IECEE OD-2055

Edition 2.1~~0~~ 201~~7~~5-0~~2~~25~~6~~-1~~7~~03

IECEE
OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Guideline Document on Medical Electrical Equipment in the CB Scheme according to the IEC 60601 and IEC/ISO 80601 Series of Standards

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

Useful links:

IEC publications search - www.iec.ch/searchpub

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,...).
It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.
Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

IECEE OD-2055

Edition 2.01 20152017-036-0301

IECEE
OPERATIONAL DOCUMENT

IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System)

Guideline Document on Medical Electrical Equipment in the CB Scheme according to the IEC 60601 and IEC/ISO 80601 Series of Standards

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE ZZ

CONTENTS

~~Foreword~~

FOREWORD

Document Owner

~~CMC TF RMTF~~CTL ETF 3

Date	Brief summary of changes
2017-03-01	Update to document based on CMC Decision 055/2015

Effective Date	**Target Revision Date**
2017-05-17	2020-05-17

~~This Guideline Document has been prepared by the IECEE MEE RM Task Force. It contains current CMC Decisions that are relevant to the evaluation of medical electrical equipment in the CB Scheme.~~

1 General

1.1 Scope

This Operational Document (OD) addresses:

– The application of the Collateral and related Standards for medical electrical equipment when issuing a CB Test Certificate and Report according to the IEC 60601 and IEC/ISO 80601 Series of Standards.

– It defines the minimum expectations for Collateral standards to be applied in the investigation of medical electrical equipment submitted for the purpose of obtaining a CB Test Certificate.

– It addresses the application of Risk Management for Power Supplies used in Medical equipment.

1.2 Purpose

The purpose of this OD is to provide instructions to all parties involved in issuing CB Test Reports and Certificates for medical electrical equipment and to ensure the consistent application of IECEE CB Scheme requirements in order to facilitate the acceptance of CB Test Certificates among IECEE members.

2 Use of Collateral and Related Standards in CB Test Reports according to the IEC 60601 and IEC/ISO 80601 Series of Standards

2.1 General

The IEC 60601 series of standards contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. As noted in Clause 1.3 of IEC 60601-1, applicable collateral standards are normative at the date of their publication and are to be applied together with the general standard.

2.2 Use of Collateral Standards for IECEE Certification

Currently, manufacturers of MEDICAL ELECTRICAL EQUIPMENT may apply for IECEE CB Scheme Test Certificates to three different editions of the IEC 60601 family, specifically: Edition 2, Edition 3 and Edition 3 with Am. 1. Because the collateral and related Standards include special requirements for application to MEDICAL ELECTRICAL EQUIPMENT, they are normative when applicable. However; IECEE has established protocols for certification and data exchange for select collateral and related standards, allowing NCBs to exclude some of these standards as part of the CB Test Report. In cases where the compiled CB Test Report does not include reports for these selected standards, the verification of compliance rests with the manufacturer.

2.3 Collateral Tables

Tables specifying the collateral and related standards that are normative for IECEE certifications to the various editions of the IEC 60601 and IEC/ISO 80601 Series of Standards are specified in the Annexes A, B and C to this OD as follows:

Annex A - Use of Standards in the IECEE system according to the IEC 60601-1 2nd edition;

Annex B - Use of Standards in the IECEE system according to the IEC 60601-1 3rd edition;

Annex C - Use of Standards in the IECEE system according to the IEC 60601-1 3rd edition with Am. 1

3 CERTIFICATION OF POWER SUPPLIES ACCORDING TO IEC 60601-1: 2005 and IEC 60601-1:2005 with Am.1:2012

3.1 General

For this section, the following definitions apply:

Component Power Supply – A power supply that is incomplete and cannot be used without incorporation into a ME/MES (e.g. Open Frame Power Supply with no enclosure).

