CSA SPE-3000:19

Model Code for the field evaluation of medical electrical equipment (MEE) and medical electrical systems (MES)

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Preface

This is the second edition of CSA SPE-3000, *Model Code for the field evaluation of medical electrical equipment (MEE) and medical electrical systems (MES)*. It supersedes the previous edition, published in 2015 as *Model code for the field evaluation of medical electrical equipment and systems*, that was referenced by the Standards Council of Canada in its terms of accreditation for field evaluation bodies. However, at the time of publication, 4 specific types of medical equipment were excluded from SPE-3000. The second edition will include the following medical equipment that was previously excluded:

a) cosmetic and hygiene equipment;
b) X-ray equipment and systems;
c) MRIs and CT scanners; and
d) laser equipment

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 federal, provincial, or municipal.

This Model Code addresses the essential construction, marking, and test requirements that MEE and MES must meet before they 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.

Where the required tests involve 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 that standard may not pass certain tests within this Model Code. The requirements of this Model Code have been accepted by the authorities having jurisdiction (AHJ). 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, under the jurisdiction of the CACES, and was formally approved by the CACES.

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 Standard 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 Standard.*
4) *To submit a request for interpretation of this Standard, please send the following information to* ***inquiries@csagroup.org*** *and include "Request for interpretation" in the subject line:*
   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) *where possible, phrase the request in such a way that a specific "yes" or "no" answer will address the issue.*

   Committee interpretations are processed in accordance with the CSA Directives and guidelines governing standardization *and are available on the* Current Standards Activities *page at* ***standardsactivities.csa.ca****.*
5) *This Standard is subject to review within five years from the date of publication. Suggestions for its improvement will be referred to the appropriate committee. To submit a proposal for change, please send the following information to* ***inquiries@csagroup.org*** *and include "Proposal for change" in the subject line:*
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   c) *wording of the proposed change; and*
   d) *rationale for the change.*

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0 Introduction

The object of this Model Code is to facilitate a safety evaluation of medical electrical equipment (MEE) and medical electrical systems (MES). The safety considerations covered by this Code do 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 protection 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 authority having jurisdiction (AHJ).

1.3

Notwithstanding 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;