

IECEE

CB-SCHEME OD-

CB2020-Ed.1.7

OPERATIONAL & RULING DOCUMENTS

**TRF – Development,
maintenance and use**

OD-CB2020-Ed.1.7

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TRF – Development, maintenance and use

This TRF Manual has been prepared by the IECEE CMC TRF Working Group and approved by the Certification Management Committee (CMC) of the IECEE

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Part 1

General introduction to the TRF procedures

1.1 Scope

This Operational Document (OD) addresses various stages of Test Report Form (TRF) development, distribution, maintenances and use. It also includes various examples to illustrate the requirements.

1.2 Purpose

For the most part, this OD has been prepared to address the needs of TRF originators, TRF users and TRF administrators. The purpose of this OD is to guide all parties involved in the TRF procedures and to address the certification, data exchange and other IECEE community needs, as appropriate.

1.3 Definitions

Test Report Form (TRF) – A blank form prepared by the TRF originator according to Part 3 of OD CB 2020 and published according to Annexes G and H of this Operational Document.

TRF Originator – An NCB appointed by IECEE to develop a specific Test Report Form.

CB Test Report – A filled out Test Report Form (TRF), containing results of product investigation, measured test data and attachments per the list of attachments referring to supporting documents. (See Annex E for instructions).

1.4 Structure of OD CB 2020

The OD consists of six Parts and ten Annexes, which compliment each other and together describe the complete TRF process. Individual Parts may be used to serve a specific purpose, for example, Parts 4 and 5 address the needs of CB Test Report compilers.



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Part 2

Assignment and distribution process

2.1 Request for a TRF

The request for a TRF is basically made by an IECEE member, which has presumably received an application for testing and certification of product(s) falling under a determined standard. The request shall be addressed to the IECEE Secretariat in writing to the following email address: **sap@iec.ch**. Upon receipt, the IECEE Secretariat checks whether the requested TRF is:

- Already available;
- Available but requiring updates;
- In process of being originated/updated by an assigned IECEE member;
- Not available.

2.1.1. If the requested TRF is already available or in process of being originated/updated, the requesting IECEE member is notified by the Secretariat.

2.1.2. If TRF is not available or an update is needed but not available:

- a). In case the requested TRF is an update and has been previously assigned to or prepared by other member, the IECEE Secretariat will consult with that member prior to making any additional inquiries among participating NCBs.
- b). In case the originator is not able to update the TRF within a defined time frame, or there is no assigned originator for the TRF, the requesting IECEE member will be asked to originate the relevant TRF. However, as a pre-condition, the requesting member must have been accepted to issue CB Test Certificates based on the relevant IEC standard.
- c). If the requesting member is not prepared to develop the TRF, the IECEE Secretariat immediately starts a formal consultation among other members seeking an NCB willing to originate the missing TRF.

Note: *It is assumed that the NCB, which has got the application for certification purpose, will undertake the responsibility of originating the TRF, should the consultation made by the IECEE Secretariat among the IECEE members lead to a no-offer. In case no originator can be found, the requesting member is expected to drop the TRF request.*

2.2 Appointment of TRF Originator

The IECEE Secretariat will formally appoint an IECEE member as a TRF Originator according to a), b) or c) above, as appropriate.

The originator will develop the assigned TRF following the requirements in Part 3.

2.3 TRF Distribution of new and modified TRFs

Once the appointed originator completed the TRF, the originator forwards the relevant TRF in MS Word format to the IECEE Secretariat via email. See Annex H.

The TRF originator shall advise the IECEE Secretariat whether the TRF should be distributed via regular or via simplified procedure (See Annex G and clause 6.3 for details).



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2.4 TRF Trial and Comment Period

New TRFs that are not distributed via simplified procedure can be used on a trial bases for three to six months. IECEE distributes the TRF to members and publishes on the IECEE Website as a provisional TRF.

During the trial and comment period, users are expected to provide feedback to the IECEE Secretariat (See Part 6). IECEE Secretariat informs the TRF originator about the findings and requests that comments be addressed, when appropriate.

