodated on the basis of medical need and are provided with continuing medical care and supporting diagnostic and therapeutic services.

Health care facility, Class B — a facility whose residents cannot function independently because of a physical or mental disability and are accommodated because they require daily care by health care professionals.

Note: Class B facilities provide, e.g., extended, multi-level, hospice, psychiatric, or intermediate care. The definition includes rehabilitation facilities and group homes.

Health care facility, Class C — a facility where ambulatory patients are accommodated on the basis of medical need and are provided with supportive, diagnostic, and treatment services. **Note:** Class C facilities include, e.g., outpatient and surgical clinics, dental offices, doctors' clinics, and private residences.

Health care facility administration — the unit responsible, under the authority of a health care facility governing board, for planning, organizing, directing, and controlling the health care facility in accordance with the bylaws of the health care facility, the policies of the health care facility governing board, and government statutes, regulations, and directives.

Intermediate care area — a patient care area where body contact between a patient and medical electrical equipment is frequent or normal.

Note: See Clause 4.2.6.1.

Isolated system — an electrical distribution system in which no circuit conductor is connected directly to ground.

Line isolation monitor — a device that measures and displays the total hazard index of an isolated electrical system and provides a warning when the index reaches a pre-set limit.

Medical electrical equipment — electrical equipment that has only one connection to a particular supply main; is intended to diagnose, treat, or monitor a patient under medical supervision; and comes into physical or electrical contact with a patient, and/or transfers energy to or from a patient, and/or detects energy transfer to or from a patient.

Medical electrical system — a combination of two or more items of medical electrical equipment, or of medical electrical equipment and non-medical electrical equipment, that by interconnection between devices behaves as a unit with specified functions.

Normal supply — the main electrical supply into a building or building complex. It can consist of one or more feeders, each capable of supplying all of the loads in the building or building complex.

Oxygen-enriched atmosphere (OEA) — the space in which the concentration of oxygen or nitrous oxide exceeds 23.5% by volume at one atmospheric pressure.

Note: In air, the concentration of oxygen is approximately 21% by volume. Nitrous oxide is included in the calculations because it dissociates into nitrogen and oxygen at elevated temperatures.

Patient — a person undergoing medical investigation, care, or treatment.

Patient care area — an area intended primarily for diagnosis, therapy, or care.

Note: The administrator is responsible for determining whether an area should be classified as a patient care area (and, if so, whether it is a basic, intermediate, or critical care area [see Clause 4.2.6.1]). Bathrooms and washrooms are not always considered part of the patient care area.

Patient care environment — a zone in a patient care area that has been preselected for the accommodation of a patient bed, table, or other supporting mechanism, and for the accommodation of equipment involved in patient treatment, and which includes space within the room 1.5 m beyond the perimeter of the bed in its normal location and to within 2.3 m of the floor (see Figure 1). The patient care environment is a zone fixed to the supporting mechanism and does not move with the patient as the patient moves through the health care facility or the room.

Patient care equipment — equipment used directly for patient treatment, diagnosis, or both.

Patient current — a current that is intentionally applied to a patient for therapeutic or diagnostic purposes.

Patient leakage current — current flowing from the patient connections via the patient to ground or originating from the unintended appearance of a voltage from an external source on the patient and flowing from the patient via the patient connections of a Type F applied part to ground.

Permanently connected equipment — equipment that is electrically connected to the supply by connectors that can be accessed, loosened, or tightened only by a tool.

Prime mover — an engine designed to drive an electrical generator or alternator.

Procedure — a treatment or care process categorized in terms of the type of electrical contact between the patient and the medical electrical equipment (see **Body contact**, **Cardiac contact**, and **Casual contact**).

Risk — The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm. **Note:** *This definition is identical to that in ISO 14971.*

Risk class — a classification that indicates the degree of confidence (probability) that a piece of medical electrical equipment is not a source of or sink for current that could harm a patient.

Risk class 1 part — a part where the contact is casual or non-essential for the function of the equipment.

Risk class 2 part — an intentionally applied part that comes into contact with an anatomical structure other than the heart or great vessels and which in fulfilling the necessary function of the equipment can conduct risk current to or from the equipment to which it is connected.

Risk class 2G part — a part that is bonded to parts of the equipment connected to earth, or connected to such parts through an impedance sufficiently small that it cannot meet the risk current limits of a patient-applied part or dielectric strength test for risk class 2.

Risk class 3 part — an intentionally applied part that comes into contact with the heart or great vessels and which in fulfilling the necessary function of the equipment can conduct risk current to or from the equipment to which it is connected.

Risk current — a current, other than a patient current, that can flow through a patient, an operator, or a bystander.

Note: The term "risk current" was chosen to avoid the conceptual limitation of the term "leakage current", which is well established as a definition for current flowing from the power supply of equipment to exposed non-current-carrying parts, and thence to ground.

Supply utility — an authority or utility supplying electrical energy from a public, private, or on-site source.

4 Electrical safety

4.1 Safety philosophy

4.1.1 Underlying principle

The risk associated with an electrical hazard can be controlled by a combination of four activities:

- (a) proper design of the building electrical system;
- (b) proper education of the entire care team;
- (c) proper design of the medical electrical equipment; and
- (d) proper management and use of all electrical equipment.

This philosophy recognizes that faults and user errors will occur, but a single fault will produce only a low risk if other protective features are in place.

Note: See Annex B for additional information.

4.1.2 Risks in patient procedures

Patient procedures for diagnosis, treatment, or care are determined by the patient's medical needs and physiological condition. The types and severity of medical risk vary from procedure to procedure.

4.1.3 Risks of medical devices

Medical devices can present use-related hazards. The risks associated with these hazards can be minimized by applying appropriate measures. International standards and regulations on risk management of medical devices should form the basis for determining these measures. Effective risk management processes can include facility design, equipment management, and training and education.

Note: See Annex B for additional information.

4.1.4 Risk management program

A risk management program shall include procedures for identifying hazards associated with the application of medical electrical equipment, estimating the risk associated with those hazards, and managing that risk. The risk management program shall provide for the determination and teaching of normal operating rules for the safe use of medical electrical equipment when the available equipment and facilities match the requirements of the procedures to be performed. If the available equipment or facilities are not matched to the procedure, or if a combination of procedures produces conflicting requirements, the safety program shall provide for the teaching of how to recognize the hazards and how to use special precautions to reduce the risks to acceptable levels.

4.1.5 Procedure classification

Patient procedures are classified according to the type of contact between the patient and the medical electrical equipment required for the procedure. Three categories of contact are defined:

- (a) cardiac contact (greatest risk);
- (b) body contact (moderate risk); and
- (c) casual contact (least risk).

This classification is based on the electrical shock current limits for the three types of contact.

4.1.6 Equipment and area classification

Equipment and patient care areas may be marked to indicate to the user the level of protection they incorporate. The categories of equipment type used in this Standard are based on levels of protection against electric shock defined in international Standards.

4.1.7 Management of safety factors

The safety philosophy of this Standard dictates that all elements of electrical safety shall be effectively managed by the health care facility administrator. A safety program that is simple to teach and use shall be established to define and manage the elements that promote safety.

4.2 Electrical safety program

4.2.1 General

The health care facility shall develop a documented electrical safety program encompassing the administrative, advisory, educational, and technical aspects of the use of electricity and electrically powered equipment in patient care areas. The program shall apply to new construction, renovations, and existing facilities and equipment.

4.2.2 Responsibilities

The health care facility shall ensure that expert advice concerning electrical safety, electrical installations, and patient care equipment is available to it.

4.2.3 Qualified personnel

The person(s) responsible for the electrical safety program shall have suitable training and experience, and understand the hazards inherent in the use of electricity in patient procedures. It shall not be necessary for the person(s) responsible for the electrical safety program to be on the staff of the health care facility. Such person(s) may be consultants or available through a shared service or similar program.

4.2.4 Basic elements

The basic elements of the electrical safety program shall include, but not be limited to,

- (a) education of the technical staff who operate or are otherwise associated with medical electrical equipment;
- (b) a patient care area classification plan;
- (c) a program to control medical and non-medical electrical equipment and patient-owned electrical devices introduced into patient care areas;
- (d) an inspection, testing, and maintenance program that covers all medical and non-medical electrical equipment introduced into patient care areas;
- (e) a program for the design and management of electrical installations; and
- (f) a program for the responsible disposal of medical and non-medical electrical equipment that has reached the end of its life.

4.2.5 Education

Educational programs shall be delivered to operators and technical staff. These programs shall address the following topics:

- (a) the hazards of equipment use to both the operator and the patient;
- (b) contraindications for use of specific equipment with specific patient types; and
- (c) basic operational maintenance requirements for equipment.

4.2.6 Patient care area classification

4.2.6.1 General

The administrator, clinical staff, and facility designers shall clearly define which types of procedures are to be frequently or normally performed in specified areas of the health care facility. The area classifications shall be those specified in Section 24 of the *Canadian Electrical Code, Part I*, which are as follows:

- (a) basic care area: a patient care area where body contact between a patient and medical electrical equipment is neither frequent nor usual. Examples include
 - (i) patient examination rooms;
 - (ii) patient rooms in a long-term care facility; and
 - (iii) patient rooms in general, specialty, and rehabilitation hospitals where body contact between a patient and medical electrical equipment is neither frequent nor usual;
- (b) intermediate care area: a patient care area where body contact between a patient and medical electrical equipment is frequent or normal. Examples include
 - (i) wards and treatment and examination rooms in general, specialty, and rehabilitation hospitals;
 - (ii) renal dialysis units;
 - (iii) areas for non-invasive electrodiagnosis (ECG, EEG, EMG);
 - (iv) patient preparation areas;
 - (v) physiotherapy departments;
 - (vi) ultrasound suites;
 - (vii) dental clinics;
 - (viii) chiropractic clinics;
 - (ix) physicians' offices; and
 - (x) patient bedrooms; and
- (c) critical care area: a patient care area where the induction and maintenance of general anaesthesia routinely occurs in connection with the examination or treatment of patients, or where cardiac contact between a patient and medical electrical equipment is frequent or normal. Examples include
 - (i) angiographic laboratories;
 - (ii) cardiac catheterization laboratories;
 - (iii) cardiac care units;
 - (iv) emergency trauma suites;
 - (v) intensive care units;
 - (vi) intensive care neonatal units;
 - (vii) operating rooms; and
 - (viii) burn units.

4.2.6.2 Area reclassification

When a procedure is performed repeatedly in an area, it becomes frequent and normal or usual for that location. If a procedure is not appropriate for an area's classification,

- (a) a new, appropriate area for its performance shall be chosen;
- (b) the electrical installation serving the area shall be upgraded;
- (c) the area shall be given a more appropriate classification; or
- (d) staff shall be instructed on the additional precautions to be taken to ensure the safety of patients and equipment operators.

Note: Because this Standard is not intended to be retroactive and it is unlikely that facilities will immediately upgrade their electrical installations in response to this Standard, such facilities should periodically inspect and test their electrical systems as specified in Clause 5.

4.2.6.3 Classification system

The administrator shall document whether a patient care area is classified as

- (a) basic care;
- (b) intermediate care; or
- (c) critical care.

If signs are used to identify a patient care area, they shall be of a type that is unlikely to be lost or misplaced, and located so that they are readily visible to health care facility and medical personnel.

4.3 Electrical equipment control and use

4.3.1 General

4.3.1.1 Equipment control policies and approval

The administrator shall establish equipment control policies for the acquisition, acceptance, maintenance, and use of all equipment.

All electrical equipment shall be approved.

Notes:

- (1) "Approved" is defined in Section 0 of the Canadian Electrical Code, Part I. The definition is reproduced (with minor editorial changes) in Clause 3.
- (2) Rule 2-204 of the Canadian Electrical Code, Part I, states that "Electrical equipment used in electrical installations within the jurisdiction of the inspection department shall be approved and shall be of a kind or type and rating approved for the specific purpose for which it is to be employed."

4.3.1.2 Oxygen-enriched atmosphere

Electrical equipment to be used in an oxygen-enriched atmosphere (OEA) shall be approved (see Clause 4.3.1.1) for use in such an environment.

Note: See Annex C for information on OEAs.

4.3.2 Medical electrical equipment

4.3.2.1 General

All medical electrical equipment shall be approved (see Clause 4.3.1.1) to CAN/CSA-C22.2 No. 114, CSA C22.2 No. 125, or the CSA C22.2 No. 60601 series of Standards, as applicable, and shall be covered by the health care facility's electrical safety program (see Clause 4.2).

Note: CSA has embarked on an adaptation of the medical electrical Standards in the IEC 60601 series of Standards. The adaptation will be complete when CAN/CSA-C22.2 No. 114 and CSA C22.2 No. 125 are phased out. Before December 31, 2002, CAN/CSA-C22.2 No. 114, CSA C22.2 No. 125, and the CSA C22.2 No. 60601 series of Standards were accepted as equivalent for certification purposes. As of December 31, 2002, new products have been certified only to the CSA C22.2 No. 60601 series of Standards. After January 1, 2005, all equipment previously manufactured and certified to CAN/CSA-C22.2 No. 114 or CSA C22.2 No. 125 will be required to comply with the applicable Standards in the CSA C22.2 No. 60601 series of Standards.

4.3.2.2 Markings

All medical electrical equipment shall have markings that indicate

- (a) an appropriate risk class in accordance with the requirements specified in CSA C22.2 No. 125; or
- (b) an appropriate applied part type in accordance with the requirements specified in CAN/CSA-C22.2 No. 601.1 and any other applicable Standard in the CSA C22.2 No. 60601 series of Standards. Markings shall be acceptable to the applicable provincial or territorial electrical inspection authority.

Note:

- (1) See Table 1 for the risk classes and applied part types associated with the patient procedures described in Clause 4.1.5.
- **(2)** See Annex D for information on CSA's certification program.

4.3.2.3 Leakage and risk currents

The following requirements shall apply to leakage and risk currents:

- (a) when measured in accordance with the CSA C22.2 No. 60601 series of Standards, the leakage current of medical electrical equipment certified to CAN/CSA-C22.2 No. 601.1 or its equivalent shall not exceed the limits specified in Table 2; or
- (b) when measured in accordance with CSA C22.2 No. 125, the risk currents of medical electrical equipment certified to CSA C22.2 No. 125 shall not exceed the limits specified in Table 3.

When a piece of medical electrical equipment has been certified to the requirements of one Standard, it shall continue to meet those requirements on subsequent testing. If it does not meet those requirements, it shall be removed from service.

Note: Although they are equivalent in terms of safety, CAN/CSA-C22.2 No. 601.1 does allow higher leakage current levels than CSA C22.2 No. 125.

4.3.3 Safety requirements for medical electrical systems

The safety requirements for medical electrical systems specified in CAN/CSA-C22.2 No. 60601-1-1 shall be met, and the equipment system as a whole shall provide the following:

- (a) in the patient care environment, the same level of safety as medical electrical equipment complying with CAN/CSA-C22.2 No. 601.1; and
- (b) outside the patient care environment, the level of safety appropriate for non-medical electrical equipment complying with the applicable equipment-specific CSA Standards.

Notes:

- (1) In health care facilities, complex and extensive systems of electrical equipment are used in the diagnosis, therapy, and monitoring of patients. It is common practice for equipment of different risk classes or equipment types to be intermixed when medical procedures are performed in a patient care area. Increasingly, systems of electrical equipment consist of interconnected devices originally manufactured for use in variety of fields (not necessarily medical). It is thus possible that medical electrical equipment complying with CAN/CSA-C22.2 No. 601.1 or CSA C22.2 No. 125 will be connected to non-medical electrical equipment that, even if it meets the requirements of the applicable non-medical electrical equipment Standard, will not meet this Standard's safety requirements for medical electrical requirement, and as result compromise the safety of the entire system.
- **(2)** See Table 4 for leakage requirements for the safety of medical electrical systems.

4.3.4 Non-medical electrical equipment used in patient care areas

4.3.4.1 General

Non-medical electrical equipment shall be approved (see Clause 4.3.1.1) to the applicable Standard and shall be covered by the health care facility's electrical safety program.

4.3.4.2 Patient environment requirements

In addition to meeting the requirements specified in Clause 4.3.4.1, non-medical electrical equipment to be used in the patient care environment shall

- (a) be battery powered and less than 30 V;
- (b) be limited to extra-low-voltage Class 2 circuits; or
- (c) have a leakage current, chassis to ground, of less than 500 µA.

4.3.4.3 Acquisition and training

When non-medical electrical equipment to be used in patient care areas is being acquired, engineering staff associated with the health care facility should help educate staff on the use of the equipment and serve as consultants for equipment selection and deployment.