Stand-Alone Power Supply – A power supply that is a complete device, provided with a connection to a SUPPLY MAINS (e.g. appliance inlet or power supply cord) and a full enclosure that is intended to be used without modification or incorporation into an ME/MES (e.g. “brick” power supplies, direct plug-in power supplies).

The IECEE MEE RM Task Force considered the issue of certification of stand-alone and component power supplies that may be incorporated into medical electrical equipment which are intended to be certified to IEC 60601-1:2005, 3rd Edition and IEC 60601-1:2005 with Am.1: 2012.

3.2 Possible certification scenarios:

1) A component power supply may be certified to a number of standards other than IEC 60601-1, 2005. If that component power supply is subsequently incorporated into a medical electrical equipment or system, the complete equipment including the power supply will be evaluated for certification against all applicable clauses/requirements of IEC 60601-1: 2005 or IEC 60601-1: 2005 with Am. 1:2012, including all applicable risk management requirements.

2) A component power supply can be issued its own CB Test Certificate to IEC 60601-1:2005, 3rd Edition .and IEC 60601-1:2005, 3rd Edition with Amendment 1. :Where the supplier does not perform a Risk Management Process as required by IEC 60601-1

   The CB Test Certificate shall have the Risk Management Process exclusion clearly stated (see note below);

– All applicable type testing required for component power supplies shall be performed;

– In cases where compliance with a requirement relies entirely on Risk Management Process, the component power supply manufacturer must provide documentation indicating how the relevant clauses were addressed (for example, IEC 60601-1: 2005, Clauses 8.10.1, 8.10.2, 8.10.5, and 8.11.5);

– Partial application of the Risk Management Process is not permitted. If the Risk Management Process is used to modify/reduce any requirement in the standard then the Full Risk Management Process must be performed using the entire standard IEC 60601-1:2005, 3rd Edition or IEC 60601-1:2005 with Am.1:2012, as applicable.

  Note: The following wording must be used on the Certificate when the risk management process was not assessed:: “The risk management requirements of the standard were not addressed.”

3) Power supplies meant for specific use in Medical Electrical Equipment (e.g. Medical Grade High Voltage Power Supplies/Generators for X-Ray Equipment) must additionally meet the applicable requirements from relevant particular standards (e.g. IEC 60601-2-43, IEC 60601-2-54).

4) If a ~~stand-alone~~standalone power supply is submitted for CB Test Certificate against IEC 60601-1, 2005 or IEC 60601-1-2005 with Amendment 1, it shall be evaluated against all clauses/requirements of the standard that are applicable for that device. This will include the full Risk Management Process using the entire standard IEC 60601-1:2005, 3rd Edition or IEC 60601-1:2005 with Am. 1:2012, as applicable.

3.3 Additional considerations for certification of stand-alone and component power supplies – Application of Annex B or ~~Annex C~~Annex C as applicable.

Component power supplies may also be exempt from the requirements of Annex B or Annex C as applicable, provided any applicable collateral standards not evaluated are specifically

indicated on the Certificate using the following or equivalent wording: “Compliance with IEC 60601-1-XX was not evaluated for the models covered by this Certificate.”

Stand-Alone power supplies are subject to the requirements of Annex B or Annex C as applicable and all applicable collateral standards must be applied except as noted in Annex B or Annex C, as appropriate.

4 CERTIFICATION OF COMPONENTS ACCORDING TO IEC 60601-1: 2005 and IEC 60601-1:2005 with Am.1:2012

The IECEE MEE RM Task Force considered the issue of certification of components that may be incorporated into medical electrical equipment which are intended to be certified to IEC 60601-1:2005, 3rd Edition and IEC 60601-1:2005 with Am.1: 2012.

At the present time, only component power supplies have established methods for handling these issues which have been formalized through a CMC Decision (See Clause 3 of OD 2055) .