For new or updated TRFs, the IECEE Secretariat will verify the correct Test Report Reference Number, layout, editing, etc prior to publishing the TRF in the relevant areas of both, the IECEE Web Site for the members and the IEC Web Store for outsiders, or return to the originator for corrections.

The IECEE Secretariat informs the IECEE members about the publication through e-mails each time a new TRF(s) are posted on the IECEE Web Site and IEC Web Store.

Part 6 of this OD describes the process addressing users' requests for modifications to the content of a TRF, as well as, administrative changes.

Annexes G and H describe the procedure for TRF modification requests and distribution.

2.5 Simplified procedure for TRF distribution

The simplified procedure for TRF distribution is described in Clause 6.4 and in Annex G.



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Part 3 Guidelines on how to prepare new TRFs

3.1 General rules

The originator shall always use [the latest TRF template](http://www.iecee.org/cbscheme/html/cbtrep.htm) available on the IECEE Website. (<http://www.iecee.org/cbscheme/html/cbtrep.htm>). This applies to the TRF itself and to the National Differences TRFs.

3.1.1. As a basic rule, one TRF covering IEC requirements shall be developed. For the EN standard an EN Annex covering EN Differences shall be attached to the IEC TRF. If a separate TRF according to the EN standard is necessary due to a considerable number of EN Differences, this shall be agreed with the IECEE Secretariat.

3.1.2. The EN Annexes and in specific situations, EN TRFs respectively, shall be prepared by the originator located within EU countries, which might result in a different originator for the IEC Test Report Form and for the Annex with EN Differences. The originator shall always use the latest EN Differences and National Differences templates available from the IECEE Website.

3.1.3. In general, a separate TRF shall be prepared for Part 1 and for each Part 2 standard. However, the originators may choose to prepare a TRF for a combined Part 1 and one or more Part 2 standards (Example: IEC 60335 and IEC 60598 Series). For uniformity of all TRFs in a particular series of standards, the originator shall always start with the approved Part 1 TRF, when available, and incorporate into it Part 2 requirements (See Clause 3.7.3).

3.2 Formatting requirements

The following formatting and identification instructions shall be taken into account when preparing new or modifying old test report forms (TRF):

File format:	MS Word format "97-2002 + 6.0/95 - RTF" or "97-2003 + 6.0/95 - RTF"
Font:	Normal text: Arial 10 pt (True Type) Special characters (e.g. °, Δ): Symbol (True Type)
Paper size:	A4 (210 x 297 mm)
Margins:	Top 2 cm, Bottom 2 cm, Left 3 cm, Right 1 cm (standard margins) Optional: Left 2 cm, Right 2 cm (CBTL using double sided printing may modify the margins)
Language:	English (UK)

3.3 Identification of the IEC Standard, TRF number and Master TRF

The TRF standard shall be identified on the front page as follows:

Standard: IEC 6xxxx - x-xx: YEAR (xx Edition)

For Part 2 TRF the above shall be followed by the reference to the correct Part 1.

Examples:

- IEC 60601-2-2:2006 (Fourth Ed.) for use in conjunction with IEC 60601-1 (1988), Amts 1 (1991) and 2 (1995)
- IEC 60601-2-22: 2007 (Third Ed.) for use in conjunction with IEC 60601-1: 2005 (Third Edition)
- IEC 60335-2-4:2002 (5th Ed.) and IEC 60335-2-7:2002 (6th Ed.) for use in conjunction with IEC 60335-1:2001 +A1:2004



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Test Report Form Number:

The TRF Number providing reference to the IEC standard shall be identified on the front page. A letter code shall be added to the number to identify the TRF version.