4.3.5 Patient-owned electrical devices

The following requirements shall apply to patient-owned electrical devices:

- (a) The administrator shall develop a program to control entry of patient-owned electrical devices into patient care areas. The program should include the following:
 - (i) written policy: the policy should be in writing and available to everyone responsible for patient admission and care;
 - (ii) notification: before and after admission, all patients should be informed of the facility's policy on control of patient-owned electrical devices; and
 - (iii) control on admission: at the time of admission, patient-owned electrical devices should be examined, tagged for inspection, and tagged with the patient identification number or name. This should be done by personnel qualified to carry out these tasks. Only devices permitted by the policy shall be allowed into patient care areas.
- (b) Patient-owned electrical devices shall not be permitted in critical care areas where medical equipment potentially susceptible to interference is being used with patients. The administrator shall establish a policy for the use of these devices in other areas of the facility.
- (c) Low-power battery-powered devices such as clocks, radios, and tape players (but not battery chargers) may be permitted in patient care environments.
- (d) Patient-owned electrical devices shall be in a safe condition, without evidence of excessive wear, deterioration, or repairs. Particular attention shall be given to the power cord and ventilation openings. The power cord shall be free of fraying, burns, cuts, crushing, exposed insulation, missing strain reliefs, and bent or missing pins. Ventilation openings shall be clean and grilles or screening shall be in place, if applicable.

Notes:

- (1) Most electrical devices that patients wish to bring from home pose very little risk and can make their stay more comfortable. However, certain precautions should be taken to ensure that safety is not compromised.
- (2) It is possible that area-specific policies will need to be adopted, because it can be more appropriate for the facility to provide equipment in a specific area than to permit patients to bring in their own equipment.
- **(3)** The facility's administrator should reserve the right to waive the control policy should medical conditions or treatment warrant it.

4.3.6 Specific equipment

4.3.6.1 Extension cords

Extension cords shall not be permitted in patient care areas.

4.3.6.2 Hospital-grade power bars

The following requirements shall apply to hospital-grade power bars:

(a) Power bars shall not be used as a permanent solution for an inadequate building installation. They are the least desirable alternative to a permanent solution; however, when used, they shall meet the requirements specified in CAN/CSA-C22.2 No. 60601-1-1.

Notes:

- (1) If power bars are being used constantly, the electrical distribution system should be upgraded.
- (2) In CSA's certification Standards, power bars are called "cord-connected multiple receptacle extension boxes". For the purposes of this Standard, such devices are called power bars, and those that meet the requirements specified in CSA C22.2 No. 21 for medical applications are called "hospital-grade power bars".
- (b) Use of power bars to supply medical electrical equipment shall be minimized. Acceptable alternatives to the use of a power shall bar include, but not be limited to,
 - (i) appropriate selection of the patient care environment so that a power bar becomes unnecessary;
 - (ii) installation of electrical receptacles in appropriate locations;
 - (iii) installation of an appropriate number of electrical receptacles; and

(iv) replacement of the equipment's original power cord with a longer cord.

- (1) If in-house modification of the equipment's original power cord is performed, it is possible that the equipment will need to be specially inspected by CSA, because modifications can invalidate a CSA certification.
- **(2)** Because the bonding conductors of a hospital-grade power bar serve as the bonding connection to ground for an equipment set, the continuity of the bonding conductors is extremely important. A power bar can require more frequent inspection than other types of similar equipment, depending on how much use it receives.
- (c) Any power bar meeting the requirements specified in CAN/CSA-C22.2 No. 60601-1-1 (see Clause 4.3.3) shall be used in patient care areas as follows:
 - (i) the power bar shall not be used in series with an extension cord or another power bar;
 - (ii) the power bar shall be placed on the health care facility equipment inventory list for preventive maintenance at specific intervals, and the continuity of the wiring in the power bar, particularly the bonding conductors, shall be tested at regular intervals;
 - (iii) if mounted on a cart, the power bar shall be protected from the entry and entrapment of liquids from spills or when the cart is being used for cleaning; and
 - (iv) the receptacle end of the power bar shall be mounted or supported above the level of the floor to prevent contact with liquids that might pool on the floor.

4.3.6.3 Electric hospital beds

Electric hospital beds shall included in the facility's preventive maintenance program.

Note: The use of hydraulic or manual beds in pediatric wards should be considered in order to prevent patient injuries.

4.3.6.4 Luminaries

The following requirements shall apply to luminaries:

- (a) luminaries with integral pull chain switches shall have pull chains composed entirely of insulating material or containing one or more links made from insulating material; and
- (b) cord-connected luminaries of the movable or flexible arm type used in patient care environments shall provide protection from electric shock by bonding to ground through a three-wire power cord and a three-pin attachment plug, or by being of double-insulated construction.

Notes:

- (1) See CAN/CSA-Z317.5 for information on luminaries.
- (2) Inspection of both cord-connected and permanently connected luminaries should include examination of the physical integrity of the power cord at the sites on the cord that experience maximum bending and compression.

4.3.6.5 Housekeeping equipment

Line-powered housekeeping equipment shall be included in the facility's electrical safety program.

Whenever possible, line-powered housekeeping equipment should not be operated in patient care environments while patients are undergoing body or cardiac contact procedures.

Notes:

- **(1)** Because housekeeping equipment usually experiences considerable wear and tear, it should be carefully selected and frequently inspected.
- **(2)** See Table 4 for leakage requirements for the safety of medical electrical systems.

4.3.6.6 Electrosurgery units

The requirements specified in CAN/CSA-CEI/IEC 1289-1 and CAN/CSA-CEI/IEC 1289-2 shall apply to electrosurgery units.

4.3.6.7 Defibrillators

The requirements specified in CAN/CSA-CEI/IEC 1288-1 and CAN/CSA-CEI/IEC 1288-2 shall apply to defibrillators.

4.3.6.8 Permanently connected medical equipment

General-purpose receptacles provided as part of permanently connected medical equipment shall be subject to the performance requirements specified in Clause 5.

4.3.7 Electromagnetic interference and electromagnetic compatibility

(1) It has been recognized that the proper and reliable operation of some medical equipment can be adversely affected by radio-frequency electromagnetic fields. Sources of radio-frequency electromagnetic fields can be broadly divided into external (e.g., commercial transmitters and paging services) and internal (e.g., portable radios, cell phones, electrosurgery units, and power line spikes). The strength of these fields can vary from 10⁻³ to 10¹ V/m, depending on the power of the source, the distance from the source, obstruction attenuation, and, possibly, multi-path standing waves.

The susceptibility of medical equipment to these fields is determined by a multitude of variables, which can be generic to a particular model or specific to an individual unit. The severity of an interference-induced malfunction may be classified as a technical malfunction (i.e., the degree of actual equipment malfunction) and as a medical malfunction (i.e., the degree of the effect on the patient).

(2) See Annex E for further information on electromagnetic interference and electromagnetic compatibility (EMI/EMC).

4.3.7.1 Administration of electromagnetic emitting devices

4.3.7.1.1

The administrator shall ensure that

- (a) personnel are educated about the possible effects and consequences of EMI/EMC; and
- (b) policies for dealing with potential EMI/EMC problems are developed or adopted, enforced, and regularly reviewed.

Note: Policies on EMI/EMC can include, but are not limited to,

- (a) internal radio communications policy, including issues such as security, ambulances, porters, and facility-owned radio-frequency-emitting devices and medical equipment; and
- (b) a visitor and patient communications policy, including issues such as use of cellphones and other wireless devices, signage indicating restricted areas or devices, distribution of pamphlets explaining the policy, and labels to indicate possibly susceptible movable medical equipment (e.g., infusion pumps).

4.3.7.1.2

When appraising an EMI/EMC situation, the administrator shall

- (a) investigate the presence of all external and internal sources; and
- (b) estimate or measure the intensity of the electromagnetic fields in the clinical areas.

4.3.7.1.3

Newly purchased medical electrical equipment shall meet the requirements specified in CAN/CSA-C22.2 No. 60601-1-2. An EMI/EMC clause shall be included in the written purchase procedures for all new medical electrical equipment.

4.3.7.2 Wireless communication devices

The following requirements shall apply to wireless communication devices:

- (a) the health care facility shall perform a risk analysis on the use of wireless communication devices in the facility; and
- (b) the health care facility shall use the risk analysis to create a policy on the use of wireless communication devices.

Notes:

- (1) Wireless communication devices can interfere with the operation of medical equipment (e.g., infusion pumps, ventilators, infant incubators, and motorized wheelchairs), with various consequences (e.g., altered display outputs and unexplained alarms).
- (2) The degree to which medical equipment can be affected by a wireless communication device is a function of several factors, most notably the equipment's susceptibility to interference and the transmitter's power and frequency. Generally, the greater the distance between the medical equipment and the wireless communication device, the less likely it is that the medical equipment will be affected. It should also be noted that structures such as walls can be transparent to radio waves.
- (3) Industry Canada's ICES-001 sets out the technical requirements for radiated and conducted radio noise emissions from digital apparatus.

4.3.7.3 Radio-frequency interference testing

If radio-frequency testing is performed on-site, the requirements specified in IEEE C63.18 shall be followed.

4.3.7.4 Design

EMI/EMC issues shall be reviewed during the planning of every health care facility design and major renovation. Equipment likely to generate strong stray electromagnetic fields (e.g., transformers, motors, large power cables, large underfloor heating cables, free-air-rated feeders, and high-intensity discharge lamps) should be installed to minimize interference to equipment used in patient care. Most EMI and radio-frequency interference (RFI) problems may be addressed by employing the following strategies:

(a) spatial separation (see Table 5);

Note: *Table 5* is intended only as a general guide for assessing potential interference from various sources.

- (b) temporal separation;
- (c) screening of sources or measuring sites. Screening of sources (e.g., by steel conduit) is usually more effective than screening of rooms. The screening of rooms is the most expensive option, and is often ineffective at physiologic frequencies.

The possible interactions between intense EMI/RFI fields and cardiac pacemakers should be considered. Signs warning of a potential interaction hazard should be posted in areas where such interactions could occur.

4.3.8 Line-borne electrical interference

Non-linear loads that generate harmonics in the electrical system should be controlled.

Note: *See the following publications for further information:*

- (a) IEEE C37.90.1;
- (b) Ontario Hydro Standard Specification A-28; and
- (c) Freund (1988).

4.4 Inspection, testing, acquisition, and maintenance of electrical equipment

Note: This Clause specifies requirements for the inspection and testing of medical and non-medical electrical equipment to verify compliance with this Standard

- (a) when the equipment is delivered to the health care facility; and
- (b) during the lifetime of the equipment.

4.4.1 General

It is the responsibility of the health care facility to ensure that the inspection and testing required by this Standard is performed. The testing should be based on user experience and the equipment manufacturer's recommendations.

4.4.2 Maintenance

Maintenance of medical and non-medical electrical equipment may be performed by in-house or contract maintenance personnel. The administrator shall ensure that all maintenance personnel are competent.

4.4.3 Action criteria and maintenance log

Inspections, tests, and maintenance, as described in this Standard, shall be

- (a) performed whenever equipment fails to operate properly;
- (b) performed at the intervals indicated in this Standard for each test or inspection;
- (c) performed in accordance with a written plan approved by the administrator; and
- (d) recorded in a maintenance log that forms a part of the facility's permanent record. The maintenance log shall contain a page, card, or file for each item of medical electrical equipment.

All substandard conditions (e.g., deviation from this Standard's requirements or the manufacturer's specifications, or physical damage) shall be corrected, and the dates on which each substandard condition was noted and corrected shall be entered in the log.

4.4.4 Notification

Equipment service information (e.g., repairs, maintenance, calibration, compliance with the preventive maintenance program) shall be made available to equipment users to ensure that they are kept informed of the status of the equipment.

4.4.5 Training

Equipment operators and service personnel shall complete a maintenance training program appropriate to their level of involvement with and responsibility for the equipment.

4.4.6 Documentation

Health care facilities shall have a documented process for selecting and acquiring medical and non-medical electrical equipment (see Annex F). Selection and acquisition shall involve, but not be limited to, the following key elements related to electrical safety:

- (a) clear and comprehensive specifications, including compliance with relevant Standards; and
- (b) impact on installation and maintenance support services.

The evaluation process for purchased equipment shall also be applied to donated, leased, and borrowed equipment.

4.4.7 Acceptance tests

All medical and non-medical electrical equipment shall be inspected on delivery to the health care facility. The administrator shall specify who is responsible for acceptance testing. Acceptance testing shall ensure compliance with

- (a) the purchase conditions;
- (b) local and national Standards, as applicable; and
- (c) appropriate sections of the manufacturer's published performance levels.

These requirements shall apply to all equipment received (e.g., purchased equipment, donated equipment, leased equipment, equipment returned after repairs, and equipment on trial). See Annex F for further information.

4.5 Maintenance of medical and non-medical electrical equipment

4.5.1 General

There shall be a written facility-specific preventive maintenance plan that

- (a) includes every item of electrical equipment used in patient care areas;
- (b) lists the codes, Standards, and guidelines pertaining to each item of equipment; and
- (c) identifies the frequency and nature of periodic inspection and maintenance.

Note: The purpose of periodic maintenance is to ensure

- (a) proper and reliable performance of equipment; and
- (b) safety for the patient, the operator, and persons in surrounding areas.

4.5.2 Verification criteria

Periodic maintenance shall verify

- (a) the integrity of all covers and insulation designed to prevent access to live parts;
- (b) correct operation of key functions of the device;
- (c) that leakage currents are within proper limits; and
- (d) that the resistance between the bonding point and any accessible conductive parts is within acceptable limits.

4.5.3 Inspection and maintenance criteria

Inspection and maintenance shall be performed if

- (a) the equipment has been subjected to extreme mechanical stress (e.g., has been dropped);
- (b) liquids have been spilled into or on the equipment;
- (c) the equipment has been subjected to extreme temperatures;
- (d) the equipment's performance appears to have changed;
- (e) parts of the equipment's enclosure are cracked, have been removed, or are missing; or
- (f) an attachment plug, power supply cord, or patient connection shows signs of deterioration.

5 Building electrical system

Notes:

- (1) Clause 5 specifies requirements for the design of building electrical systems in patient care areas and for testing such systems. These requirements supplement those specified in the Canadian Electrical Code, Part I, particularly Sections 24 and 52,
 - (a) at the completion of new construction, renovations, or additions to existing installations; and (b) during the lifetime of a system.
- (2) Table 6 provides a summary of the tests required by Clause 5.
- (3) See Annex G for test sheets.
- (4) Annex H compares grounded and isolated building electrical systems in order to help engineers and others responsible for designing such systems for health care facilities to select the best system for a particular application.

5.1 General

The health care facility shall ensure that the design, inspection, and testing requirements specified in this Standard are implemented. The methods described in this Standard shall be regarded as reference methods. Other methods that can be demonstrated to achieve equivalent results may be used if acceptable to the health care facility.

5.2 Inspection and testing

5.2.1 Application

The test methods specified in this Clause are intended for branch circuits that are described in Section 24 of the *Canadian Electrical Code, Part I,* and operate at rated voltages of 120, 208, and 240 V. The test methods are as follows:

- (a) the two-wire single-phase grounded neutral 120 V circuit with a bonding conductor; and
- (b) the two-wire single-phase isolated circuit with a bonding conductor and three-wire three-phase isolated circuit. A variety of other types of circuits are used for special applications (e.g., three-phase three-wire and three-phase four-wire circuits). Some of the tests described in this Standard will be unsuitable for some of these systems, in which case the health care facility shall establish appropriate test methods.

5.2.2 Measurement circuits

The test measurements shall meet the requirements of each test (see Figures 2 and 4).

5.2.3 Design

Designs for new construction or renovation involving alteration or extension of electrical circuits shall be undertaken only by a professional engineer licensed under provincial or territorial regulations. The health care facility shall engage a professional engineer to

- (a) review the installation and testing specified in this Standard; and
- (b) provide a written statement expressing an opinion on whether the installation has been completed in accordance with this Standard.

5.2.4 Conditions for inspection and testing

The inspections and tests specified in Clause 5 shall be conducted

- (a) at the intervals indicated in the description of each test or inspection, or at other intervals if such factors as usage (light or heavy) and experience so indicate;
- (b) following repairs to or replacement of branch circuit components; and
- (c) in accordance with a written plan approved by the health care facility.

5.2.5 Fault or substandard condition

If a fault or a substandard condition is discovered during inspection, testing, or commissioning,

- (a) the dates on which the condition was discovered and corrected shall be entered in the log;
- (b) the cause shall be identified and corrected;
- (c) the tests that identified the fault or substandard condition shall be repeated for that branch circuit; and
- (d) any previous tests directly affected by the tests that identified the fault or substandard condition shall also be repeated.

5.3 Conductor insulation integrity test

5.3.1 General

Compliance with the conductor insulation requirements specified in Clause 5.3.2 shall be verified on completion of new construction or major alterations or additions to existing installations.