It is noted that there are generally two cases of medical-specific components:

1. Those where a Particular Standard (IEC 60601-2-XX) explicitly addresses and establishes requirements for sub-assemblies, accessories and similar modules, as illustrated by the following examples:

    - IEC 60601-2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

    - IEC 60601-2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (Scope includes X-RAY TUBE ASSEMBLIES and components thereof)

2. Those where a Particular standard currently does not explicitly address and establish requirements for sub-assemblies, accessories and similar modules, as illustrated by the following examples:

    - IEC 60601-2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

    - IEC 60601-2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use

From a Certification perspective, it is only possible to formalize the method of handling Risk Management and Essential Performance of the Case 1 components, due to the fact that explicit requirements exist in a Part 2 Standard. It may be possible to address the Case 2 components at some time in the future, pending development of formal requirements by the associated IEC Technical committee responsible for the Part 2 standard involved.

For the Case 1 components, the RM Task Force recommends the following to establish consistent practices in Certification:

1.1 Test Report Forms for the involved Part 1 and Part 2 standard are mandatory and must be applied in full.

1.2 What can and cannot be excluded and how to report it -

- The CB report must address all applicable clauses involving basic safety and safety testing. All practical testing would need to be conducted, such as input, heating, leakage current, component failure, dielectric, etc.

- Clauses involving Essential Performance should be marked N/A, and the TRF should clearly indicate that Essential Performance was not considered under the general section of the report, unless the component is a stand-alone device where the aspect of the standard can be applied. Further, the TRF shall state that it is the responsibility of the end-product manufacturer to consider Essential Performance aspects of the component as it is applied in the end-equipment (see 1.3 below).

- Any requirement from the Part 1 or Part 2 standard for which compliance cannot be verified due to the nature of the component should be marked N/A and it must clearly indicate that this requirement must be addressed in the end-product, (example, component has no enclosure and will rely on the end product enclosure to satisfy accessibility requirements).

1.3 Disclaimer on CB Test Certificate –

- The CB test certificate would have to indicate that essential performance was not evaluated. The only exception to this would be if the accessory was a stand-alone device, where it is possible to assess essential performance on the accessory alone and where the accessory would not impact the overall systems essential performance.

- Typical statement on the certificate should read: “Essential Performance of this component was not evaluated”.

For the Case 2 components, the RM Task Force recommends the following to establish consistent practices in Certification:

A CB Test certificate is not allowed for components where the Particular standard does not explicitly address and establish requirements for sub-assemblies, accessories and similar modules

Annex A - Use of Standards in the IECEE system according to the IEC 60601-1 2nd edition

IEC 60601-1 2nd edition (including Am. 1 & Am. 2) for Medical Electrical Equipment – Part 1: General Requirements for Safety	Collateral and Related standards Required to be included in CBTC		Acceptable to issue a separate CBTC and CBTR	
Standards	**Yes**	**No**	**Yes**	**No**
IEC 60601-1-1, ed. 2:2000, Medical electrical equipment - Part 1-1: General requirements for Safety - Collateral standard: Safety requirements for medical electrical systems	X			X
IEC 60601-1-2, ed. 2:2000 and Am.1:2004, Medical electrical equipment - Part 1-2: General requirements for Safety - Collateral standard: Electromagnetic compatibility - Requirements and tests		X	X	
IEC 601-1-3, ed1:1994 Medical electrical equipment - Part 1-3: General requirements for Safety - Collateral Standard: Radiation protection in diagnostic X-ray equipment	X			X
IEC 60601-1-4, ed1:1996 and Am.1:1999, Medical electrical equipment - Part 1: General requirements for Safety - Collateral standard: Programmable electrical medical systems		X		X
IEC 60601-1-6, ed1:2004, Medical electrical equipment - Part 1-6 General requirements for Safety - Collateral standard: Usability		X		X
IEC 60601-1-8, ed1:2003 and Am.1:2006, Medical electrical equipment - Part 1-8: General requirements for Safety - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	X			X
ISO 10993-1, ed. 3:2003 – Biological evaluation of medical devices — Part 1: Evaluation and testing		X		X