The format of the TRF identification shall include the following elements:

IEC6xxxx_x_xxx followed by suffix letter

Examples:

- IEC60950_1F: means a TRF for IEC 60950-1, TRF version “F”
- IEC60601_2_22C means a TRF for IEC 60601-2-22, TRF version “C”
- IEC60335_2_4&7D: means a TRF for IEC 60 335-2-4 and IEC 60 335-2-7, TRF version “D”
- IEC60335_2_23B_delta: means a TRF for IEC 60 335-2-23 covering differences between version “A” and version “B” (See Clause 3.7.1).
- IEC60950_1&IEC60601_1A: means a TRF covering two different standards IEC 60950-1 and IEC 60601-1, TRF version “A” (see Clause 3.7.2).
- EU_GD_IEC60335_2_14F means a TRF covering European Group Differences for IEC60335-2-14 version “F” (see Clause 3.4.5)
- US_ND_IEC60065_7th.ed.am.1 means a TRF covering US National Differences for IEC60065, 7th ed. with am.1 (see Clause 3.4.5)
- MY_ND_IEC60065_7th.ed means a TRF covering Malaysian National Differences for IEC60065 TRF, 7th ed.

Note: *The suffix letter in the TRF identification number is reserved for a version and is added by the TRF Originator. (In case of doubt, the IECEE Secretariat acting as the TRF Administrator will verify the correctness of the TRF number).*

Master TRF: The date of Master TRF shall be the date of TRF publication. See also Clause 6.3.7.

3.4 TRF structure

A Test Report Form must be easy to fill in and shall not include macros, except for the Test Report Number and the page numbers. Check boxes may be used as allowed by the TRF template. The originator may add protected fields but only if necessary. See instructions in Annex A.

A blank Test Report consists of four sections as specified below. The Testing Laboratory always completes the first four sections including the critical components (section four). (See Annex E). If National Differences are included during product investigation (see clause 3.4.4) then an attachment covering National Differences shall also be completed.

3.4.1. General information section (Section 1 of the TRF)

The first section is a cover page – applicable to all Test Reports - that contains the general information, such as names and addresses of Testing Laboratory and Applicant/Client, Report reference number, standard used, TRF number, product name and product rating, trademark and other information.

An example of the first page of TRF is shown in Annex C.

Pages that follow the cover page (normally three or more pages) contain specific information related to testing procedure and testing locations, list of attachments, product under testing, investigated National Differences, general tests and samples information.

An example of information pages can be found in Annex C.



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3.4.2. Compliance checklist (Section 2 of the TRF)

This section of the TRF is a standardized section consisting of a checklist, referencing clause by clause the requirements of a particular IEC standard.

Note 1: *Sub-clauses that are explanatory notes do not need to be detailed in the checklist.*

The compliance checklist section is formatted into 4 columns. For practical reasons each column heading (below) appears as a table heading on each page of this section, e.g. the whole section may be one table and the table heading is repeated at the beginning of each page. When this is not practical, the table may be split into several smaller tables, however, **the headers are repeated on each page.**

Cl.	Requirement - Test	Result	Verdict
-----	--------------------	--------	---------

In order to fully utilize the available space on each page, the typical width of each cell in the test case section shall be as follows: 2 cm, 8.3 cm, 5 cm and 1.6 cm. (Note: A4 page width is 21 cm, margins 4 cm and about 0.1 is left for lines width).

Cl./Clause: a reference to the standard's clause or sub-clause

Note 2: *Identical clause numbers of subsequent test cases are not repeated (printed) in the compliance checklist table.*

Requirement – Test: a summary of the requirement and/or an abbreviated description of a test.

Different test case types may be presented in one of the following ways (each type is followed by an example).

3.4.2.1. Test case types

Heading

Cl.	Requirement - Test	Result	Verdict
30	CONSTRUCTION		

Sub-heading

Cl.	Requirement - Test	Result	Verdict
10.5	Markings for Class II appliances		Pass

Regular test case

Cl.	Requirement - Test	Result	Verdict
21.1.1	Marking on main part		Pass

When regular test case requires a specific result or comment in addition to the verdict, it needs to be identified by a dotted leader as in the example below:



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Cl.	Requirement - Test	Result	Verdict
20.5	Length \geq 10 m :	12,5	Pass

Auxiliary test case, not requiring a verdict but additional information only, needs to be identified by a shaded verdict field (shading is 12.5% gray):

Cl.	Requirement - Test	Result	Verdict
3.2.1	Test temperature ($^{\circ}$C)..... :	23,5	—

3.4.2.2. Results and verdicts

Result: Any information that results from column 2, such as a measured value, a remark or an explanation, if applicable.