5.3.2 Insulation resistance

When completed with all wiring devices (receptacles, switches, etc.) connected, each branch circuit supplied by a grounded system shall have an insulation resistance

- (a) of not less than 10 k Ω for all neutral conductors to ground; and
- (b) of not less than 500 k Ω for all ungrounded conductors to ground.

Note: When insulation resistance tests are performed, precautions should be taken to ensure that voltage-sensitive devices such as ground fault circuit interrupters are not subjected to voltages that will damage those devices.

5.3.3 Measurement

The resistance measurement specified in Clause 5.3.2 shall be performed using a megohmmeter with an open-circuit voltage of 500 V dc.

5.4 Branch circuits

5.4.1 General

Branch circuits shall meet the requirements specified in Section 24 of the Canadian Electrical Code, Part I.

5.4.2 Voltage drop requirements for grounded systems

Grounded systems shall meet the voltage drop requirements specified in Rule 8-102 of the *Canadian Electrical Code, Part I.* Accordingly, the voltage drop at any receptacle, measured as described in Clause 5.4.3, shall not exceed 5%. If it exceeds 3% but is less than 5%, every effort should be made to identify the source of the voltage drop and correct the voltage drop below 3% by using larger branch or feeder circuit conductors, or both.

Note: The requirements specified in this Clause can usually be met by using No. 12 AWG copper conductors for circuits up to 20 m long, and No. 10 AWG copper conductors for circuits between 20 and 30 m long, provided that the splices and joints are well made and that the number of splices and joints is kept to a minimum. Wherever possible, branch circuit panelboards should be located in a way that avoids the necessity for branch circuits longer than 30 m. Designers of patient care electrical distribution systems should consult the voltage drop tables specified in Rule 8-102 of the Canadian Electrical Code, Part I, to ensure adequate sizing of the panelboard feeder circuit conductors.

5.4.3 Voltage drop test for grounded systems

5.4.3.1

The voltage drop test for grounded systems should be performed using the test circuit depicted in Figure 2, as follows:

- (a) connect the test circuit to the outlet;
- (b) apply a load of 80% of the rated current of the circuit between the receptacle poles for 1 to 5 s;
- (c) record the current;
- (d) record the terminal voltage under load as V_1 ; and
- (e) open the switch SW and immediately record the terminal voltage without load as V_0 .

For safety reasons, the test shall not be performed while the circuit is supplying energy to connected equipment.

5.4.3.2

The voltage drop $(V_0 - V_1)$ shall not exceed 5% of V_0 .

Compliance with the voltage drop requirements specified in Clause 5.4.2 shall be verified on completion of new construction, or on completion of major renovations of or additions to existing installations.

5.5 Branch circuit breakers — Mechanical operation test

To verify its mechanical operation, each circuit breaker should be switched on and off at least three times, preferably while its leads are unplugged or switched off. This shall be done once each year, or more frequently if directed by the circuit breaker manufacturer.

Notes:

- (1) The purpose of a circuit breaker is to interrupt the flow of current to a load if the current exceeds the rated current of the circuit breaker (i.e., it provides overcurrent protection). Circuit breakers are included in the electrical installation to protect the electrical insulation of the conductors in the branch circuit from thermal damage caused by heat generated when the load current exceeds the rated design current and to protect electrical equipment against faults.
- (2) Circuit breakers are designed so that the overcurrent protection function cannot be controlled by the operating handle of the breaker. Although manually switching off the breaker does not trigger the overcurrent protection (tripping) function, it does distribute the lubrication in the mechanical portion of the breaker and remove any high-resistance film that has formed on the contact surfaces.

5.6 Receptacles

5.6.1 General requirements

5.6.1.1 General

The minimum number and general arrangement of receptacles in patient care areas should be as specified in Table 7. Additional receptacles and circuits shall be provided for equipment placed in a patient care environment more or less permanently (e.g., patient monitors and bedside computer terminals). When a non-medical computer communications outlet and power receptacle are provided in a patient care area, the receptacle shall be located outside the patient care environment and carefully positioned and identified so that it cannot be inadvertently used for equipment that will be connected to the patient. If the outlet and receptacle use isolated power, the receptacle shall not be connected to the patient care isolated power distribution system.

Note: Receptacles, other electronics and electrical services, and medical gas outlets are often provided using a medical supply unit (also known as a patient service module). See CAN/CSA-Z305.8 for requirements relating to medical supply units.

5.6.1.2 Requirements for non-medical equipment

At least one receptacle shall be provided for use with housekeeping equipment, but not necessarily in every patient care area. Housekeeping receptacles shall be permitted to share circuits with other housekeeping receptacles if appropriate. It shall not be necessary to supply housekeeping receptacles from the emergency power system. Housekeeping receptacles shall not be connected to an isolated power distribution system.

5.6.1.3 Retentive force testing

Section 24 of the *Canadian Electrical Code, Part I*, requires that all 15 and 20 A non-locking receptacles in patient care areas be hospital grade. Such receptacles shall resist removal of a test pin and test plug of a commercially available receptacle retention tester by a pull of up to

- (a) 1.1 N (112.2 gf) using a round test pin in the ground slot;
- (b) 2.2 N (224.3 gf) for one pin, using either a one- or two-pin test plug; and
- (c) 13 N (1325.6 gf) for both pins combined, using a two-pin test plug.

5.6.2 Connection

In view of the varied and critical uses of receptacles in patient care areas, particular care shall be taken to ensure that

- (a) the connection polarity is correct (i.e., the neutral and "live" conductors are connected to the silver and brass screws, respectively, in grounded circuits, and the orange and brown conductors are connected to the silver and brass screws, respectively, in isolated circuits);
- (b) the bonding conductor is connected to the outlet box bonding screw; and
- (c) all bonding conductors are brought to a separately installed bonding bus bar or to the bonding bus at the panelboard.

5.6.3 Isolated ground receptacles

Isolated ground receptacles (also known as "clean ground" receptacles) should not be used in patient care areas. If used as intended, the isolated ground terminal of such a receptacle shall be bonded to ground only at a remote location, in which case it is possible that there will be a high impedance for fault currents.

5.6.4 Computerized equipment

Measures other than the use of isolated ground receptacles should be used to enhance the operation of computerized equipment. For example, a dedicated neutral conductor and a dedicated copper bonding conductor can minimize power-line-induced problems. Integral protection against transients in the power system can be specified for susceptible equipment, or externally mounted protectors can be used.

5.6.5 Receptacle identification

Each receptacle shall have the circuit number and the supplying panelboard permanently identified at the outlet. This identification shall be visible when the receptacle cover plate is in place, shall be in a position where it is not likely to be painted over, and shall not be on the cover plate itself.

Circuit identification information (the branch circuit number and the designation of the panelboard supplying the circuit) shall not be placed on the cover plate, as cover plates can be mistakenly interchanged during painting and maintenance.

The circuit breaker at the panelboard should be actuated to ensure that the receptacles are correctly marked as corresponding to that breaker.

5.6.6 Testing

5.6.6.1 Retentive force testing

Compliance with the pullout requirements specified in Clause 5.6.1.3 shall be verified using a commercially available receptacle retention tester

- (a) on completion of new construction, major renovations, or receptacle replacement;
- (b) in basic care areas at least every two years after initial verification; and
- (c) in intermediate and critical care areas at least every year after initial verification.

5.6.6.2 Polarity testing

Compliance with the requirements specified in Clause 5.6.2(a) shall be verified

- (a) on completion of new construction or major renovations; and
- (b) every time a receptacle is replaced.

5.7 Panelboards

5.7.1 General

Panelboards (including their installation in patient care areas) shall meet the requirements specified in Section 24 of the *Canadian Electrical Code, Part I.*

5.7.2 Location

Panelboards shall be located with due regard for the need for convenient access by persons authorized to operate or reset circuit breakers. Access may be controlled by panelboard locks or prudent selection of a panelboard location.

Note: When circuit breakers trip, it can be important in some circumstances to restore service as soon as possible. For this reason, persons knowledgeable about the operation and location of the circuit breakers should be available at all times.

5.7.3 Identification

Every panelboard supplying a patient care area shall be given a unique identifier (e.g., by designating a normal panelboard on a third floor "3A", and its emergency counterpart "3EA").

5.7.4 Load directory

Every panelboard supplying a patient care area shall have an understandable, clear, and neatly lettered directory that indicates the circuit number and the type and location of all loads supplied from it. The directory shall be kept up-to-date.

5.7.5 Receptacle and load grouping

If branch circuits from one panelboard supply receptacles or loads not only in patient care areas but also in other areas, the circuits serving patient care areas shall be marked distinctly by colour, location, grouping, or a similar method so that they can be readily identified.

5.8 Bonding to ground

5.8.1 General

Bonding to ground shall meet the requirements specified in Section 24 of the *Canadian Electrical Code, Part I.*

5.8.2 Exemptions

It shall not be necessary for parts of the building structure and miscellaneous small conductive parts that are not likely to become energized (e.g., metal door frames, window frames, and soap dishes) to be bonded to ground.

5.9 Voltage difference between ground points

5.9.1 Voltage difference limits

In each patient care environment, the maximum potential difference between the bonding poles of receptacles designated for patient care, and between those poles and all other exposed conductive non-current-carrying parts in the same patient care environment, shall be less than 20 mV when tested as required by Clause 5.9.2.

Note: The purpose of this Clause is to limit the voltage difference in the vicinity of the patient and thus minimize the risk of electric shock.

5.9.2 Test method

Using the standard load and measuring device depicted in Figure 3, the following test procedure shall be performed at the completion of new construction or major renovations or additions to existing installations:

- (a) confirm that all receptacles have been installed;
- (b) confirm that no cord-connected utilization equipment is connected to the system;
- (c) energize the system;
- (d) select a local reference point known to be bonded to ground; and
- (e) measure the voltage between the reference point and
 - (i) each receptacle ground pole designated for patient care in the patient care environment being tested; and
- (ii) each exposed conductive non-current-carrying metal part in the patient care environment; and (f) note each instance where the measurements exceed 20 mV.

If the test leads are long, the readings should be corrected for pickup (zero reading) when connected together.

This test shall be repeated (except for Item (a)) at least every five years after the initial test is conducted.

5.10 Ground return path voltage rise for grounded systems

5.10.1 General

Bonding conductors shall be sized and installed in such a manner that the voltage rise at the ground slot of each receptacle designed for patient care in a patient care area is not more than 3 V when tested in accordance with Clause 5.10.2.

5.10.2 Test method

5.10.2.1 General

5.10.2.1.1 Ground return path voltage rise

After the test required by Clause 5.9 is completed, the ground return path voltage rise for grounded systems shall be verified using the test circuit depicted in Figure 4, as follows:

- (a) Connect the test circuit to the outlet.
- (b) With switch SW open, record the voltage indicated by voltmeter V_1 as V_N , the neutral to ground voltage without load. If it exceeds approximately 2 V, determine the cause and correct the defect.
- (c) Using the low-voltage supply (nominally 5 V open circuit), apply a load of 80% of the rated current of the circuit between the neutral and the bonding conductor for 1 to 5 s. To ensure accuracy, the low-voltage supply should be energized from a circuit other than the one being tested.
- (d) Record the current I and the voltage indicated by voltmeter V_2 as V_R .

Notes:

- (1) This test measures the grounding effectiveness of the bonding conductor and other associated ground path conductors by simulating the effect of a fault current returning to the source ground through the ground path.
- **(2)** Measured under low-current conditions, a deficient ground path can appear adequate. However, when measured under simulated fault conditions with a greater current, deficiencies are likely to be detected.

5.10.2.1.2 Retentive path voltage rise

The return path voltage rise, V_R , shall be not greater than 3 V.

5.10.2.2 Verification

Conformity with the requirements of Clause 5.10.1 shall be verified

- (a) on completion of new construction or major renovations; and
- (b) for individual receptacles that are replaced.

5.11 Isolated power systems

5.11.1 General

Use of isolated power is not required by the *Canadian Electrical Code, Part I*, or by this Standard. When isolated power is provided, it shall meet the applicable requirements specified in Section 24 of the *Canadian Electrical Code, Part I*. When the total leakage current in a single system might exceed the allowed total hazard index, or when the anticipated load might exceed the rating of a single isolation transformer, more than one isolated power system may be used in any location. See Annex H.

5.11.2 Test of impedance to ground (single-phase and three-phase isolated systems) and hazard index monitoring

5.11.2.1 Single-phase isolated system

The system hazard index of a single-phase isolated system shall be tested as follows:

- (a) confirm that all receptacles and permanently connected equipment (e.g., surgical luminaries) are installed and functioning;
- (b) confirm that all permanently connected equipment is switched off and all cord-connected equipment is disconnected;
- (c) verify that the system is ungrounded;
- (d) energize the system's isolation transformer, distribution panelboard, and branch circuits other than the line isolation monitor branch circuit;
- (e) using the standard load and measuring device shown in Figure 3, record the measured voltage between a chosen reference ground and the energized conductor designated
 - (i) Line 2 as V_{MLINE1} ; and
 - (ii) Line 1 as V_{MLINE2} ;

(f) calculate the current flow as the greater of the following two values:

```
I_{max} = V_{MLINE1} \times 1000
= V_{MLINE2} \times 1000
where
I_{max} = \text{current flow, mA}
```

(g) verify that the measured current does not exceed the value $i_{max} = 2E$ where

 i_{max} = measured current, mA

E = nominal voltage between the energized conductors, V

5.11.2.2 Three-phase isolated system

The system hazard index of a three-phase isolated system shall be tested as follows:

- (a) confirm that all receptacles and permanently connected equipment (e.g., surgical luminaries) are installed and functioning;
- (b) confirm that all permanently connected equipment is switched off and all cord-connected equipment is disconnected;
- (c) verify that the system is ungrounded;
- (d) energize the system's isolation transformer, distribution panelboard, and branch circuits other than the line isolation monitor branch circuit;
- (e) using the standard load and measuring device shown in Figure 3, record the measured voltage between a chosen reference ground and the energized conductor designated

```
(i) Line 3 as V_{MLINE1/2};
```

- (ii) Line 2 as $V_{MLINE1/3}$; and
- (iii) Line 1 as $V_{MLINE2/3}$;
- (f) calculate the current flow as the greater of the following three values:

```
I_{max} = V_{MLINE1/2} \times 1000
= V_{MLINE2/3} \times 1000
= V_{MLINE1/3} \times 1000
where
I_{max} = current flow, mA
```

(g) verify that the measured current does not exceed the value $i_{max} = 2E$

where

 i_{max} = measured current, mA

E = nominal voltage between the energized conductors, V

5.11.2.3 Testing interval

The tests specified in Clauses 5.11.2.1 and 5.11.2.2 shall be conducted on completion of new construction and following renovations to systems with or without line isolation monitors.

For systems that are not equipped with line isolation monitors, the tests specified in Clauses 5.11.2.1 and 5.11.2.2 shall be conducted at least once a year after initial testing.

5.11.2.4 Maximum hazard

The maximum hazard index readings on the line isolation monitor shall be taken with

- (a) all circuit breakers closed;
- (b) all permanently connected equipment switched on; and
- (c) all cord-connected equipment disconnected.

The readings shall be recorded and compared to previous readings. When a reading is more than 20% greater than any previous reading, authorized maintenance personnel shall investigate the source of the increased leakage by conducting tests on individual circuits, and shall repair or replace the faulty wiring or equipment.

5.11.2.5 Testing interval

For systems that are equipped with line isolation monitors, the tests specified in Clauses 5.11.2.1 and 5.11.2.2 shall be conducted on completion of new construction and following renovation to such systems, and at least once a year after initial testing.

24 September 2004

5.12 Wiring accessories

5.12.1 Power cord adapters

5.12.1.1

The following adapters shall not be used in patient care areas:

- (a) three-pin to two-pin adapters; and
- (b) 20 to 15 A adapters.

5.12.1.2

Power cord adapters shall not be used as a permanent measure for dealing with an inadequate building installation. When the use of adapters is unavoidable, special-purpose adapters for use with standardized receptacles shall

- (a) be inspected regularly as part of a preventive maintenance program;
- (b) be not longer than 300 mm; and
- (c) meet the requirements specified in CSA C22.2 No. 21 and C22.2 No. 42, as applicable.

Note: If power cord adapters are constantly being used, the electrical distribution system is inadequate for the load demands and should be upgraded.

5.12.2 Ground fault circuit interrupters

5.12.2.1

Ground fault circuit interrupters (GFCIs) shall comply with the requirements specified in CAN/CSA-C22.2 No. 144. Installation of GFCIs in patient care areas shall be undertaken in accordance with the requirements specified in Section 24 of the *Canadian Electrical Code, Part I*.

