Special Announcement – SPE-3000-15 New Special Inspection Program

Date: December 8, 2016
Apply any time to have your products evaluated

Announcing: Publication of the New Special Inspection Program under CSA Special Publication SPE-3000-15 Model Code for the field evaluation of medical electrical equipment and systems
To purchase this Special Publication, visit us at www.shop.csa.ca

Who is affected?
Clients using the CSA Special Inspection Service and Provincial and Territorial Inspection Authorities.

Introduction:
Products that are eligible for Special Inspections under this service are as stated in the clause 1.2 of SPE-3000-15, which are represented in the Attachment 1.

Background and Rationale:
The Special Inspection Service was developed to address the need for an electrical safety evaluation on unapproved Medical Equipment. The Model Code addresses the minimum requirements for Medical Electrical Equipment and Medical Electrical Systems as they pertain to electrical safety. Equipment in compliance with the requirements and bearing the Special Inspection Service label shall be considered acceptable to the AHJ. The label is represented in the Attachment 2.

Effective
The requirements contained in SPE-3000-15 will be used for the field evaluation of Medical Electrical Equipment and Medical Equipment Systems commencing December 8, 2016.

Direction
Clients that submit products for Special Inspection after the Effective date will have their products assessed to SPE-3000-15.

For questions specific to your file or products contact your CSA Group technical staff associate.
Go to http://www.csagroup.org/services/testing-and-certification/certified-product-listing/ and enter your Master Contract # and the class numbers associated with this Informs to view your certified products.

For technical questions on this Informs
Contact Randy Wyrha
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ATTACHMENT 1

Major Revisions

1.1
This Model Code applies to the basic safety of MEDICAL ELECTRICAL EQUIPMENT (MEE) and MEDICAL ELECTRICAL SYSTEMS (MES). 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 code are not covered by specific requirements in this 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 or subassemblies 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, 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.
ATTACHMENT 2

Special Inspection – SPE-3000

Sample: Special Inspection Service label for Electrical – Medical Equipment