Verdict: A judgment resulting from analysis of columns 2 and 3. Allowed verdict choices are:

Pass
Fail
N/A **(Not applicable)**

3.4.3. Measurement section (Section 3 of the TRF)

This section contains tables with the measured values, specific test conditions, test remarks and additional testing information. All measurement tables shall have supplementary information field at the bottom of the table to provide room for clarification of test parameters. An example of a measuring section is shown in Annex C and Annex E.

3.4.4. Critical components and/or materials section (Section 4 of the TRF)

A table describing critical components and/or materials is an integral part of each TRF. The Critical Components and Materials table shall be the last section after the measurement section to assist in prompt identification of component information in the Test Report. This table has only the title and no number. It can have two styles of rows. The first style has six columns:

- a). Object / part No. => name of component or identifier, for example mains switch, T10, C3, F1 (ID of the components on schematics, wiring diagrams, and similar), main enclosure, bottom plate, terminal pins....
- b). Manufacturer/trademark => the manufacturer's name shall be specified, except for some materials (for example metal plate, heat sink, terminal pins) or for generic components specified in CTL Decisions, such as PWB.
- c). Type / model => When applicable, a designation that allows identification of the component
- d). Technical data => relevant ratings and/or characteristics for components that are critical for compliance with the standard (for example the following may apply but is not limited to electrical component ratings, material thickness, flammability rating and similar)



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- e). Standard => Applicable IEC or National harmonized component standard, or product standard if investigated as part of the product
- f). Mark(s) of conformity => Provided evidence ensuring the agreed level of compliance. See OD-CB2039.

The second row style is to allow more space for additional information. This row consists of two columns: "Description" and a free text field.

A typical component table has the following layout:

TABLE: List of critical components					
Object/part No.	Manufacturer/ trademark	Type/model	Technical data	Standard (Edition / year)	Mark(s) of conformity ¹⁾
- Description:					
Supplementary information: 1) Provided evidence ensures the agreed level of compliance. See OD-CB2039.					

Note: The free text field provides additional space for information that may not fit in the standard cell format. The use of this row is optional, and when used, it is always in conjunction with the object/part number specified in the row above it. A completed table is provided in Annex E.

3.5 Standardized attachments

3.5.1 National Differences (when applicable)

a). This attachment is used for National Differences requirements. The National Differences Test Report Forms are structured as described in Clause 3.4.2 except a unique cover page is used for National Differences TRFs. A measurement section may also be included (as in clause 3.4.3) when needed to record specific measurements.

Note: By National Differences it is meant National Differences, Group Differences and Special National Conditions. Normally, the National Differences TRFs are provided by Member Bodies at the time of the Acceptance of Standards used in the IECEE CB Scheme as the basis for the national certification or are prepared by the originator appointed by IECEE Secretariat.

b). Countries listed in the "Summary of compliance with National Differences" field may only include those countries for which either a completed National Differences TRF is attached or those countries that declared no National Differences.

c). When the investigation covers more than one edition of the standard, a TRF that includes the requirements from more than one standard edition may be used (see clause 3.7). In this case the attached National Differences TRFs may also address National Differences to more than one edition of the standard as applicable for the target countries requested by the Applicant.



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d). Individual National Differences TRFs may be combined into one attachment with all pages numbered sequentially or each National Differences TRF might be placed one after the other, however, the list of attachments must include the list of all National Differences TRFs attached. A separate National Differences TRF for Part 1 and Part 2 Standards may also be combined into one attachment with all pages numbered sequentially.

Examples of TRFs for National Differences are shown in Annex C and in Annex E.

3.5.2. List of Test Equipment (when applicable)

The CB Test Reports generated under Manufacturer's Testing Programs, TMP and WMT shall contain an attachment, listing test equipment utilized during the testing. The equipment list is optional for SMT and RMT programs.

Note: Annex C and E include an example of the required attachment for testing conducted under the manufacturer testing programs, TMP and WMT. The form is optional for SMT and RMT programs. Other forms with a different layout but containing corresponding information are also acceptable.

3.6 Instructions for TRF originators

3.6.1. The "Requirement – Test" column in the TRF is a summary of the requirement. The full text of the standard shall not be repeated.