Note: Class A GFCIs are designed to interrupt 120 V/60 Hz power to a circuit when there is a nominal 5 mA leakage of current to ground. The primary function of these devices is to protect against electric shocks, meaning, in this context, macroshock hazards. GFCIs cannot protect against cardiac contact shock (microshock) hazards.

5.12.2.2

GFCIs shall be used only in solidly grounded power distribution systems and only in areas specified in Rule 24-106 of the *Canadian Electrical Code, Part I*.

GFCIs shall not be used in locations where sudden, unplanned power interruptions cannot be tolerated. **Note:** *GFCIs are available in three basic types:*

- (a) receptacle-type GFCIs: receptacles that incorporate a Class A GFCI with or without "feed-through" provision (i.e., the ability to provide ground fault protection to non-GFCI receptacles on the same branch circuit downstream from the GFCI receptacle);
- (b) circuit breaker GFCIs: circuit breakers that incorporate overcurrent protection and Class A ground fault protection and are intended for installation in a panelboard or load centre; and
- (c) portable GFCIs: portable plug-in devices that incorporate Class A ground fault protection for a standard receptacle installed in the device.

GFCIs are active devices — they need to mechanically open contacts in the power supply line to provide protection. Consequently, they are tested periodically to ensure that they will function when a ground fault occurs. All GFCIs contain user-operable test circuits to permit this testing to be performed without additional equipment.

In the case of receptacle-type GFCIs, testing is simplified because each receptacle can be tested independently without affecting other receptacles connected to the same branch circuit. They should be tested each time a receptacle is used. In contrast, caution is needed when circuit breaker GFCIs are being tested because their actuation will result in a loss of power to all receptacles relying on the single GFCI for protection.

The interval between tests depends primarily on the environment. In clean, dry environments, monthly or quarterly testing is sufficient, but where damp and corrosive atmospheres exist, more frequent testing should be undertaken. Prudence suggests that, under such conditions, permanently installed receptacle-type GFCIs should be tested each time they are used.

6 Essential electrical systems

6.1 General

Essential electrical systems shall meet the requirements specified in Section 24 of the Canadian Electrical Code, Part I.

Notes:

- (1) The requirements of this Clause apply to separate electrical systems that are considered essential for life and fire safety as specified in Article 3.2.7.9 of the National Building Code of Canada, for effective and safe patient care, and for the effective operation of the health care facility during an interruption of the normal electrical supply for any reason.
- (2) This Clause (along with Clauses 6.3 and 6.4) does not preclude transferring to the emergency supply at one time the loads of the vital branch (see Table 8) or any of the other loads that are part of the essential electrical system. However, this option can lessen the assurance that the vital branch of the system will have power when required, and therefore should be chosen only after a study of the system has shown that power will be available when required.

6.2 Installation

Installation shall be undertaken in accordance with the requirements specified in Section 24 of the Canadian Electrical Code, Part I.

6.3 Transfer

6.3.1 Vital and delayed vital branches

The vital and delayed vital branches shall be connected to the emergency power supply by one or more transfer switches that are arranged to allow the vital and delayed vital branch loads to be transferred and retransferred automatically.

6.3.2 Conditional branch

The conditional branch shall be manually or automatically connected to the emergency power supply.

6.4 Essential areas and functions

Except as specified in Clause 6.6, the vital, delayed vital, and conditional branches shall partially or totally supply voltage to selected lighting and receptacles and permanently wired electrical apparatus serving the areas or functions, or both, specified in Table 8.

Note: Table 8 identifies a minimum set of areas and functions that, when present in a health care facility, should be classified in accordance with the Table for planning an essential electrical system. It is not intended to exclude from an essential electrical system areas or functions that have not been identified, which should be placed in the vital, delayed vital, or conditional categories so as to be consistent with the classifications already in the Table.

6.5 Maintenance or repair

If maintenance or repair of a transfer switch or switches is necessary, power to the areas identified with an asterisk in Table 8 shall be ensured by

- (a) the presence of at least one receptacle and one lighting fixture connected upstream of the transfer switch(es); or
- (b) a bypass system around the transfer switch(es).

Note: Work on a transfer switch usually disrupts both normal power and emergency power to most rooms. It is the intent of this Clause to have at least one receptacle and one lighting fixture in each room that will not be affected when this occurs.

6.6 Battery-operated emergency lighting

Battery-operated emergency lighting meeting the requirements specified in CSA C22.2 No. 141 shall be provided in

- (a) operating rooms;
- (b) delivery rooms;
- (c) angiographic laboratories;
- (d) cardiac catheterization laboratories;

- (e) emergency generator rooms; and
- (f) by the automatic transfer switch and manual bypass switch, if installed in a room other than a generator room.

6.7 Emergency electrical power supply system

6.7.1 Working space

A minimum clearance of 1 m shall be maintained on all sides of the generator set within the enclosure to permit servicing in all types of weather.

6.7.2 Temperature

The prime mover (engine) shall be equipped with an automatically controlled heater to keep the jacket water temperature at a minimum of 40 °C.

6.7.3 Fuel system

A fuel supply sufficient for operating the engine under full load for at least 24 h shall be maintained on-site at all times. Provision shall be made for automatic refilling of the day tank(s) from a fuel supply stored elsewhere on-site.

6.8 Normal supply and performance

Note: The requirements of this Clause

- (a) apply to electrical installations that
 - (i) are needed to transmit power from a supply utility to a health care facility; and
 - (ii) can be part of a health care facility itself or of the utility installations supplying the health care facility; and
- (b) are intended to provide minimum criteria for the normal power supply of a health care facility, with the objective that the health care facility's power supply will be as reliable as that of the utility providing the supply.

6.8.1 General

6.8.1.1 Utility feeders

When technically and economically viable, an agreement with a supply utility for a normal high-voltage power supply shall provide for

- (a) the selective use of two or more utility feeders, each capable of supplying the entire health care facility load; and
- (b) an automatic transfer arrangement to effect the selection of another feeder within 10 s of an unsatisfactory condition in the feeder in use.

Note: Utility feeders assigned for use in accordance with this Clause should be chosen to achieve the greatest possible degree of independence in the utility system.

6.8.1.2 Transformer feeder arrangement

The transformer substations shall be fed with two high-voltage feeders when

- (a) required by the regulatory authority; and
- (b) a high voltage is used in the distribution system throughout a health care facility complex.

6.8.1.3 Transformer redundancy

If the normal supply primary voltage is higher than the utilization voltage(s) in a health care facility, the capacity of the necessary step-down transformers shall be achieved by two or more transformers arranged such that on failure of any one of them, the total remaining capacity will be not less than 50% of the normal load to be supplied or 100% of the vital load, except when the agreement with the utility providing the normal supply includes a satisfactory assurance that the utility will be able to provide, within not more than 24 h, an emergency transformer with a capacity equivalent to at least 50% of the normal health care facility load or 100% of the vital load.

Note: This Clause also applies to installations such as three single-phase transformers, provided that, on failure of any one of them, the total remaining capacity will be not less than 50% of the normal load, and be capable of carrying all vital and delayed vital loads.

6.8.1.4 Grounding

Grounding of electrical installations shall meet the requirements specified in the Canadian Electrical Code, Part I.

6.8.1.5 Location

All electrical equipment composed of essential electrical systems described in Clause 6 shall be located to minimize danger from flooding.

6.8.1.6 Generator sets located on the premises

When the normal supply consists of generators located on the health care facility premises, it shall comprise, when practicable, three or more generator sets of such capacity and so arranged that the normal load of the health care facility can be supplied by any two of the generator sets.

6.8.2 Use of generator sets for peak shaving

6.8.2.1

Use of generator sets for peak shaving shall be acceptable provided that

- (a) they comply with the requirements of the applicable regulatory authority; and
- (b) all non-essential loads are instantly dropped when utility power is lost.

6.8.2.2

When the generator set or sets of the essential electrical system are used for peak shaving, only the conditional load should be considered, unless the generator(s) are sized to carry all loads (vital, delayed vital, and conditional).

6.9 Emergency supply and performance

Note: This Clause applies to emergency supplies for health care facility essential electrical systems provided by emergency generators.

6.9.1 General

6.9.1.1 Components

The emergency supply shall be a generator set or sets driven by a prime mover and located on the health care facility's premises.

6.9.1.2 Prime mover operation

The prime mover of the generator set or sets specified in Clause 6.9.1.1 shall be capable of operating independently of fuel and water supplies from public utilities.

Note: Examples of features used to achieve the purpose of this Clause include the following:

- (a) direct air cooling of the prime mover;
- (b) cooling of an engine by a closed-circuit jacket water system that includes an engine-mounted or remote radiator; and
- (c) operation of prime movers from a fuel source that can be stored on the premises (e.g., diesel fuel, propane gas).

6.9.1.3 Generator set control and performance requirements

An emergency supply generator set shall meet the control and performance requirements specified in Clauses 6.9.3 and 6.10.

6.9.1.4 Transformer feeder arrangement

When a high voltage is used in the distribution system for emergency power throughout the health care facility complex, the transformer substations shall be fed with two high-voltage feeders. If a high-voltage distribution system is chosen, the capacity of the step-down transformers shall be selected so that if one transformer bank fails, the total remaining capacity is not less than 100% of the essential load to be supplied.

6.9.2 Use of emergency supply

6.9.2.1 Generator set redundancy

When an emergency supply for a health care facility comprises two or more generator sets, and one is inoperative, automatic or manual means shall be provided to enable all of the vital loads to be served by the remaining generator set(s).

6.9.2.2 Distribution

It shall be possible to make emergency power available to the loads to be served through low-voltage or high-voltage supply systems, depending on which systems are best under the circumstances.

6.9.2.3 High-voltage switching

When high-voltage distribution systems are used (see Clause 6.9.2.2), the use of suitable high-voltage switching equipment shall be permitted where reference is made in this Standard to transfer switches.

6.9.2.4 Low-voltage distribution systems

In a low-voltage distribution system, the emergency supply shall be automatically connected to the essential electrical system by transfer switches, with voltage sensing at the transfer switch feeding point in accordance with the following requirements:

- (a) failure of the normal supply at a transfer switch feeding point shall automatically initiate the start-up of the generator set(s); and
- (b) transfer of the emergency supply to the essential electrical system shall be automatic, with automatic transfer back to the normal supply on return of a stabilized normal supply voltage.

Note: When microprocessor controls requiring a pre-transfer signal from the transfer switch are used, the installer or designer should ensure that the system and its components have the ability to accommodate such microprocessor controls.

6.9.2.5 High-voltage distribution systems

In a high-voltage system, the emergency supply shall be automatically connected to the essential electrical system by suitable switching equipment, with voltage sensing and control sequences on the line side of the switching equipment in order to

- (a) automatically initiate start-up of generator set(s) on failure of the normal supply;
- (b) automatically trip out and reclose downstream switching equipment to the vital, delayed, and conditional branches in proportion to the amount of emergency power available; and
- (c) following the return of a stabilized normal supply voltage,
 - (i) initiate a shutdown of generator set(s); and
 - (ii) allow for transfer back to the normal supply.

6.9.2.6 Bypass

The essential electrical system shall use a bypass to minimize discontinuity of supply to the vital and delayed vital branches under the following conditions:

- (a) failure of an automatic transfer switch to transfer, when required, from a normal supply to an emergency supply; and
- (b) during maintenance, when there exists a need to bypass a transfer switch to a vital or delayed vital branch that will cause a supply interruption of 10 s or less.

6.9.3 Control sequence

Note: This Clause deals with the automatic and manual control of an essential electrical system, including the starting of a generator set and the actuation of automatic transfer switches to connect a load to the emergency supply and to reconnect it to the normal supply.

The sequence of events in the automatic control of an essential electrical system shall be as follows:

(a) When the normal supply at the transfer switch on one or more phases has been interrupted or is at a voltage less than 90% of the nominal system voltage for 2 s, the generator set shall be started.

Note: The 2 s waiting period is specified to avoid the unnecessary start-up of a generator in installations where the normal supply is frequently restored within 2 s after it is interrupted. This Standard requires that the generator set be ready to accept load within 10 s of the loss of normal power. In some circumstances it is necessary to reduce the waiting period to ensure that the generator is ready within 10 s.

- (b) When the voltage and frequency of the emergency supply have reached the prescribed levels on all phases at the transfer switch, and provided that the voltage and frequency of the normal supply have not been restored to nominal levels, a transfer switch or switches shall operate to connect to the emergency supply all the vital loads and any other loads that have been arranged for transfer at the same time.
- (c) Following the transfer of vital loads, the transfer switch(es) controlling the delayed vital loads shall operate as soon as practicable, but not later than 2 min after the loss of normal power, to ensure that prescribed voltage drops due to inrush load conditions are not exceeded.
- (d) On restoration of the normal supply and after voltage and frequency have been maintained at nominal levels on all phases of the transfer switch for an adjustable period of 1 to 30 min, the automatic transfer switches shall operate to transfer the loads back to the normal supply, except in the case of failure of an emergency supply, when the transfer shall occur without delay.

 Note: See Annex I for a discussion of the precautions needed for the transfer or retransfer of certain loads.
- (e) The transfer of the conditional branch of an essential electrical system to the emergency supply by manual transfer switches shall be performed at a time dictated by the prevailing need, and retransfer to the normal supply shall be at the discretion of those responsible for the emergency supply.
- (f) After the transfer of loads back to the normal supply, the manual or automatic shutdown of the generator set shall be delayed for 5 min in order to stabilize the operating temperature under no-load conditions.

6.10 Emergency generating plants

Note: This Clause specifies detailed requirements for generating plants designed to provide an emergency supply for the essential electrical system of a health care facility for at least 24 h, and includes requirements to ensure reasonable consideration of their reliability and effect on the health care facility environments.

6.10.1 Frequency

The prime mover shall be equipped with an isochronous governor that will ensure that

- (a) the generator frequency
 - (i) does not fall by more than 10% of rated value on application of the maximum load that can be applied at one time in accordance with the control sequence for the essential electrical system (see Clause 6.9.3); and
 - (ii) returns to a steady state within 3 s;
- (b) the steady state generator frequency between no-load and full load is isochronous, i.e., 0; and
- (c) the variation in generator frequency at any constant load does not exceed 0.25% from the mean.

6.10.2 Generator set location

The following generator set location requirements shall apply:

- (a) only generator sets and auxiliary equipment such as disconnecting means and engine and generator control panels shall be located in a generator room;
- (b) controls and distribution equipment other than those described in Item (a) shall be located in a room separate from the prime mover and generator;
- (c) emergency electrical power supply plants shall be located within one storey of grade; and
- (d) notwithstanding Item (c), when an emergency supply comprises more than one generating set and the facility has at least two elevator banks, with each elevator bank supplied from a separate generator set, the generator sets shall be permitted to be located within one level of any floor accessed by the elevators.

6.10.3 Generators, exciters, and voltage regulators

A generator, in association with its prime mover, exciter, and automatic voltage regulator, shall be capable of providing stable voltage and frequency within \pm 1% of the rated values within 10 s of loss of normal power.

30 September 2004

6.10.4 Testing and commissioning of new and relocated auxiliary essential power generating sets

A health care facility administrator shall be present at all testing and commissioning of new and relocated auxiliary essential generator sets.

6.10.5 Voltage and frequency

Voltage and frequency variations during load switching shall be measured and recorded as follows:

- (a) install continuous strip chart recorders to record frequency and voltage variations during load-switching procedures;
- (b) delay each load change until steady state conditions exist; and
- (c) switch increments to include typical loads such as
 - (i) no load to full load to no load:
 - (ii) no load to 70% load to no load;
 - (iii) 40% load to 60% load to no load; and
 - (iv) 60% load to 80% load to no load.

6.10.6 Oil analysis

After 24 h of installed generator, running time, a sample of the engine oil shall be extracted and analyzed in order to detect any copper, bronze, water, glycol, or other contaminants. The test results should be saved for comparison with future routine scheduled analyses.

6.11 Transfer switches

6.11.1 Control device

The voltage- and frequency-sensing devices and program control devices (e.g., time delay) that are associated with automatic load-switching means shall be arranged so as to initiate the start-up of an emergency supply engine generator set and the transfer of loads in accordance with the sequence specified in Clause 6.9.3.

6.11.2 Bypass system

The following bypass system requirements shall apply:

- (a) a bypass system shall be provided for maintenance or repair of the transfer switch (see Clause 6.9.2.6); and
- (b) a manual bypass shall be installed on both the normal and the emergency side of the transfer switch.

6.11.3 Automatic transfer switch requirements

The use of closed-transition transfer switches shall be acceptable, provided that they meet all applicable regulatory requirements or comply with the requirements of CSA C22.2 No. 178.

6.11.4 Manual (non-automatic) transfer switch

A manual (non-automatic) transfer switch shall comply with the requirements specified in Rule 24-304 of the Canadian Electrical Code, Part I.

