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**SPE-3000-15**

# **Model Code for the field evaluation of medical electrical equipment and systems**

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***Model Code for the field evaluation  
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# Contents

Canadian Advisory Council on Electrical Safety	3
CACES Subcommittee on SPE-3000	5
Preface	6
<b>0 Introduction</b>	<b>8</b>
<b>1 Scope</b>	<b>8</b>
<b>2 Reference publications</b>	<b>9</b>
<b>3 Definitions (See Figure 1)</b>	<b>11</b>
<b>4 General requirements and construction</b>	<b>18</b>
4.1 General requirements	18
4.1.1 Compliance	18
4.1.2 Safety and protection	19
4.1.3 Materials	23
4.1.4 Current-carrying parts	23
4.1.5 Electrical insulation	24
4.1.6 Classification of applied parts	24
4.2 Construction	24
4.2.1 Electrical components	24
4.2.2 Enclosures	29
4.2.3 Openings in enclosures	30
4.2.4 Mechanical assembly	32
4.2.5 Stability	33
4.2.6 Interlocks	33
4.2.7 Cord-connected equipment	34
4.2.8 Permanently connected equipment	36
4.2.9 Supply circuit disconnecting means	37
4.2.10 Bonding	38
4.2.11 Double insulation	39
4.2.12 Isolation from the supply mains	39
4.2.13 Interconnections	40
4.2.14 Busings	41
4.2.15 Internal wiring	41
4.2.16 Overcurrent, overload, and overtemperature protection devices	42
4.2.17 Fuses and fuseholders	43
4.2.18 Motor controls	44
4.2.19 Equipment containing batteries	44
4.2.20 Multivoltage equipment	45
4.2.21 Spacings	45
4.2.22 Accessible circuits	46
4.2.23 Capacitors	47
4.2.24 Suppressors	48

4.2.25	Heaters and heating elements	48
4.2.26	Thermal insulation	49
4.2.27	Backflow prevention	49
4.2.28	Refrigerant-containing parts	50
4.2.29	Water-heating tanks	50
4.2.30	Protection of water heaters	50
4.2.31	Direct plug-in equipment	51
4.2.32	Installed equipment	51
4.2.33	Specific requirements	51

**5 Marking** 51

5.1	General	51
-----	---------	----

**6 Tests** 58

6.1	Cautions regarding testing of MEE	58
6.2	Standard tests (mandatory, to be performed on 100% basis)	58
6.2.1	Dielectric voltage withstand	58
6.2.2	Flame test	60
6.2.3	Strain relief	60
6.2.4	Leakage current	60
6.3	Other tests	62
6.3.1	General	62
6.3.2	Input rating	62
6.3.3	Temperature	63
6.3.4	Abnormal tests	63
6.3.5	Test for stability	63
6.3.6	Submersible equipment	64
6.3.7	Supporting device test	64
6.3.8	Impact	65
6.3.9	Starting	65
6.3.10	Measurement of insulation resistance	65

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Annex A (informative)	— Essential requirements of particular CSA Canadian Electrical Code, Part II standards (See Clause 4.1.1.4.)	81
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Annex B (normative)	— Field evaluation/Special inspection labels	87
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# Preface

This is the first edition of CSA Model Code SPE-3000, *Model Code for the field evaluation of medical electrical equipment (MEE) and medical electrical systems (MES)*.

Field evaluation of MEE and MES in accordance with this Model Code should be undertaken only by fully qualified and competent persons. These persons should have at least five years of experience in conducting field evaluation and field testing of electrical/electronic equipment, or three years of experience in testing and certification of medical electrical equipment and systems to Canadian standards or other equivalent nationally or internationally recognized standards.

Because field evaluation of MEE and MES is conducted to the requirements of this Model Code, it is not equivalent to an evaluation in support of certification, which is conducted to the requirements of the applicable product standard. Consequently, equipment and products that are field evaluated and labelled cannot be claimed to be certified.

Field evaluation of electrical equipment in accordance with the requirements of this Model Code is intended to be conducted by an inspection body accredited by Standards Council of Canada (SCC). Inspection body accreditation is the process of assessing and publicly recognizing the integrity, reliability, and technical competence of an organization's inspection services. Accreditation of an organization's inspection services by the SCC is a means of demonstrating that those services (within the scope of their formal accreditation) conform to an accepted set of requirements.

This Model Code addresses the minimum requirements for MEE and MES as they pertain to safety. Where other authorities have jurisdiction, they must be consulted by the equipment owner or the owner's agent as to conformance to specific legislation. This legislation may be either federal, provincial, or municipal.

This Model Code addresses the essential construction, marking, and test requirements that MEE and MES must meet before it can be labelled. It allows for the evaluation of MEE and MES, with the objective of minimizing the risk of degrading the safety of the equipment or system through the procedures used in the field evaluation.