3.6.2. All pages of the Test Report Form shall be numbered continuously with the total number of pages indicated.

3.6.3. The TRF is a part of the conformity assessment, therefore, the wording used in the "Requirement – Test" column needs to be simple and needs to prompt for a clear "Pass", "Fail" or "N/A" verdict. (Acceptable verdicts are also repeated in the [TRF template](#)).

3.6.4. Words such as "shall" and "should" are normally reserved for requirements and recommendations in the standard, respectively. Since the Test Report requires a confirming verdict for each clause, it is necessary to use indicative rather than imperative phrases when abbreviating the requirements.

*(Example:
Instead of: "Time-delay fuse shall be used", the correct wording in the TRF states "Use of time-delay fuse".)*

3.6.5. Sub-header style in the TRF should be used when many regular test cases apply to the same header. However, the use of too many sub-headers in a sequence without any regular test case entries that follow the sub-headers should be avoided when possible. It makes the TRF too lengthy, difficult to handle and computerize.

3.6.6. Special care must be taken to avoid situations in which a "Fail" verdict in the Test Report could be acceptable in overall product compliance.

*(Example:
Provided example is based on the IEC 60950, Third Edition.
The standard calls for a flammability test and allows repeating that test or running an alternate test in case of a failure. Therefore, the "Fail" verdict would be entered in the TRF for the first test, in which the failure occurred. In order to avoid this situation, the TRF originator must design the report form in such a way as to avoid the negative results. This could be accomplished by any of the methods presented below or similar, equally effective.)*



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3.6.6.1. TRF may provide instructions for CBTL in the “Remarks” column:

A.6	Flammability tests for classifying materials V-0, V-1 or V-2		Pass
A.6.1	Samples, material..... :	Material designation FR-556	—
	Wall thickness (mm)..... :	0.5	—
A.6.5	Flammability test compliance criteria	Note: This clause is not applicable if test per A.6.6 was conducted	N/A
A.6.6	Permitted re-test	All samples of the second set met the relevant criteria.	Pass

3.6.6.2. TRF may combine both tests in one clause and a comment can clarify the testing.

A.6	Flammability tests for classifying materials V-0, V-1 or V-2		Pass
A.6.1	Samples, material..... :	Material designation FR-556	—
	Wall thickness (mm)..... :	0.5	—
A.6.5 A.6.6	Compliance criteria and permitted re-testing	All samples passed the permitted re-testing.	Pass

3.6.6.3. TRF may utilize "type 3 verdict" (Auxiliary test case, requiring additional information but not a verdict):

A.6	Flammability tests for classifying materials V-0, V-1 or V-2		Pass
A.6.1	Samples, material..... :	Material designation FR-556	—
	Wall thickness (mm)..... :	0.5	—
A.6.5	Flammability test..... :	Add comment as appropriate	—
A.6.6	Permitted re-test..... :	Add comment as appropriate	—
	Compliance criteria for flammability tests and re-tests		Pass

3.7 TRF Originator’s responsibility before submitting Test Report Form to IECEE

- 3.7.1 Care must be taken to avoid common TRF mistakes before submitting the TRF to IECEE for distribution to members.
- 3.7.2 The originators are expected to validate the TRF using the checklist for TRF Originators (See Annex B).

3.8 Special case TRFs

Special case TRFs are only developed when IECEE members have identified market needs. They are not applicable and /or practical for all product categories.



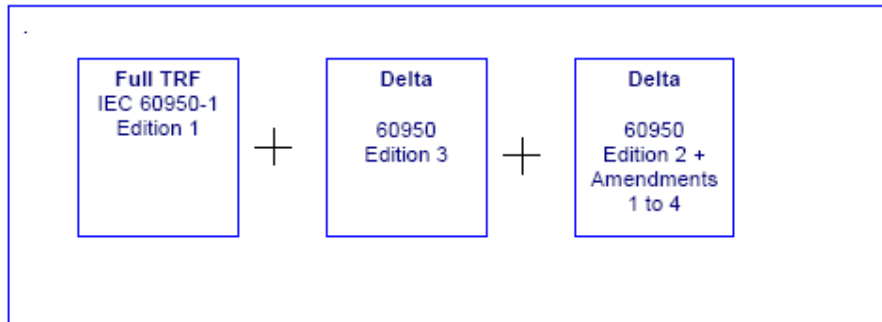
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3.8.1 Generating integrated TRFs covering different editions of the same standard

Note: Model 3 TRF described in Document IECEE CMC/509/RMC.

