

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.