6.12 Operation and maintenance program

6.12.1 Tools

Special tools and gauges required for routine maintenance shall be kept in a secure location or locations that are accessible to the operating and maintenance staff when required.

Note: A suitable location might be an area where an engine-generator set is installed.

6.12.2 Operational tests

6.12.2.1 Weekly tests

The emergency electrical power supply system shall be completely tested, in accordance with the inspection test and maintenance requirements of CAN/CSA-C282 (Tables 2 and 3), at least once a week.

6.12.2.2 Other tests

Semi-annual, annual, and five-year tests shall be conducted as specified in Tables 4 to 6 of CAN/CSA-C282.

6.12.3 System operational test

6.12.3.1 General

The emergency electrical power system shall be maintained as specified in the manufacturer's operations and maintenance manual.

6.12.3.2 Frequency of procedures

The following requirements relating to frequency of procedures shall apply:

- (a) except as permitted in Item (b), the frequency of maintenance procedures shall be as specified in the manufacturer's operations and maintenance manual; and
- (b) the frequency of maintenance procedures identified in the manufacturer's manual may be revised from time to time, provided that
 - (i) the decision to revise is acceptable to those who developed the manual; and
 - (ii) the reason for the revision is documented in the manual or some other permanent record.

6.12.3.3 Records

A permanent log of maintenance work shall be maintained in accordance with the manufacturer's operations and maintenance manual and shall include at least the following:

- (a) the date on which the work was done;
- (b) the name of the person who performed the work;
- (c) an entry noting any unsatisfactory condition discovered and the steps taken to correct it;
- (d) an entry noting any parts replaced; and
- (e) an entry verifying that switches and controls deactivated for safety reasons during maintenance have been restored to their intended operating condition.

6.12.3.4 Safety

The following safety requirements shall apply:

- (a) if any maintenance procedure involves a risk of injury from moving parts or energized electrical parts, steps shall be taken before the work is begun to deactivate all automatic and manual control devices for the parts with which contact will be made; and
- (b) signs shall be installed on the equipment at the entrance to the enclosure, stating that the equipment is automatically controlled and can start at any time.

Table 1 Risk classes and applied part types associated with patient procedures

(See Clause 4.3.2.2.)

Patient procedure (see Clause 4.1.5)	CAN/CSA-C22.2 No. 125 risk class	CAN/CSA-C22.2 No. 601.1 applied part type		
Cardiac contact	3	CF		
Body contact	2	B, BF, or CF		
Casual contact	1 or 2G	В		

Note: See Clause 3 for risk class definitions.

Table 2 Allowable values of continuous leakage and patient auxiliary currents, mA*

(See Clause 4.3.2.3 and Figure 3.)

	Type B		Type BF		Type CF	
Current	Normal condition	Single- fault condition	Normal condition	Single- fault condition	Normal condition	Single- fault condition
Earth leakage current (general)	0.5	1†	0.5	1†	0.5	1†
Earth leakage current for equipment‡§	2.5	5†	2.5	5†	2.5	5†
Earth leakage current for equipment**	5	10†	5	10†	5	10†
Enclosure leakage current	0.1	0.5	0.1	0.5	0.1	0.5
Patient leakage current	0.1	0.5	0.1	0.5	0.01	0.05
Patient leakage current (mains voltage on the signal input part or signal output part)	_	5	_	_	_	_
Patient leakage current (mains voltage on the applied part)	_	_	_	5	_	0.05
Patient auxiliary current						
dc ac	0.01 0.1	0.05 0.5	0.01 0.1	0.05 0.5	0.01 0.01	0.05 0.05

^{*}Adapted from CAN/CSA-C22.2 No. 601.1.

‡Equipment that has no protectively earthed accessible parts, no means for protective earthing of other equipment, and complies with this Table's requirements for the enclosure leakage and patient leakage currents (if applicable) (e.g., some computers with a screened mains part.)

§Mobile X-ray equipment and mobile equipment with mineral insulation.

Examples of such equipment include

- (a) major components of an X-ray installation, e.g., an X-ray generator or examination or treatment table;
- (b) equipment with mineral-insulated heaters; and
- (c) equipment with an earth leakage current greater than that specified in this Table for earth leakage current (general) because of compliance with requirements for radio interference suppression.

[†]The only single-fault condition for the earth leakage current is the interruption of one supply conductor at a time.

^{**}Equipment to be permanently installed with a protective earth conductor that is electrically connected in a way that ensures that the connection can be loosened only with the aid of a tool, and which is fastened or otherwise mechanically secured at a specific location in a way that ensures that it can be moved only with the aid of a tool.

Table 3 Risk current test limits*

(See Clause 4.3.2.3.)

Risk class	Part being tested	Part regarded as	Risk current, μA rms
1	Chassis	Source	500
2G	Chassis	Source	100
	Patient-applied part	Source	100
2	Chassis	Source	100
	Patient-applied part	Source or sink	100
3	Chassis	Source	100
	Patient-applied part	Source or sink	100

^{*}Adapted from CSA C22.2 No. 125.

Note: See Clause 3 for risk class definitions.

Table 4
Leakage requirements for the safety of medical electrical systems
(See Clauses 4.3.3 and 4.3.6.5.)

Electrical systemNormal condition
(ground intact), μA
(Type B and BF applied parts)Single-fault condition
(loss of ground), μΑMedical electrical equipment: maximum allowable
enclosure leakage current from or between parts of the
equipment system in the patient environment100500Non-medical electrical equipment: maximum
allowable enclosure leakage current limits100500

Table 5 Approximate spacing for interference-free working with unfiltered equipment*

(See Clause 4.3.7.4.)

	Distance, m					
Source of interference	EMG sensitivity 20 μV/cm	EEG sensitivity 100 μv/cm	ECG sensitivity 1000 μv/cm			
Short-wave diathermy	30	30	18			
Electrosurgical units	9	5	3			
Linear accelerator† (impulse generator)	30	21	15			
Low-frequency inductive loop (paging) distance outside loop‡	6	0	0			
Elevator motor rooms (controls unsuppressed)	3	9	6			
Power transformers (≥ 100 kVA)	9	9	9			
Small transformers (< 100 kVA)	2	2	2			
Commutator motors (unsuppressed)	6	5	3			
Relays and other switching devices (unsuppressed)	6	5	2			
Fluorescent and high-intensity discharge lamps	5	3	3			
Incandescent lamps (ac supply)	3	2	2			
Walkie-talkies (5 W)	2	2	2			
Cellphone and personal communication systems	1	1	1			

^{*}Adapted from Ministry of Health (United Kingdom), Abatement of Electrical Interference.

Note: The specified distances are for free space. They can be reduced when there are one or more barriers between the source of the interference and the susceptible equipment.

[†]Interference can occur when the generator is installed outside the radiation screening. When it is installed within the radiation screening, interference is not to be expected.

[‡]Although interference is possible within a low-frequency inductive loop with ECG and EEG apparatus, it is much more likely with EMG apparatus.

Table 6 **Summary of testing for building electrical systems** (See Clause 5.)

Test	Clause(s)	Grounded system?	Isolated system?	Testing at completion of new construction or major renovations?	Testing at times other than completion of new construction or major renovations?
Conductor insulation integrity test	5.3	Yes	No	Yes	No
Voltage drop test for grounded systems	5.4.3	Yes	No	Yes	No
Branch circuit breakers: mechanical operation	5.5	Yes	Yes	Yes	Annually
Receptacles Retentive force	5.6.1.3/ 5.6.6.1	Yes	Yes	Yes	When receptacles are replaced. At least every two years for basic care areas and at least every year for intermediate and critical care areas.
Polarity	5.6.2.(a)/ 5.6.6.2	Yes	Yes	Yes	When receptacles are replaced
Voltage difference between ground points	5.9	Yes	Yes	Yes	Every five years
Ground return path voltage rise for grounded systems	5.10	Yes	No	Yes	When receptacles are replaced
Impedance to ground Single-phase isolated system	5.11.2.1/ 5.11.2.3	No	Yes	Yes	Annually (for systems without line isolation monitors and for multiple systems with line isolation monitors)
Three-phase isolated system	5.11.2.2/ 5.11.2.3	No	Yes	Yes	Annually (for systems without line isolation monitors)

36 September 2004 (See Clause 5.6.1.1.)

	Housekeeping		Electric bed (if applicable)	Patient care			
	No. of receptacles per room	Type of branch circuits	No. of receptacles per bed	No. of branch circuits per bed*	No. of duplex receptacles per patient care location	No. of branch circuits per patient care location*		
Basic care area	1 duplex	Shared	1	0.5	1	0.5		
Intermediate care areas	1 duplex	Shared	1	0.5	3	1.5		
Critical care areas (intensive care units, cardiac care units, and intensive care nurseries)	As required	Shared	1	0.5	8	4		
Operating rooms	_	_	_	_	14 in total, located as follows: 6 on the walls and 8 on ceiling or floor-mounted service units, at a minimum of 2 locations	7		

^{*0.5} means one circuit shared by two beds or patient care locations. 1.5 means one dedicated circuit plus one circuit shared by two beds or patient care locations.

Note: Consideration should be given to supplying some receptacles from the normal system and some from the emergency system so that a failure of one system will not deprive an entire area of electrical power.

September 2004

Table 8 Classification of loads and branches

(See Clauses 6.1, 6.4, and 6.5.)

		Essential system loads			Essential system branches		
Item	Area and/or function	Lighting	Receptacles	Electrical apparatus permanently wired	Vital (10 s)	Delayed vital (2 min)	Conditional
Public	safety						
1	Directional signs and lights	Total			Χ		
2	Stairwells and ramps	Selected			Χ		
3	Corridors	Selected			Χ		
4	Fire alarm system			X	Χ		
5	Sprinkler alarm system			X	Χ		
6	Automatic fire detection system			X	Χ		
7	Fire pump motor (if installed and electrically operated)			Х		Χ	
8	Smoke control fans (if provided)				Χ		
Patient	t care						
9	Surgical suite	Total*	Total	X	Χ		
9(a)	Surgical suite — ventilation only			X		Χ	
10	Labour and delivery suite	Total*	Total	X	Χ		
10(a)	Labour and delivery suite — ventilation only			Х		Х	
11	Post-operative recovery rooms	Total*	Total*	X	Χ		
11(a)	Post-operative recovery rooms — ventilation only			Х			X
12	Obstetrical recovery rooms	Total*	Total*	X	Χ		
12(a)	Obstetrical recovery rooms — ventilation only			Х			X
13	Infant nurseries (newborn, pediatric, and premature)	Total*	Total*	Х	Χ		
13(a)	Infant nurseries — ventilation only			X		X	
14	Emergency department treatment rooms	Total*	Total*	Х	Х		

Table 8 (Continued)

		Essential system loads			Essential system branches		
Item	Area and/or function	Lighting	Receptacles	Electrical apparatus permanently wired	Vital (10 s)	Delayed vital (2 min)	Conditional
14(a)	Emergency department treatment	Lighting	Receptacies	X	(10 3)	(2 11111)	X
(u)	rooms — ventilation only			Λ			~
15	Intensive care unit	Total*	Total*	Χ	Χ		
15(a)	Intensive care unit — ventilation only			Χ			Χ
16	Coronary care unit	Total*	Total*	Χ	Χ		
16(a)	Coronary care unit — ventilation only			X			X
17	Hyperbaric facilities	Total	Total	Χ	Χ		
17(a)	Hyperbaric facilities — ventilation only			X			Χ
18	Hyperbaric compressors			X			Χ
19	Ward rooms containing general care beds		One/bed-wall		Χ		
20	Psychiatric patient bed areas	Selected	One/bed-wall		Χ		
21	Medication preparation areas	Selected			Χ		
22	Nurses' station work areas	Selected	One		Χ		
23	Ward treatment rooms	Selected	One		Χ		
24	Nurses' call systems			Χ	Χ		
25	Telephone switchboard room	Selected		X	Χ		
26	Blood bank typing and	Selected	Selected		Χ		
	cross-matching areas						
27	Blood bank refrigerators			Χ		Χ	
28	Intercom system			Χ	Χ		
29	Radiology						
	X-ray machine	Selected	One			Χ	
	X-ray film developer	Selected	One			X	
30	Paging systems						
	Public address			X	X		
- 4	Doctors			X	Χ	.,	
31	Blood, bone, and tissue banks; storage			Х		Χ	
22	of biological and perishable drugs	Č. l l	0 //		V		
32	Emergency department wards	Selected	One/bed	V	Χ		V
32(a)	Emergency department wards — ventilation only			X			X

Table 8 (Continued)

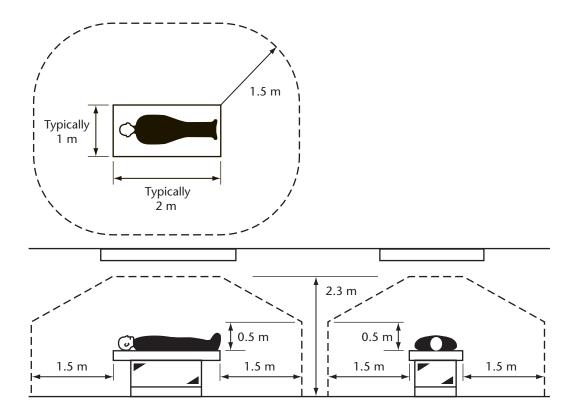
	Area and/or function	Essential syst	em loads	Essential system branches			
Item		Lighting	Receptacles	Electrical apparatus permanently wired	Vital (10 s)	Delayed vital (2 min)	Conditional
33	Laboratories	Selected	One in each		Х		
34	Master alarm panel(s) for all medical gases and vacuum			Х	Х		
34(a)	Local emergency alarm panel(s) for all medical gases and vacuum			Х	Х		
Specia	l procedures rooms						
35	Cardiac catheterization labs	Total*	Selected		Χ		
35(a)	Cardiac catheterization labs — ventilation only			Х			Х
35(b)	Cardiac catheterization labs — X-ray units			Х			Х
36	Human physiology labs	Selected	Selected	Χ	Χ		
37	Angiographic labs	Total*		X	Χ		
37(a)	Angiographic labs — X-ray units			X			X
38	Dialysis units	Selected	Selected	Χ	Χ		
Supply	system						
39	Pharmacy dispensing areas	Selected	Selected		Х		
40	Fume hoods			Χ		X	
Admin	istrative system						
41	Medical records storage	Selected					X
House	keeping system						
42	Refrigeration equipment			X			X

Table 8 (Concluded)

		Essential system loads				Essential system branches		
Item	Area and/or function	Lighting	Receptacles	Electrical apparatus permanently wired	Vital (10 s)	Delayed vital (2 min)	Conditional	
Utilitie	es system							
43	Elevator (selective connection — one from each elevator bank)			Machine room control		Χ		
44	Cab lighting				Χ			
45	Elevator public address system			X	Χ			
46	Heating plant (one unit and auxiliaries)	Selected					Χ	
46(a)	Heating plant — controls			Fan motor,		Χ		
				temperature, fuel pump, hot water				
46(b)	Heating plant — combustion air only			X		X		
47	Sewage ejector pump (if installed)			X		X		
48	Sump pump (if installed)			X		X		
49	Emergency generator room	Selected	Selected	^	Х	^		
49(a)	Emergency generator room — ventilation; battery charger or air compressor for starting engine	Science	Science	X	X			
50	Emergency generator derangement signals			X	Χ			
51	Central medical air system pumps			X		Χ		
52	Medical gas system manifolds and controls for pressure gases			Χ		X		
53	Central medical vacuum system pumps			X	Χ			
54	Electrical and mechanical equipment rooms	Selected	Selected			Χ		
55	Essential heating						X	
56	Electrical — mechanical maintenance	Selected	Selected				X	
57	workshops Primary air system for building with sealed windows						Х	

Notes:

- (1) The need for smoke control fans (Item 7) is covered in the National Building Code of Canada.
- (2) Emergency lighting (Items 1 to 3) is covered in the National Building Code of Canada.
- (3) Non-essential loads are not considered in this Table.



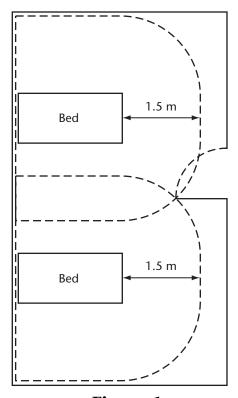
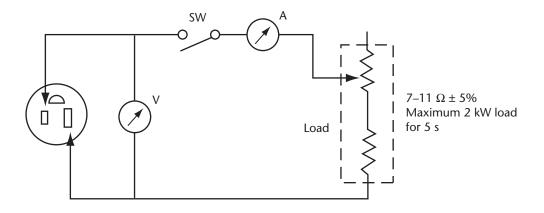


Figure 1
Patient care environment

(See the definition of "patient care environment" in Clause 3.)