3.8.1.1 In order to efficiently cope with situations where manufacturers target the worldwide market and wish to seek a CB Test Certificate that covers more than one edition of a particular standard (e.g. IEC 60950-1, First edition and IEC 60950, Third edition and IEC 60950, Second edition with Amendments 1-4), a TRF that includes the requirements from more than one standard edition may be developed.

- a) The structure of the TRF (shown here based on the example of IEC 60950) shall be as follows:



- b) Full TRF is based on the latest standard edition
c) Delta TRFs include the requirements from the previous edition(s).

3.8.1.2 Rules for the preparation of Delta TRFs:

- a) If the latest edition has more stringent requirements, the Delta TRF does not need to list these requirements
b) If an alternate or new test method is in the latest edition, the old test method needs to be included in the Delta TRF
c) The Delta TRF shall always contain more stringent requirements not existing in the latest edition.

Note: If there are conflicting requirements in the previous and the new edition, or when the product cannot meet the more stringent requirements in the new edition, the NCB must use the TRF for the previous edition of the standard. The use of Delta TRFs is not allowed in this case.

3.8.1.3 Proposed wording when completing Delta TRFs:

In case the TRF originator feels that for the clarity of the overall Report, the Delta TRF should contain clauses that are already included in the new edition TRF, the following wording may be used when completing the Delta TRF:

"Compliance with Clause XX of the new edition of the standard fulfils the requirements of this Clause."

3.8.1.4 TRF identification:

The Delta TRF is identified by suffix "delta" added to the TRF reference number according to Clause 3.3.



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Example: The suffix “delta” added to the “B” version means a TRF, which covers differences between version “A” and version “B” of the corresponding editions of the IEC standard.

3.8.2. Generating integrated TRFs covering two different standards

3.8.2.1 This type of product combination TRF benefits particular segments of some industries where there is a need to have the identical device complying with more than one IEC standards.

Note: *An example within the medical industry includes power supplies, which often need to comply with two safety standards, IEC 60601-1 for Medical products and IEC 60950-1 for IT products. Typically, these are IT equipment and associated power supplies that will need to additionally comply with IEC 60601-1 either due to a specific application or in consideration of the manufacturer’s desire for broader market access.*

3.8.2.2 Product combination TRFs are supplements to the existing TRFs based on a product and not on a single IEC standard; they may be developed across various categories.

3.8.2.3 When creating a product combination TRF, one standard is selected as the main standard. The selected main standard shall cover the majority of the required tests.

Example: IEC 60950-1 selected as main standard and supplement TRF for combination with IEC 60065, or IEC 60601-1, or IEC 61010-1.

3.8.2.4 TRF Originator shall identify the most severe requirements in all applied standards and eliminate Clauses that are not applicable to the investigated product.

3.8.2.5 The originator shall identify common requirements to avoid duplication in the supplementary TRF.

3.8.2.5 Any additional requirements that address the use (for example: outdoor use, high altitude use, hospital environment or other application considerations) are to be identified and included in the combination TRF.

3.8.2.6 The combination TRFs shall be so designed that the supplemental Annex can only be used for a specific product it has been prepared for and together with the main standard TRF.

3.8.2.7 Cross references as in the example below are acceptable.

In a supplement TRF developed to include IEC 60601-1 requirements for product investigated according to IEC 60950-1:

Clause	Requirement + Test	Result - Remark	Verdict
1.1.1	Test name (for example input test)	See Test Report for IEC60950-1	Pass

3.8.2.8 To ensure the acceptance of product combination TRFs by Receiving NCBs, the appointment of TRF originator and the distribution of TRF shall follow the OD CB 2020. Only the approved and officially published product combination TRFs shall be used.