Annex B - Use of Standards in the IECEE system according to the IEC 60601-1 3rd edition

IEC 60601-1 3rd edition (2005-12)*, Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	Collateral & Related Standards Required to be included in CBTC		Acceptable to issue a separate CBTC and CBTR	
Standards	**Yes**	**No**	**Yes**	**No**
IEC 60601-1-2, ed. 3:2007, Medical electrical equipment - Part 1-2: General requirements for Basic Safety and essential performances - Collateral standard: Electromagnetic compatibility - Requirements and tests		X	X	
IEC 60601-1-3, ed. 2:2008, Medical electrical equipment - Part 1-3: General requirements for Basic Safety and essential performances- Collateral Standard: Radiation protection in diagnostic X-ray equipment	X			X
IEC 60601-1-6, ed. 2:2006 or IEC 60601-1-6, ed. 3:2010, Medical electrical equipment - Part 1-6 General requirements for Basic Safety and essential performance - Collateral standard: Usability - See Note 3 and 4~~Note: IEC 60601-1-6 edition 2 or edition 3 apply as determined by national requirements~~		X**		X
~~IEC 60601-1-6, ed. 3:2010, Medical electrical equipment - Part 1-6 General requirements for Basic Safety and essential performance – Collateral standard: Usability, and IEC 62366 ed.1:2007, Medical devices – Application of Usability Engineering to Medical Devices~~		~~X*~~		~~X~~
IEC 60601-1-8 ed. 2:2006, Medical electrical equipment - Part 1-8: General requirements for Basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	X			X
IEC 60601-1-9, ed. 1:2007, Medical electrical equipment - Part 1-9: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design		X		X
IEC 60601-1-10, ed. 1:2007, Medical electrical equipment - Part 1-10: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers	X			X
IEC 60601-1-11, ed. 1:2010, Medical electrical equipment - Part 1-11: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	X			X
ISO 10993-1, ed. 4:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process		X		X

~~*Note 1: Any CB Test Report addressing Collateral standards IEC 60601-1-11 and IEC 60601-1-8 requires Usability Engineering Process according to IEC 60601-1-6. This is due to the fact that the primary concern of home health care applications (IEC 60601-1-11) and alarms (IEC 60601-1-8) is whether the users and patients respond appropriately to the medical device equipment; this is mitigated through the Usability Engineering Process of the IEC 60601-1-6 standard.~~

~~Note 2: All applicable collateral standards must be included in the CB Test Report when applicable.~~

*Note 1: All collateral standards must be included in the CB Test Report as applicable.

**Note 2: Any CB Test Report addressing Collateral standards IEC 60601-1-8 and IEC 60601-1-11 requires Usability Engineering Process according to IEC 60601-1-6. This is due to the fact that the primary concern of alarms (IEC 60601-1-8) and home healthcare (IEC 60601-1-11) applications is whether the users/operators and patients respond appropriately to the medical electrical equipment; this is mitigated through the Usability Engineering Process of the IEC 60601-1-6 standard.

Note 3: Alternative editions (including amendments) of the standards listed above apply as determined by national requirements

Note 4: Applicable Clauses of IEC 62366 must be addressed in the CB Test Report for IEC 60601-1-6:2010 but IEC 62366 **is not** to be listed on the CB Test Certificate as certification standard together with IEC 60601-1-6. However, including IEC 62366 in “additional information” (for example by saying: *In addition, all applicable Clauses of IEC 62366 have be addressed*) is permitted.