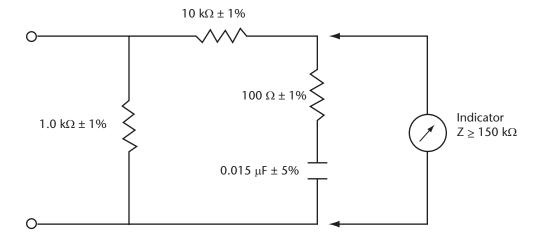


Notes:

- (1) Ammeter "A" shall
 - (a) indicate the applied load to within \pm 5%; and
 - (b) have a minimum resolution of 0.5 A.
- (2) Voltmeter "V" shall
 - (a) have an input impedance of at least 150 k Ω ;
 - (b) indicate the applied potential to within \pm 2%; and
 - (c) have a minimum resolution of 0.1 V.
- **(3)** If the voltmeter test leads are long, the readings shall be corrected for pickup (zero reading) when connected together.

Figure 2 Voltage drop test for grounded systems

(See Clauses 5.2.2 and 5.4.3.1.)

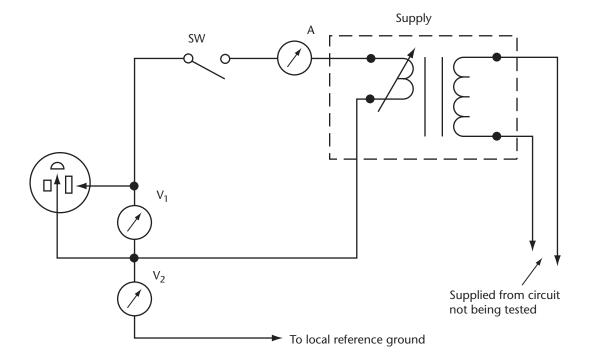


Notes:

- **(1)** The standard load and measuring device shall consist of the following:
 - (a) a standard test load or measuring impedance that is equivalent to the circuit illustrated here; and
 - (b) an indicator that
 - (i) has an input impedance of at least 150 k Ω ;
 - (ii) indicates the applied potential to within \pm 5% of the potential corresponding to the leakage current limits specified in Table 2 over the frequency range of dc to 1 kHz (the circuit will reduce the effects of frequency components exceeding 1 kHz); and
 - (iii) has a minimum resolution of 0.5 mV.
- **(2)** The components of the standard load and measuring device were chosen to take account of the frequency-dependent electrical sensitivity of a patient.

Figure 3 **Standard load and measuring device**

(See Clauses 5.9.2, 5.11.2.1, and 5.11.2.2.)



Notes:

- (1) The low-voltage supply secondary shall be nominally 5 V open circuit.
- (2) Ammeter "A" shall
 - (a) indicate the applied load to within \pm 5%; and
 - (b) have a minimum resolution of 0.5 A.
- (3) Voltmeters "V1" and "V2" shall
 - (a) have an input impedance of at least 150 k Ω ;
 - (b) indicate the applied potential to within \pm 2%; and
 - (c) have a minimum resolution of 0.1 V.
- **(4)** If the voltmeter test leads are long, the readings shall be corrected for pickup (zero reading) when connected together.

Figure 4 Ground return path voltage rise for grounded systems

(See Clauses 5.2.2 and 5.10.2.1.1.)

Annex A (informative)

Electric shock

Note: This Annex is not a mandatory part of this Standard.

A.1 Electric shock

Electric shock is caused by an electric current flowing through part of the human body. To enable such current to flow, the following three conditions need to be satisfied simultaneously:

- (a) one part of the body is in contact with a conductive surface (point 1 in Figure A.1).
- (b) a different part of the body is in contact with a second conductive surface (point 2 in Figure A.1); and
- (c) a voltage source (point 3 in Figure A.1) that can drive current through the body between points 1 and 2 is present.

Usually, several independent and separable factors need to combine simultaneously to satisfy these three conditions.

A.2 General factors to consider

A.2.1

When evaluating an electric shock hazard, one should consider the probability of the following:

- (a) that a unit of line-powered equipment will be in contact with a person. In this regard, it is important to evaluate
 - (i) the impedance of the contact (is it through isolation or insulation?); and
 - (ii) the nature of the contact (is it casual or intended?);
- (b) that the equipment will be damaged or malfunction in a way that causes a voltage be applied to the surface in contact with the person; and
- (c) that the person will make good contact with a second exposed electrical conductive surface at a time when it has become grounded.

A.2.2

The chance of a person actually receiving an electric shock is directly proportional to the probability that the three events described in Clause A.2.1 will occur simultaneously. If the probability of occurrence of any one event is close to zero, the risk of receiving an electric shock will also be close to zero. The three links in the causal chain need to be intact before a shock can be received. If any one link can be made extremely weak, either by equipment design or operating procedure, the chance of receiving an electric shock will be very slight.

A.2.3

Minimizing the occurrence of one event will achieve one layer of protection, and minimizing the occurrence of a second event will achieve a second layer of protection. However, extending the process to minimize the occurrence of all events can lead to overdesign and less-than-cost-effective use of available resources.

A.3 Shock prevention

A.3.1 By insulation and enclosure

The following actions related to insulation and enclosure can prevent shock:

(a) non-insulated energized conductors should be placed in suitable enclosures, or be covered completely with an insulating material appropriate for the voltage and environment; and

- (b) persons should be insulated from ground as much as possible
 - (i) by avoiding, wherever possible, the attachment of grounded leads to a person; and
 - (ii) by avoiding grounding of conductive items that cannot accidentally become energized (e.g., curtain rails, window and door frames, and metal cabinets).

Note: Item (b) should not be taken as a directive to create an insulated environment, but simply as a recommendation to avoid intentional grounding of otherwise "dead" metal surfaces.

A.3.2 By grounding

The following actions related to grounding can prevent shock:

- (a) a low-impedance path to ground for fault currents should be provided
 - (i) to minimize that portion of the fault current that might flow to ground through a person;
 - (ii) to operate overcurrent devices intended to reduce the possibility of damage and fire; and
 - (iii) to provide a path for leakage currents; and
- (b) the line cord of each item of line-powered cord-connected electrical equipment that is not double insulated and is in a patient care environment should contain a bonding conductor that will carry leakage and fault currents directly to ground.

A.3.3 By equipment design

The following actions related to equipment design can prevent shock:

- (a) the use of medical electrical equipment not designed and manufactured in compliance with CAN/CSA-C22.2 No. 114 or CSA C22.2 No. 125 should be prohibited; and
- (b) the use of other electrical equipment not designed and manufactured in compliance with CAN/CSA-C22.2 No. 0 should be prohibited.

A.3.4 By fast disconnection from the supply

The use of ground fault circuit interrupters can prevent shock in locations where an interruption of the electric supply can be tolerated.

Note: Although a current of 5 mA passing through a human body for even a few seconds can cause severe shock and tissue damage, if the current can be interrupted within 20 ms, at most only minor tissue damage will result.

A.3.5 By isolation of the supply

To prevent shock, the use of an isolated power system may be considered when procedures employing medical electrical equipment with body or cardiac contact are performed and interruption of the electric supply cannot be tolerated.

A.3.6 By attention to user practices

The following actions related to user practices can prevent shock:

- (a) having a good staff education program in place, and including in that program a requirement that all damage to equipment, no matter how small, must be reported, even if the equipment appears to remain functional:
- (b) organizing procedures in such a way that a minimum of line-powered electrical equipment is within reach of patients;
- (c) performing procedures in locations where are minimal amounts of grounded metal (e.g., door and window frames, piping) are within reach of patients;
- (d) using equipment with small exposed conducting surfaces; and
- (e) regulating testing equipment grounding and bonding in accordance with this Standard and the manufacturer's manual.

A.4 References

CSA (Canadian Standards Association)

CAN/CSA-C22.2 No. 0-M91 (R2001)

General Requirements — Canadian Electrical Code, Part II

CAN/CSA-C22.2 No. 114-M90 (R2001)

Diagnostic Imaging and Radiation Therapy Equipment

C22.2 No. 125-M1984 (R1999) Electromedical Equipment

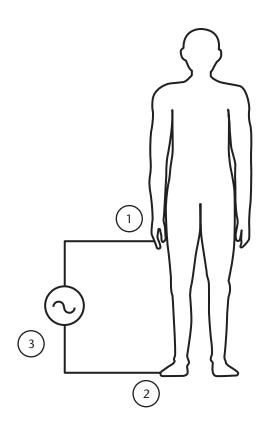


Figure A.1 Conditions resulting in electric shock (See Clause A.1.)

Annex B (informative) Risk management

Note: This Annex is not a mandatory part of this Standard.

B.1 A philosophy for the development of safety Standards

Absolute safety is unattainable. Moreover, it is clear that not all Standards-related measures that would increase safety can be achieved without prohibitive cost, either in terms of the cost of Standards development or the cost of Standards implementation. Thus, a significant task of a Standards development organization is to select wisely those changes in design or behaviour that are likely to be most cost-effective in increasing safety. CSA has attempted to select Standards development projects on this basis. However, at the Technical Committee level, decisions on specific requirements are often argued for on the basis that they will increase safety, without adequate consideration of the associated cost.

This Annex describes a philosophy which will ensure a more cost-effective result if adopted by the persons responsible for Standards development.

Since the purpose of a safety Standard is to reduce the risk of harm resulting from identified hazards, it can be helpful to consider the concept of risk of harm in more detail. A hazard is defined by ISO 14971 as a "potential source of harm". Harm is defined as "physical injury or damage to the health of people, or damage to property or the environment". Obviously, harm is a broad concept. A particularly interesting model used by the National Council on Bioethics in Human Research (NCBHR) separates the probability of a harmful event from the severity of that event (see Miller [1993], 33–36). The risk of harm associated with a hazard is a function of those two variables. Thus, risk can range from negligible probability of negligible harm to substantial probability of substantial harm. The NCBHR also suggests a similar approach to the benefit side of the harm/benefit ratio to permit a rational analysis of the ratio. This approach is found as well in some international Standards.

In attempting to achieve a simple quantification of the risk of harm due to medical research, the NCBHR model departs from a straightforward, logical approach. For example, it equates minimal, moderate, and substantial probability of moderate harm, and ranks them with minimal or moderate probability of substantial harm (level 3 risk). As well, the model deals specifically with the risk of harm to a single individual, and separates the benefit to that individual and the benefit to society.

These concepts should be considered in Standards development, although with a more logical approach to numerical evaluation. The probability of harm should be estimated in some manner as negligible (0), minimal (1), moderate (2), or substantial (3), taking into account both the probability of harm to a single individual and the number of individuals potentially affected. As well, the magnitude of harm should be estimated as negligible (0), minimal (1), moderate (2), or substantial (3). The risk of harm is determined by multiplying the probability of harm by the magnitude of harm, with possible scores ranging from 0 to 9.

A very precise mathematical analysis is not always possible or desirable, and the risk scores in the proposed model do not have a linear relationship to risk. However, the potential importance of probability analysis in Standards applications is clear. The model can be used when accurate estimates of harm or probability are not available. The model is particularly helpful in illustrating an important truth: one can reduce risk by reducing either the probability of an event or its severity, as can be visualized by referring to Figure B.1. The model can be used, then, to evaluate the reduction in risk that might be brought about by implementing a proposed Standard, in order to quantify the benefit of that Standard and permit that benefit to be balanced against the cost of developing or implementing the Standard.

As an example, consider a piece of electrical equipment without protective covering. This equipment creates a substantial risk of someone coming into contact with live parts and substantial harm resulting from the contact. In Figure B.1, this quantified risk would occur at point A and be deemed intolerable.

Some Standards concentrate on minimizing the probability of a harmful event. For example, Standards for protective enclosures reduce the probability that an individual can touch equipment inside an enclosure, but do not change the severity (magnitude of harm) of such touching. The probability of

touching live parts can be reduced to negligible, but the severity of contact can still be substantial. In Figure B.1, this quantified risk would occur at point B and be deemed broadly acceptable.

Many Standards, recognizing that a risk is intolerable, rely on reducing the severity of an event. For example, requirements for the use of ground fault circuit interrupters (GFCIs) reduce the severity (magnitude) of an electric shock but not the probability of its occurrence. Using a GFCI to protect an unenclosed electrical device can still entail a substantial probability of touching live parts, but the severity of contact will be reduced to at least the level of minimal. This is a risk mitigation strategy intended to drive the risk down below the intolerable level into what is referred to as the ALARP region of Figure B.1 (point C). It should be pointed out that risk can be determined to fall within the ALARP region of Figure B.1 only after some risk mitigation action has taken place. Before risk mitigation, a risk is either broadly acceptable or intolerable. It is impossible to know whether the risk is as low as reasonably possible unless some risk control measures have been instituted.

When both a protective enclosure and a GFCI with an electrical device are employed, the probability of contact can be reduced to negligible, and the severity of potential contact reduced to minimal. In Figure B.1, this quantified risk occurs at point D in the "broadly acceptable" region.

B.2 Single-fault philosophy

Note: The concept of the single fault is pervasive in this Standard and in the CSA C22.2 No. 60601 series of Standards. This Clause outlines the principles of the single-fault philosophy set forth in IEC/TR3 60513.

IEC/TR3 60513 addresses fundamental aspects of safety Standards for medical electrical equipment. It is intended to be used by Standards development committees to develop safety Standards for medical electrical equipment. The single-fault philosophy is the basis of IEC/TR3 60513 and rests on the following principles:

- (a) A single fault, i.e., the failure of a single element in a piece of medical electrical equipment, will not result in a hazard.
- (b) The probability of a single fault occurring in a safety-related component in a piece of medical electrical equipment is low.
- (c) If the probability of a single fault occurring in a safety-related component in a piece of medical electrical equipment is low, the probability of two single faults occurring simultaneously in safety-related components will be very low. As such, it is acceptable for a multiple-fault condition to produce a hazard.
- (d) When a single fault directly causes another single fault, the probability of the second fault occurring is the same as that of the first fault. As such, the situation outlined in Item (c) applies.
- (e) When two faults can result from a common cause (e.g., the short-circuiting of both layers of double insulation by conductive liquids or metal objects), the probability of each of the two faults occurring is the same as the probability of the common cause.
- (f) When a fault cannot be detected during maintenance and is unlikely to be noticed by the operator (i.e., the fault does not affect the functioning of the equipment in question), the high probability of that fault remaining undetected for an extensive period is to be considered during development of the Standard for the equipment.

B.3 References

CSA (Canadian Standards Association)

C22.2 No. 60601 series of Standards *Medical Electrical Equipment*

IEC (International Electrotechnical Commission)

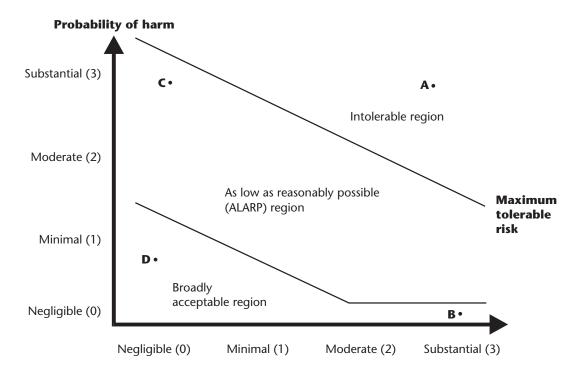
IEC/TR3 60513 (1994:01)

Fundamental aspects of safety standards for medical electrical equipment

50 September 2004

Other publications

Miller, J. 1993. *Reflections on Research Involving Children*. Ottawa: National Council on Bioethics in Human Research.



Note: When a risk of harm falls within the ALARP region, consideration should be given to reducing that risk of harm as much as is reasonably possible.

Figure B.1 Risk chart (See Clause B.1.)

Annex C (informative)

Electrical equipment in oxygen-enriched atmospheres

Notes:

- (1) This Annex is not a mandatory part of this Standard.
- (2) This Annex addresses only the use of electrical equipment in oxygen-enriched atmospheres. It does not address non-electrical hazards such as smoking, spark-producing toys, butane-powered equipment (lighters and curling irons), etc. For information on these hazards, see NFPA 99 and 550.

C.1 General

C.1.1

Factors affecting the size of a space considered to be an oxygen-enriched atmosphere (OEA) include

- (a) method of gas delivery (e.g., cannula, mask, ventilator);
- (b) flow rate of the gas;
- (c) improper use of equipment, including lack of patient supervision;
- (d) equipment operation defects; and
- (e) the ventilation system in the patient care area.

C.1.2

Because oxygen rapidly diffuses into the surrounding air, the space considered to be an OEA is relatively small. For general purposes, it is

- (a) the space 0.3 m from the surface of any equipment used to administer the gas;
- (b) the space 0.3 m from the site of intentional venting of the gas to the atmosphere, except where a high flow rate is used, in which case the OEA is considered to be the space 0.5 m from the surface of the equipment; or
- (c) the space 1.5 m from the surface of the equipment when the equipment contains more than 2 L of oxygen (at one atmospheric pressure) (e.g., an oxygen tent).

