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ELECTRICAL BULLETIN
2016-01

From: David MacLeod, C.E.I., P. Eng.
Provincial Chief Electrical Inspector

Date: July, 2016

Subject: **Adoption and Enforcement of the CSA Model Code SPE-3000-15**
Field Evaluation of Medical Electrical Equipment and Medical Electrical Systems

The first edition of the **CSA Model Code SPE-3000-15**, **Model Code for the Field Evaluation of Medical Electrical Equipment and Medical Electrical Systems** has been published by the Canadian Standards Association.

Where medical electrical equipment or systems have not received full certification by a Certification Organization the equipment may receive a field evaluation (special inspection) by an Inspection Body (IB) within the limitations and conditions as described in this Bulletin and will be considered approved and acceptable for sale and use in Nova Scotia by the Provincial Chief Electrical Inspector.

The following are scenarios of where this Model Code may apply:

(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 IB
(d) equipment not obtainable as “certified” under a regular certification program
(e) equipment already installed or ready for use on-site and is not certified
(f) complete systems or subassemblies; or
(g) as permitted by the Provincial Chief Electrical Inspector (PCEI)

Note: *Where it is unclear or there is any uncertainty as to whether any equipment can be field evaluated under the classifications of the above identified scenarios, the PCEI should be consulted for clarification prior to the sale, purchase, installation or use of any such item.*

Effective **July 25th, 2016** the field evaluation of any medical electrical equipment or medical electrical systems in NS shall only be performed by an IB and in accordance with the Model Code SPE-3000-15 and any limitations and conditions as identified within this Bulletin.

Products that are evaluated to the requirements of the Model Code SPE-3000-15 must be marked with a recognized field evaluation label that identifies the product as being approved under this program.

Field evaluation of medical electrical equipment or systems to the Model Code is not the equivalent to certification, and therefore equipment and products that have been field evaluated and labelled under the SPE-3000 program cannot be claimed to be certified.

Using the field evaluation program is not a means to bypass the full certification process and therefore a limit of no more than 30 pieces of the same type of medical electrical equipment or systems may receive a field evaluation under this program per year within NS. The limit applies to the sale, installation or use of medical electrical equipment or systems by any person, contractor, owner, facility, organization, association, business, company, institution, health authority or similar such group.

Any non-certified medical electrical equipment or medical electrical systems must receive a field evaluation prior to being sold where the company is located within NS and any medical electrical equipment or system must be approved prior to being energized.

Any exemption to the requirements identified within this Bulletin must be obtained from the PCEI prior to the sale, installation or energization of any piece of medical electrical equipment or medical electrical system.

Any person or company within NS found selling non-certified or non-approved medical electrical equipment or systems may be charged with a summary offence and the installation of such equipment or systems found not to be certified or approved may be ordered disconnected.

Any IB found not to be in compliance with the requirements of this bulletin or any other direction provided by the PCEI may be refused further acceptance of their field evaluation services for NS.

The Provincial Chief Electrical Inspector may impose additional requirements or conditions in addition to the SPE-3000-15 requirements to allow any item to be sold or installed in NS that utilizes the field evaluation program for approval.

Notes:

1. Health Canada may require that certain medical electrical devices have the manufacturer be licensed in order to sell the device in Canada.

2. A manufacturer licensed by Health Canada to sell certain medical electrical devices does not imply that the device(s) they are selling are approved for electrical safety and unless the device has a separate label to indicate it is approved for electrical safety the device may not be sold or used in NS.

Definitions:

1) Certification Organization - an organization accredited by the Standards Council of Canada and is recognized by the Provincial Chief Electrical Inspector to certify electrical equipment in accordance with the appropriate standards.

2) Inspection Body-for the purpose of this Bulletin is an organization accredited by Standards Council of Canada and is recognized by the Provincial Chief Electrical Inspector to approve medical electrical equipment or medical electrical systems by performing field evaluations in accordance with the requirements of SPE-3000-15 Model Code and this Bulletin.

The Provincial Chief Electrical Inspector makes the final determination as to the allowance and acceptance of any item sold or installed that is approved under this program.

The Provincial Chief Electrical Inspector may amend, revise or delete any of the above requirements of this Bulletin at any time in the future.

**Any questions or request for a deviation or clarification regarding this bulletin may be forwarded to the Provincial Chief Electrical Inspector David MacLeod, P.Eng. @ 902-424-8018 or email: David.MacLeod@novascotia.ca