The requirements contained in this Model Code are based on the applicable requirements of SPE-1000 and selected requirements of CAN/CSA-C22.2 No. 60601-1 and IEC 62353.

Where the required test or test procedures deemed to present a hazard to the safety of the particular equipment, such tests may be carried out on a separate representative sample supplied for the sole purpose of testing. Alternatively, other means may be taken to determine conformance, such as the evaluation of relevant test data presented in support of an application for field evaluation.

Due to alternative evaluation criteria contained in IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, Edition 3 and Edition 3.1* MEE and MES constructed to those standards may not pass certain tests within this Model Code. The requirements of this Model Code have been accepted by the authorities having jurisdiction (AHJs). It is within the purview of the AHJ in whose jurisdiction the Model Code is applied to add technical or administrative stipulations to or deviations from the Model Code as deemed necessary.

This Model Code was developed by the Canadian Advisory Council on Electrical Safety (CACES) Subcommittee on SPE-3000 and was approved by CACES. Although the intended primary application of

this Model Code is stated in its Scope, it is important to note that it remains the responsibility of the users of the Model Code to judge its suitability for their particular purpose.

**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 Special Publication is stated in its Preface, it is important to note that it remains the responsibility of the users of this Special Publication to judge its suitability for their particular purpose*
- 3) *All enquiries regarding this Special Publication should be addressed to CSA Group, 178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3.*

# *SPE-3000-15*

## *Model Code for the field evaluation of medical electrical equipment and systems*

### **0 Introduction**

#### **0.1**

The object of this Model Code is to facilitate a safety evaluation of medical electrical equipment (MEE) and medical electrical systems (MES) to safety considerations that does not include requirements pertaining to risk analysis, evaluation of efficacy, or performance of products.

### **1 Scope**

#### **1.1**

This Model Code applies to the safety of medical electrical equipment (MEE) and medical electrical systems (MES) as it pertains to safety from electrical shock and fire and mechanical hazards. It provides construction, marking, and test requirements for the field evaluation of MEE and MES by a field evaluation body accredited by the SCC and/or recognized by the regulatory authority.

Equipment and systems may be evaluated at a client's facilities or at other specified locations, including the location of equipment installation.

If a clause or subclause is specifically intended to be applicable to MEE only, or to MES only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to MEE and MES, as relevant.

Hazards inherent in the intended physiological function of MEE and MES within the scope of this Model Code are not covered in this Model Code.

#### **1.2**

Field-evaluated equipment found to be in conformity with the requirements of this Model Code and bearing the appropriate label of the field evaluation body is considered to be acceptable to the AHJ.

#### **1.3**

Notwithstanding the requirements of Clauses [1.1](#) and [1.2](#), field evaluation is not intended to serve as a substitute for certification.

#### **1.4**

The following are scenarios in which this Model Code applies:

- a) custom-built equipment for special applications;
- b) equipment manufactured on a non-repetitive basis;
- c) equipment sold in quantities of not more than 500 on a national basis, per model, per year, per field evaluation body;
- d) equipment not obtainable as "certified" under a regular certification program;

- e) equipment already installed or ready for use on-site and awaiting acceptance by the AHJ; and
- f) complete systems that are all available for examination and testing during the evaluation process.

**Note:** Where it is unclear or there is uncertainty as to whether the equipment is to be field evaluated under the classifications of this Clause, the AHJ should be consulted for clarification.

## 1.5

This Model Code applies where the requirements are supplemented by requirements of particular equipment Standards, where referenced, and the installation requirements of the *Canadian Electrical Code, Part I*, and the CAN/CSA-C22.2 No. 60601 series of Standards as applicable.

## 1.6

This Model Code is not intended to apply to the re-evaluation of equipment that has been rejected due to the results of a previous evaluation conducted by a certification organization through any other existing certification service.

## 1.7

In this Model Code, “shall” is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with this Model Code; “should” is used to express a recommendation or that which is advised but not required; and “may” is used to express an option or that which is permissible within the limits of this Model Code.

Notes accompanying clauses do not include requirements or alternative requirements; the purpose of a note accompanying a clause is to separate from the text explanatory or informative material.

Notes to tables and figures are considered part of the table or figure and may be written as requirements.

Annexes are designated normative (mandatory) or informative (non-mandatory) to define their application.

## 1.8

In accordance with Clause 1.7, this Model Code has been written in mandatory language to facilitate its adoption where users of the Model Code or regulatory authority wish to do so.

# 2 Reference publications

## 2.1

General requirements applicable to this Model Code are given in CAN/CSA-C22.2 No. 0.

## 2.2

Where reference is made to other publications, such reference shall be considered to refer to the latest edition and revision thereto, unless otherwise specified. This Model Code makes reference to the following such Standards and the year dates shown indicate the latest editions available at the time of printing.