C.1.3

Using electrically powered equipment in an OEA risks creating a high temperature that could ignite one of the available fuels. The energy necessary to start a fire varies with the type of substance considered as the fuel and with the oxygen content of the space. An assessment of these variables is beyond the scope of this Standard (see NFPA 495).

C.1.4

Electrical equipment that does not meet the requirements of Clause 4.3.1.2 may be used in an OEA, provided that the medical staff have removed all potentially flammable materials from the OEA and the space is constantly supervised to ensure that no flammables are introduced into it.

Note: Some medical electrical equipment normally generates temperatures that can ignite substances in an OEA (e.g., lasers, electrosurgical units, electrocautery devices, and cardiac defibrillators [if arcing occurs at the electrodes]). When this type of equipment is used in or near an OEA, the medical staff should exercise caution to avoid igniting substances.

C.1.5

When the requirements specified in Clause 4.3.1.2 cannot be met, the equipment should be fixed-mounted outside the OEA. Portable equipment that can be inadvertently introduced into the OEA should be excluded from the site of administration (i.e., from the room or other surrounding area).

C.1.6

When isolated power is used in an area containing an OEA, the risk of ignition from a line-to-ground fault is eliminated. However, the risk of ignition from a line-to-line fault, an overheated component, or an intentionally hot component is not eliminated.

C.2 References

NFPA (National Fire Protection Association)

99 (2002)

Standard for Health Care Facilities

495 (2001)

Explosive Materials Code

550 (2002)

Guide to the Fire Safety Concepts Tree

Annex D (informative) Certification programs

Note: This Annex is not a mandatory part of this Standard.

D.1 CSA certification program

Medical electrical equipment bearing the CSA logo has been tested to and has met the requirements of CAN/CSA-C22.2 No. 114, CSA C22.2 No. 125, or the C22.2 No. 60601 series of Standards, as applicable. This means that a prototype of the equipment has been subjected to all of the construction, mechanical, and electrical requirements specified in the applicable Standard(s). This includes dielectric strength testing, flammability testing, and leakage or risk current testing.

As part of the certification agreement between the product manufacturer and CSA, unannounced follow-up inspections of the manufacturer's production facilities are conducted to ensure that the safety of the product is equivalent to that of the prototype submitted at the time of application for certification.

CSA investigates the product for protection from fire, electric shock, and mechanical hazards. The product is not investigated for physiological effects or clinical efficacy.

A product bearing the CSA logo can be sold anywhere in Canada.

D.2 CSA special acceptance and special inspection programs

For information on CSA special acceptance and special inspection programs, users of this Standard should contact CSA at the following address or telephone number:

Applications and Customer Service CSA International 178 Rexdale Boulevard Toronto, Ontario Canada M9W 1R3 (416) 747-4000

D.3 Other certification organizations

A list of other certification organizations accredited by the Standards Council of Canada is available from the Standards Council of Canada.

D.4 References

CSA (Canadian Standards Association)

CAN/CSA-C22.2 No. 114-M90 (R2002)
Diagnostic Imaging and Radiation Therapy Equipment

C22.2 No. 125-M1984 (R1999) Electromedical Equipment

C22.2 No. 60601 series of Standards Medical Electrical Equipment

Annex E (informative)

Electromagnetic interference and electromagnetic compatibility

Note: This Annex is not a mandatory part of this Standard.

E.1 General

Policies that concentrate on risk reduction in areas of the patient care environment that are of greatest concern, minimize the impact of medical equipment failure on patients, visitors, and staff, and simplify enforcement are likely to be more acceptable forms of prevention. The following is one possible approach to risk reduction:

(a) Signs posted at all public entrances notify people entering the health care facility that cellphones and portable two-way radios can interfere with the operation of medical equipment and therefore should be turned off in patient rooms.

Note: In public-use, non-patient-care areas (e.g., cafeterias, atria, waiting rooms), restrictions are unnecessary because of the low probability of interference and the fact that an effect cannot be produced unless the transmitter and the susceptible device are in close proximity.

(b) In high-risk patient care areas, i.e., where the clinical management of patients is critical and there is a great deal of equipment, "RESTRICTED AREA" signs direct persons entering the areas to turn off their cellphones and avoid using their portable two-way radios to transmit signals (receiving signals, however, is safe and acceptable).

Note: Restricted areas can include, but are not limited to,

- (a) intensive care units;
- (b) surgical suites;
- (c) labour and delivery rooms;
- (d) cardiac catheterization labs;
- (e) emergency areas; and
- (f) diagnostic imaging areas.

E.2 Transient voltage peaks

Transient voltage peaks can disturb the performance of medical electrical equipment to such an extent that the equipment becomes hazardous.

Transients can result from the operation of switches, sudden renovation (rise or decay) of magnetic fields, use of switching-type power supplies, intermittent faults, or high-frequency resonant circuits. They can originate in equipment or power lines in the vicinity of the affected equipment or be introduced by the mains distribution system from remote sources.

Because protective grounding is usually insufficient to avoid such transients, special circuit design precautions can be necessary. In the case of magnetic fields, distance is often the remedy, especially for separating sensitive medical electrical equipment for other equipment that consumes large amounts of power (e.g., X-ray machines, elevators, sterilizers, and solid state controls for large motors or heating systems, and the cables that supply such equipment). In other cases, shielding or power line filtering is necessary for sensitive medical electrical equipment.

E.3 Areas requiring reduction of ac interference

In an area where bioelectric potentials (EEG, ECG, etc.) are measured, steps should be taken to prevent interference in the area and its surrounding area if such interference can produce incorrect measurements.

Such areas include, but are not limited to,

- (a) areas specifically intended for measurement of bioelectric potentials;
- (b) intensive examination areas;
- (c) intensive care and monitoring areas;
- (d) cardiac catheterization labs;
- (e) angiographic examination areas; and
- (f) operating theatres.

E.4 Measures to reduce interference from radio-frequency electromagnetic fields

Powerful radio-frequency fields can cause interference in sensitive medical electrical equipment.

Normally, such fields exist only where short-wave diathermy or electrosurgical units are used, or close to transmitting antennae used for purposes such as staff location and ambulance communications. Strong fields can also occur near airports, commercial transmitters, and industrial facilities. The simplest measure against such interference is to locate the equipment that causes it well away from areas where sensitive medical electrical equipment is used. Additional measures include radio-frequency rejection circuits in

sensitive equipment and the use of short-wave diathermy equipment with a low modulation factor.

56

Annex F (informative)

Purchasing considerations for health care facility equipment

Note: This Annex is not a mandatory part of this Standard.

F.1 General

Many health care facilities identify the conditions they impose on suppliers by including those conditions in their purchase orders or tender documents, or on a separate document accompanying their purchase orders. These conditions commonly deal with pricing, invoicing, insurance, and delivery. In the interest of obtaining equipment that is safe and complies with local, provincial/territorial, and national codes and Standards, as well as to facilitate maintenance, comprehensive purchase conditions agreed to by both the supplier and the purchaser should be prepared.

During the preparation of these conditions, the questions specified in Clauses F.2 to F.6 should be considered.

F.2 Compliance with codes and Standards

The following questions concerning compliance with codes and Standards should be considered:

- (a) Which codes and Standards is the equipment required to meet? Examples:
 - (i) CAN/CSA-C22.2 No. 114;
 - (ii) CSA C22.2 No. 125; and
 - (iii) special inspection by the provincial or territorial electrical safety authority.
- (b) What labelling is required?

Examples:

- (i) CSA logo;
- (ii) equipment type;
- (iii) risk class; and
- (iv) restrictions on use in oxygen-enriched environments.
- (c) Who is responsible for obtaining and paying for all required approvals? (Typically, the supplier is responsible.)

Note: CAN/CSA-C22.2 No. 60601-1-2 specifies that the method used for measuring electromagnetic interference is to be disclosed.

F.3 Inspection of incoming equipment

The following questions concerning inspection of incoming equipment should be considered:

- (a) Will the equipment be required to pass an inspection by the health care facility before acceptance for clinical use?
- (b) To what equipment will the inspection apply? Examples:
 - (i) new equipment;
 - (ii) equipment returned from repair;
 - (iii) equipment on trial; and
 - (iv) equipment on loan.

(Typically, all of these types of equipment will be inspected.)

- (c) Who will perform the inspection?
- (d) What will the inspection consist of?

57

Examples:

- (i) safety inspection;
- (ii) performance checks;
- (iii) performance test;
- (iv) inspection for compliance with specifications;
- (v) inspection for compliance with codes and Standards; and
- (vi) inspection for compliance with good engineering practice.

F.4 Warranty

The following questions concerning the warranty should be considered:

- (a) What is the required duration of the warranty?
- (b) When does the warranty period begin? (Typically, the equipment is required to pass the inspection for incoming equipment before the warranty period begins.)
- (c) Will the health care facility need to reserve the right to do some repair and maintenance work on the equipment during the warranty period? (If so, the supplier's warranty should indicate that such work will be permitted without voiding the warranty.)

F.5 Operating and maintenance manuals

The following questions concerning operating and maintenance manuals should be considered:

- (a) How many sets of operating and maintenance manuals are required?
- (b) In which language(s) are the manuals to be written?
- (c) When are the manuals to be supplied?

Examples:

- (i) when the equipment is received for purchase or evaluation; and
- (ii) within a specified period following acceptance of the equipment.
- (d) What format requirements apply?

Examples:

- (i) professional appearance and content; and
- (ii) information pertaining to equipment not supplied is to be deleted from the manuals or marked not applicable.
- (e) What is the required content?

Examples:

- (i) operating manuals:
 - (1) system/equipment description;
 - (2) operating concept and instructions;
 - (3) problem identification;
 - (4) problem resolution instructions; and
 - (5) documentation of existing or potential hazards; and
- (ii) maintenance manuals:
 - (1) shop drawings;
 - (2) schematics;
 - (3) circuit descriptions;
 - (4) maintenance and preventive maintenance procedures;
 - (5) locations and telephone numbers of service representatives;
 - (6) parts list; and
 - (7) locations and telephone numbers of parts suppliers.

F.6 Operating and maintenance instruction sessions

The following questions concerning operating and maintenance instruction sessions should considered:

- (a) How many sessions are required?
- (b) What will be the minimum duration of each session?
- (c) When and where will the sessions be conducted?
- (d) What qualifications should the instructor have?

F.7 References

CSA (Canadian Standards Association)

CAN/CSA-C22.2 No. 114-M90 (R2000)

Diagnostic Imaging and Radiation Therapy Equipment

C22.2 No. 125-M1984 (R1999) Electromedical Equipment

CAN/CSA-C22.2 No. 60601-1-2:03

Medical electrical equipment, Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests

Annex G (informative) **Test sheets** (See Clause 5)

Note: This Annex is not a mandatory part of this Standard.

PATIENT CARE ISOLATED POWER DISTRIBUTION	Name				
SYSTEM COMMISSIONING RECO	Company Date				
(CSA Standard Z32-04)	(CSA Standard Z32-04)				
Name of facility					
Room no. and designation					
Panelboard designation					
Transformer: rating plate data		_			
Line isolation monitor: make, model, and	serial no.				
Panelboard			Remarks		
Directory: neatly lettered and accurate	Yes	No			
Breaker mechanical test (1)	Yes	No			
Bonding: between panelboards (2)	Yes	No			
Line isolation monitor					
Line isolation monitor alarm setting (3)	Yes	No			
Line isolation monitor test function (4)	Yes	No			
Line isolation monitor silence function (4)	Yes	No			
Auxiliary alarm function (5)	Yes	No			
Field devices					
Receptacles: red, hospital grade (6)	Yes	No			
Receptacle labels (7)	Yes	No			
Receptacle retentive force (8)	Yes	No			
Receptacle polarity (9)	Yes	No			
Voltage difference limits (10)	Yes	No			
Equipment switches: two-pole (11)	Yes	No			
Field wiring					
Wire: size (12)	L1	L2	L3		
Wire: insulation type (13)	L1	L2	L3		
Wire: insulation colour (14)	L2	L3			
System hazard index (in μA) (15)	L2	L3			
Maximum hazard index (in mA) (16)	L1	L2	L3		
Test instrument make and model no.					

(Continued)

Figure G.1
Patient care isolated power distribution system commissioning record

Test notes

- (1) For the test procedure, see Clause 5.5 of CSA Z32.
- (2) Where more than one single-phase isolated power system supplies a single location, the grounding buses of all of the systems shall be bonded together with a copper bonding conductor. See Rule 24-202(2) of the Canadian Electrical Code, Part I.
- (3) The line isolation monitor alarm level for Canada is 2.0 mA \pm 10%.
- (4) Check that the green safe lamp is on. Press and hold the test button. Verify that the hazard lamp illuminates, the green safe lamp extinguishes, and the alarm buzzer pulses audibly. Release the test button and press the silence button. Verify that the audible alarm is muted while visual indication continues. The monitor should reset itself with the green safe lamp on.
- (5) Verify auxiliary alarm functions to the manufacturer's specifications.
- (6) All 15 and 20 A non-locking patient care receptacles shall be hospital grade (identified by a green dot on the receptacle face). All receptacles that are part of an essential electrical system shall be coloured red. See Rule 24-106(6) and (7) of the *Canadian Electrical Code, Part I.*
- (7) Each receptacle's supplying panelboard designation and circuit number shall be permanently identified at the outlet, visible when the cover plate is in place, and not marked on the cover plate itself. The circuit breaker at the panelboard should be actuated to ensure that the receptacles are correctly marked as corresponding to that breaker. See Clause 5.6.5 of CSA Z32.
- (8) Receptacle retentive force: the ground pin retentive force shall be not less than 1.1 N (112.2 gf). The retentive force of each plug blade shall be not less than 2.2 N (224.3 gf). The combined retentive force of the plug blades shall be not less than 13 N (1325.6 gf). See Clause 5.6.1.3 of CSA Z32.
- (9) Polarity: for all 15 and 20 A single-phase receptacles, verify that the orange and brown conductors are connected to the silver and brass screws, respectively. See Rule 24-204 of the *Canadian Electrical Code, Part I.*
- (10) Voltage difference limits shall not exceed 20 mV. For the test procedure, see Clause 5.9.1 of CSA Z32.
- (11) Any disconnection means controlling an isolated circuit shall be two-pole (e.g., surgical luminary switch). See Rule 24-204(3) of the *Canadian Electrical Code, Part I.*
- (12) Branch circuit conductors shall be copper and shall be sized not smaller than No. 12 AWG. See Rule 24-102(3) of the Canadian Electrical Code, Part I.
- (13) Isolated circuits shall have circuit conductors of one of the types specified by Rule 24-204(2)(b) of the Canadian Electrical Code, Part I.
- (14) Circuit conductor insulation shall be orange, brown, and yellow for Line 1, Line 2, and Line 3, respectively. See Rule 24-204(2)(c) of the *Canadian Electrical Code, Part I*, and Section 160(5) of the National Fire Protection Association's *National Electrical Code* (2002).
- (15) For system requirements, see Rule 24-204(6) of the Canadian Electrical Code, Part I.
- (16) For the test procedure, see Clause 5.11.2.4 of CSA Z32.

Figure G.1 (Concluded)

PATIENT CARE ISOLATED POWER DISTRIBUTION SYSTEM MAINTENANCE LOG (CSA Standard Z32-04)		Name Company Date		
Date	Panelboard circuit breakers	Receptacle retentive force	Line isolation monitor test function	Maximum hazard index, mA

(Continued)

Figure G.2
Patient care isolated power distribution system maintenance log

Test notes

All tests shall be performed annually.

Panelboard circuit breakers: switch the breaker on and off at least three times. The breaker should toggle freely.

Receptacle retentive force: the ground pin retentive force shall be not less than 1.1 N (112.2 gf). The retentive force of each plug blade shall be not less than 2.2 N (224.3 gf). The combined retentive force of the plug blades shall be not less than 13 N (1325.6 gf).

Line isolation monitor test function: check that the green safe lamp is on. Press and hold the test button. Verify that the hazard lamp illuminates, the green safe lamp extinguishes, and the alarm buzzer pulses audibly. Release the test button and press the silence button. Verify that the audible alarm is muted while visual indication continues. The monitor should reset itself with the green safe lamp on.

Maximum hazard index: with the panelboard energized, all cord-connected equipment disconnected, all branch circuit breakers on, and all permanently wired equipment on, record the hazard current reading in milliamperes indicated on the line isolation monitor.