Annex C - Use of Standards in the IECEE system according to the IEC 60601-1 3rd edition and Am.1

IEC 60601-1 3rd edition (2005-12), Am. 1 (2012)*, Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance	Collateral & Related Standards Required to be included in CBTC		Acceptable to issue a separate CBTC and CBTR	
Standards	**Yes**	**No**	**Yes**	**No**
IEC 60601-1-2, ed.3:2007 or IEC 60601-1-2, ed.4:2014, Medical electrical equipment - Part 1-2: General requirements for Basic Safety and essential performances - Collateral standard: Electromagnetic compatibility (ed.3) / disturbances (ed.4) - Requirements and tests - See note 3		X	X	
IEC 60601-1-3, ed.2:2008 or IEC 60601-1-3, ed.2:2008 and Am1:2013, Medical electrical equipment - Part 1-3: General requirements for Basic Safety and essential performances- Collateral Standard: Radiation protection in diagnostic X-ray equipment - See note 3	X			X
IEC 60601-1-6, ed.2:2006 or IEC 60601-1-6, ed.3:2010 or IEC 60601-1-6, ed.3:2010 and Am1: 2013, Medical electrical equipment - Part 1-6 General requirements for Basic Safety and essential performance - Collateral standard: Usability- See note 3 and 4 ~~IEC 62366, ed.1:2007 or IEC 62366, ed.1 and Am1:2014, Medical devices – Application of Usability Engineering to Medical Devices~~	X			X
IEC 60601-1-8, ed.2:2006 or IEC 60601-1-8, ed.2:2006 and Am.1:2012, Medical electrical equipment - Part 1-8: General requirements for Basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems - See note 3	X			X
IEC 60601-1-9, ed.1:2007 or IEC 60601-1-9, ed.1:2007 and Am.1:2013, Medical electrical equipment - Part 1-9: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design - See note 3		X		X
IEC 60601-1-10, ed.1: 2007 or IEC 60601-1-10, ed.1:2007 and Am.1:2013, Medical electrical equipment - Part 1-10: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers - See note 3	X			X
IEC 60601-1-11, ed.1:2010 or IEC 60601-1-11, ed. 2:2015, Medical electrical equipment - Part 1-11: General requirements for Basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	X			X
IEC 60601-1-12, ed.1: 2014: Medical electrical equipment - Part 1-12: General requirements for Basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	X			X
ISO 10993-1, ed.4:2009, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process		X		X
IEC 62304, ed.1:2006, Medical device software – Software life cycle processes – See Note 2	X			X

~~Note 1: All applicable collateral standards must be included in the CB Test Report when applicable~~

~~*Note 2: Applicable clauses of IEC 62304 must be addressed in the CB Test Report but the standard IEC 62304 is not to be listed on the CB Test Certificate~~

~~Note 3: Alternative editions (including amendments) of the standards listed above apply as determined by national requirements~~

* Note 1: All collateral standards must be included in the CB Test Report as applicable.

Note 2: Applicable clauses of IEC 62304 must be addressed in the CB Test Report but the standard IEC 62304 **is not** to be listed on the CB Test Certificate. However, including IEC 62304 in “additional information” (for example by saying: *In addition, all applicable Clauses of IEC 62304 have be addressed*) is permitted.

Note 3: Alternative editions (including amendments) of the standards listed above apply as determined by national requirements

Note 4: Applicable Clauses of IEC 62366 must be addressed in the CB Test Report for IEC 60601-1-6:2010 including Am. 1:2013 but IEC 62366 **is not** to be listed on the CB Test Certificate as certification standard together with IEC 60601-1-6. However, including IEC 62366 in “additional information” (for example by saying: *In addition, all applicable Clauses of IEC 62366 have be addressed*) is permitted.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

3, rue de Varembé
PO Box 131
CH-1211 Geneva 20
Switzerland

Tel: + 41 22 919 02 11
info@iec.ch
www.iec.ch

IEC SYSTEM OF CONFORMITY ASSESSMENT SCHEMES FOR ELECTROTECHNICAL EQUIPMENT AND COMPONENTS (IECEE)

IECEE Secretariat c/o IEC
3, rue de Varembé
PO Box 131
CH-1211 Geneva 20
Switzerland

Tel: + 41 22 919 02 11
secretariat@iecee.org
www.iecee.org