Remarks:

Figure G.2 (Concluded)

PATIENT CARE GROUNDED POWER DISTRIBUTION SYSTEM BRANCH WIRING AND RECEPTACLE COMMISSIONING RECORD (CSA Standard Z32-04) Name of facility				Name Company Date Room no. a	nd designa	ntion				· ·		
Outlet location	Circuit no.			Hospital grade (3)	Receptacle retentive force (4)	Polarity (5)	V _{DIFF.} limits (6)	Ground V_{RISE} V_N (7)	Voltage V_{LOAD}	. –		% drop
Test mete	ers:	Make aı	nd model	no.		Make and r	nodel no.		Make	and mo	odel no.	

- (1) Each receptacle's supplying panelboard designation and circuit number shall be permanently identified at the outlet, visible when the cover plate is in place, and not marked on the cover plate itself. See Clause 5.6.5 of CSA Z32.
- (2) All patient care receptacles supplied from an essential electrical system shall be red, and no other receptacles shall be permitted to be red. See Rule 24-106(7) of the Canadian Electrical Code, Part I.
- (3) All 15 and 20 A non-locking receptacles shall be hospital grade (identified by a green dot on the receptacle face). See Rule 24-106(6) of the Canadian Electrical Code, Part I.
- (4) Receptacle retentive force: the ground pin retentive force shall be not less than 1.1 N (112.2 gf). The retentive force of each plug blade shall be not less than 2.2 N (224.3 gf). The combined retentive force of the plug blades shall be not less than 13 N (1325.6 gf). See Clause 5.6.1.3 of CSA Z32.
- (5) Polarity: for all 15 and 20 A single-phase receptacles, verify that the orange and brown conductors are connected to the silver and brass screws, respectively. See Rule 24-204(2)(d) of the Canadian Electrical Code, Part I.
- (6) Voltage difference limits shall not exceed 20 mV. For the test procedure, see Clause 5.9.1 of CSA Z32.
- (7) V_N is the neutral-to-ground voltage without load. V_N shall not exceed 2 V. For the test procedure, see Clause 5.10.2.1.1 of CSA Z32.
- (8) V_R is the ground path voltage rise. V_R shall not exceed 3 V. For the test procedure, see Clause 5.10.2.1.1 of CSA Z32.
- 9) For the test procedure, see Clause 5.4.3.1 of CSA Z32.

Remarks:

Figure G.3 Patient care grounded power distribution system branch wiring and receptacle commissioning record

PATIENT CARE GROU POWER DISTRIBUTION PANELBOARD COMMISSION (CSA Standard Z32	SYSTEM IING RECORD	Company	
Name of facility Panelboard designation			
Panelboard location			
No. 6 bonding conductor: essential to non-essential panelboard?(1)	Yes	No -	N/A
Panelboard directory: neatly lettered and accurate?	Yes	No -	
CCT Receptacle Wire no. location(s) size (2)	Circuit breaker mechanical operation (3)	Conductor insul (at 500 V Neutral (5)	
	1	()	()
Test instrument make and model n			

- (1) Bonding conductor. See Clause 5.8 of CSA Z32.
- (2) Branch circuit conductors shall be copper and shall be sized not smaller than No. 12 AWG. See Rule 24-102(2) of the *Canadian Electrical Code, Part I*, and Clauses 5.4.1 and 5.4.2 of CSA Z32.
- (3) For the test procedure, see Clause 5.5 of CSA Z32.
- (4) For the test procedure, see Clause 5.3 of CSA Z32.
- (5) Neutral conductor insulation resistance to ground shall be not less than 10 k Ω . See Clause 5.3.2 of CSA Z32.

Remarks:

Figure G.4 Patient care grounded power distribution system panelboard commissioning record

PATIENT CARE GROUNDED POWER DISTRIBUTION SYSTEM RECEPTACLE MAINTENANCE LOG (CSA Standard Z32-04) Name of facility				Name Comp Date Room r		esignatio	on			
Outlet location	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date

Receptacle retentive force: ground pin retentive force shall be not less than 1.1 N (112.2 gf). The retentive force of each plug blade shall be not less than 2.2 N (224.3 gf). The combined retentive force of the plug blades shall be not less than 13 N (1325.6 gf). See Clause 5.6.1.3 of CSA Z32.

Compliance with these requirements shall be verified using a commercially available receptacle retention tester at the following times:

- (a) in basic care areas, at least every two years;
- (b) in intermediate and critical care areas, at least every year; and
- (c) when a receptacle is replaced.

Remarks:

Figure G.5 Patient care grounded power distribution system receptacle maintenance log

PATIENT CARE GROUNDED POWER DISTRIBUTION SYSTEM CIRCUIT BREAKER MAINTENANCE LOG (CSA Standard Z32-04) Name of facility Panelboard designation Panelboard location				Name Company Date					
CCT no.	Date	Date	Date	Date	Date	Date	Date	Date	Date

Circuit breakers supplying patient care areas should be exercised and their mechanical operation periodically verified.

With its loads preferably unplugged or switched off, each circuit breaker should be switched on and off at least three times.

The breaker should toggle freely. This should be done once each year for each breaker, or in accordance with the circuit breaker manufacturer's directions. See Clause 5.5 of CSA Z32.

Remarks:

Figure G.6 Patient care grounded power distribution system circuit breaker maintenance log

Annex H (informative)

Building electrical systems

Notes:

- (1) This Annex is not a mandatory part of this Standard.
- (2) This Annex compares grounded and isolated building electrical systems in the hope that engineers and others responsible for designing building electrical systems for health care facilities will be better able to select the best system for a particular application.

H.1 General

H.1.1

One or more different building electrical systems can be selected to distribute electrical power throughout a health care facility. Each system will have advantages and disadvantages that make it more or less appropriate for particular applications.

H.1.2

Although a building electrical system in a health care facility may be designed to operate at any voltage or at several voltages, this Annex deals only with systems designed to deliver a nominal 120 V to receptacles and equipment.

H.2 The grounded system

H.2.1

Power at 120 V is derived from a transformer that can be owned by the supply authority or by the health care facility, and can be located inside or outside the building.

H.2.2

The transformer described in Clause H.2.1 can be the main transformer for the building, in which case it can be quite large (e.g., 1500 kVA), or it can supply only part of the building, in which case it will be smaller (e.g., 300 kVA).

H.2.3

A large transformer can provide a large amount of energy in the event of a fault.

H.2.4

In a grounded system, 120 V power is transmitted via two conductors to the end-use device. One of these conductors is connected to ground, hence the term "grounded system". The building electrical system in a standard residential, commercial, or industrial building will be of the grounded type.

H.2.5

The conductor that is connected to ground is called the "neutral" conductor. In the sizes usually used for branch circuits, it is identified by white insulation. For the larger sizes, it can be identified by white tape around the insulation at each termination. The other conductor is called the "hot", "live", or "line" conductor, and is normally identified by black, red, or blue insulation.

H.2.6

When conductors are connected to a receptacle or some other 120 V device such as a lampholder, the neutral or white insulated conductor is connected to the silver-coloured terminal and the live conductor to the brass terminal.

H.2.7

In patient care areas of new health care facilities, a third conductor (bonding conductor) with green insulation is connected to the box containing the receptacle and to the bonding bus in the panelboard supplying the receptacle. A green insulated bonding jumper connects the "U-slot" of the receptacle to the bonding screw of the outlet box containing the receptacle. The bonding bus in the panelboard is in turn bonded to ground.

H.2.8

If a switch is provided to control the power to a receptacle or outlet, it is always connected so that it opens the live conductor to disconnect the outlet or device from the supply. The neutral is never opened. Similarly, a circuit breaker or fuse is always connected in the live conductor.

H.2.9

In the grounded system, a voltage or potential difference of 120 V exists between the live conductor and the neutral. Since the neutral is connected to ground, a similar voltage exists between the live conductor and ground (see Figure H.1).

H.2.10

If a person touches both the exposed live and neutral conductors, or the exposed live conductor and any grounded surface, he or she will receive an electric shock. The magnitude of the shock will depend on the resistance of the person's skin at the points of contact. Wet, soft skin has a much lower resistance than dry, calloused skin, and therefore the shock will be more severe if contact is made with wet skin.

H.2.11

If the insulation on the live conductor is damaged and the conductor itself comes into contact with ground, there will be arcing at the contact point, a large fault current will flow, and the circuit breaker or fuse will then open the circuit, thus interrupting the supply to all equipment supplied by that branch circuit. A grounded system does not provide the "grace period" afforded by an isolated system.

H.2.12

Line isolation monitors are neither required nor provided in grounded systems.

H.2.13

The probability of persons receiving an unintended electric shock from a properly grounded system is very remote.

H.2.14

Because a grounded system does not require a line isolation monitor, isolating transformer, and special panelboard, additional space is not needed.

H.2.15

The capital cost is typically lower for grounded systems; however, additional testing is required on commissioning to ensure the safety of the system.

H.2.16

Only grounded systems are permitted in basic care areas of Canadian health care facilities.

H.3 The isolated system

H.3.1

Power at 120 V is derived from a transformer. This transformer is seldom, if ever, owned by the supply authority and is located inside the building, close to the small area it serves.

H.3.2

The transformer described in Clause H.3.1 is small (e.g., 5 to 10 kVA), has a grounded electrostatic shield between its windings (see Rule 10-112 of the *Canadian Electrical Code, Part I*), and usually supplies only one room. In some cases it supplies only part of one room.

H.3.3

A small transformer can provide only a relatively small amount of energy in the event of a fault.

H.3.4

In an isolated system, 120 V power is transmitted via two conductors to the end-use device. Neither conductor is connected to ground; in fact, considerable attention is given to keeping the impedance between both of the conductors and ground as high as possible. Isolated building electrical systems are permitted only in intermediate and critical care areas in health care facilities.

H.3.5

The two conductors are both called "live" or "line" conductors and are usually identified by orange and brown insulation.

H.3.6

When conductors are connected to a receptacle or some other 120 V device such as a lampholder, the orange insulated conductor is connected to the silver-coloured terminal and the brown insulated conductor to the brass terminal.

H.3.7

The situation described in Clause H.2.7 also applies to isolated systems.

H.3.8

If a switch is provided to control the power to a light, X-ray viewer, or any other equipment connected to an isolated supply, the switch is required to be double-pole and also required to open both live conductors simultaneously. The same requirements apply to circuit breakers. Because fuses normally open one line only, depending on which fuse melts first, their use should be avoided.

H.3.9

In an isolated system, a voltage or potential difference of 120 V exists between the two circuit conductors, but because neither of the conductors is connected to ground except through the very high impedance of the conductor insulation, only a small current flows from either conductor to ground (see Figure H.2).

H.3.10

If a person touches both exposed live conductors of an isolated system, the result will be identical to that described in Clause H.2.10. But if a person touches only one conductor and ground, only a very small current will flow through the person.

H.3.11

If the insulation on either conductor is damaged and the conductor itself comes into contact with ground (a situation referred to as a first fault condition), there will be no arcing, and only a slight fault current will

70

flow to ground. The isolated system simply becomes a grounded system and continues to provide power at full voltage to all equipment supplied by that branch circuit.

H.3.12

A line isolation monitor should be provided to alert staff that a first fault has occurred and that the system has become a grounded one capable of producing significant arcs. A line isolation monitor will sound an alarm when a first fault develops in any branch circuit of the isolated electrical system or in equipment plugged into the system.

H.3.13

The probability of persons receiving an unintended electric shock from an isolated power system is extremely remote.

H.3.14

Additional space should be provided for the line isolation monitor, isolating transformer, and associated equipment.

H.3.15

Isolated systems are typically more expensive than grounded systems. However, the amount of required testing may be reduced because of the arrangement of the system and the constant monitoring provided by the line isolation monitor.

H.3.16

In Canada, isolated systems are permitted to be used in intermediate and critical care areas of health care facilities

H.4 Choice of system

For intermediate and critical care areas, the decision to use a grounded system or an isolated system is made jointly by the provincial/territorial or federal body having jurisdiction, the health care facility administration, and the professional engineer responsible for the electrical design.

H.5 References

CSA (Canadian Standards Association)

C22.2-02

Canadian Electrical Code, Part I

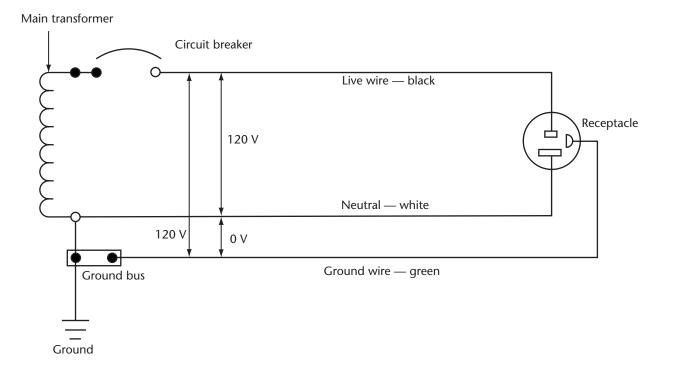


Figure H.1 Grounded system (See Clause H.2.9.)

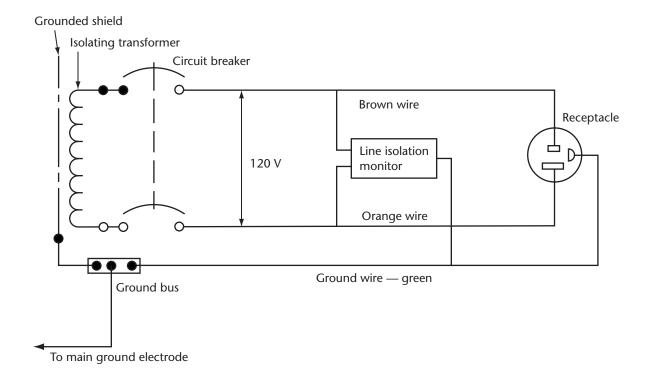


Figure H.2 Isolated system(See Clause H.3.9.)

Annex I (informative)

Precautions in transfer of loads

Note: This Annex is not a mandatory part of this Standard.

I.1 General

Many papers published by the Institute of Electrical and Electronics Engineers have been written on the high-speed transfer of rotating loads from one power source to another. High-speed transfer can result in excessive transient voltages, currents, and torques. These transient conditions have led to shearing of coupling bolts, twisting of shafts, blowing of fuses, and tripping of supply and branch breakers.

I.2 Source of the problems

The following are two of the problems associated with high-speed transfer:

- (a) the momentary interruption of power to a motor will create a voltage and current transient; and
- (b) when the transfer switch transfers the load from one power source to another, these sources can be out of phase with each other, resulting in a large inrush current and high transient torques.

I.3 Avoiding the problems

The transient problems can be reduced by ensuring that

- (a) the transfer does not take place until the two power supplies are in phase (when the transfer takes place at high speed); or
- (b) rotating equipment is disconnected from the power supply for a period long enough to permit the motor speed to decay to a low value before the equipment is connected to the second supply. This is readily accomplished by using a neutral position on the transfer switch and timers to hold the neutral position until the motor has slowed sufficiently to reduce the transient to a tolerable value.

The solution to these problems, as well as the choice of distribution system and equipment, is left to the designer of the system.

Annex J (informative)

Equipment markings

Notes:

- (1) This Annex is not a mandatory part of this Standard.
- (2) These markings appear in International Electrotechnical Commission publication IEC/TR 60878 (2003-07), Graphical symbols for electrical equipment in medical practice.

Table J.1 International Electrotechnical Commission equipment markings

Marking	Description
Marking	Type B applied part
*	Type BF applied part
	Type CF applied part

75

Proposition de modification

N'hésitez pas à nous faire part de vos suggestions et de vos commentaires. Au moment de soumettre des propositions de modification aux normes CSA et autres publications CSA prière de fournir les renseignements demandés ci-dessous et de formuler les propositions sur une feuille volante. Il est recommandé d'inclure

- le numéro de la norme/publication
- le numéro de l'article, du tableau ou de la figure visé
- la formulation proposée
- la raison de cette modification.

Proposal for change

CSA welcomes your suggestions and comments. To submit your proposals for changes to CSA Standards and other CSA publications, please supply the information requested below and attach your proposal for change on a separate page(s). Be sure to include the

- Standard/publication number
- relevant Clause, Table, and/or Figure number(s)
- wording of the proposed change
- rationale for the change.

Nom/Name:		
Ville/City:		
État/Province/State:		
Pays/Country:	Code postal/Postal/Zip code:	
Téléphone/Telephone:	Télécopieur/Fax:	
Date:		

J'accepte que la CSA conserve et utilise les renseignements ci-dessus afin de faciliter la réception de mes suggestions et commentaires. I consent to CSA collecting and using the above information to facilitate the collection of my suggestions and comments.

Consultez la politique CSA en matière de confidentialité au www.csagroup.org/legal pour savoir comment nous protégeons vos renseignements personnels.

Visit CSA's policy on privacy at www.csagroup.org/legal to find out how we protect your personal information.