3.8.2.9 The NCBs have an option of using the approved, complete TRFs for the product in question instead of the product combination TRFs.



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3.8.3. Generating TRFs combining several Part 2 standards

3.8.3.1 This type of combination TRF may benefit particular segments of the industry where there is a need for a report addressing products combining several features into one appliance within the same product category.

Note: Examples of such TRFs within the HOUS category are

- a washing machine with a spin extractor and tumble dryer (IEC60335_2_4&7&11)
- stationary cooking ranges, hobs, ovens and deep fat fryers or frying pans (IEC60335_2_6&13)
- a room heater and clothes dryer/towel rail IEC60335_2_30&43.

3.9 An example of a Test Report Form

For an example of a TRF see Annex C.

Note: The selected example is from the TRF for IEC 60601 Part 2 and contains a statement:

"This Test Report Form is intended for the investigation of in accordance with IEC 60601-2-xx. It can only be used together with the IEC 60601-1 Test Report."

For TRFs that combine Part 1 and Part 2 requirements into a one Test Report Form, this statement is not applicable.

3.10 Use of landscape oriented pages in the TRF

The Test Measurement section of TRF may contain large tables. If it is not practical to continue the table using the "portrait" orientation due to the large size, the table may be designed and printed in the landscape format. An example of a TRF page in landscape orientation is shown in Annex D.

In case of the landscape orientation the margins shall be as follows:

- 3 cm from the top of the table and 2 cm from the bottom, and
- 2 cm left and right margin from the table.

3.11 Use of abbreviations used in the report TRF

When abbreviations are used throughout the report, they shall be clarified. See an example in Annex F, Page 60.



Part 4
Guidelines on how to fill in TRFs

The following shall be taken into account when completing a test report form (TRF):

Examples of completed Test Report pages and instructions on how to complete Test Report page are in Annex E.

4.1. Modifications to the TRFs

The Test Report Forms shall not be modified. However, to help preserve the environment, when compiling the Test Report, whole clauses of the TR may be omitted as specified in Annex E if they are not applicable to specific product.

4.2. Completing TRFs

When completing each sub-clause of the TRF, comments indicating why the particular item passed, failed or is not applicable should be included as necessary for clarity. The Report shall provide sound, sufficient information to grant the certification without the necessity to conduct additional evaluation or testing.

Note: Therefore, whenever possible the Test Report should also be accompanied by additional information, such as schematics, insulation diagram, detailed component information and report on compliance with National Differences.

4.3. A blank Test Report consists of four sections.

Testing Laboratories shall complete, as a minimum, these four sections. The Test Report shall include photos (see clause 4.10.1). The Report may also contain additional attachments, such as for example, National Differences TRF(s).

4.4. First section of the TRF

The first section (general information) includes a cover page that contains the general information, such as names and addresses of Testing Laboratory and Applicant/Client, testing location, standard used, product name, model(s) and rating(s). This page shall be always completed.

4.4.1 In case of the LTR program use, the following cases may apply:

- When LTR is associated only with the NCB:

CB Testing Laboratory: N/A – LTR program used under the supervision of the NCB

- When a CBTL is appointed for the supervision of the LTR:

CB Testing Laboratory: The name and address of the appointed CBTL

4.4.2 Pages behind the cover page contain signature page, testing laboratory information, factory list, specific information related to the product under test, marking details, and other general testing and report information.



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4.5. Second section of the TRF

4.5.1. The compliance checklist is the second section of the Test Report formatted into 4 columns. The first two columns titled: "Clause" and "Requirement-Test" are provided for reference only and shall not be modified by the Testing Laboratory. For the complete text of the requirement, testing engineers shall refer to the standard. In case of any discrepancy between the standard and the TRF, the standard text shall prevail.

4.5.2. The next column, called "Result", needs to be completed as part of the investigation. In this column a measured value or an explanation shall be typed; anything that results from the requirement in column two. The fourth column confirms the compliance, states non-compliance or declares the particular clause as not applicable. The verdicts can be "Pass" ("P"), "Fail" ("F") or "N/A". See also [TRF template](#).

4.5.3. Since there are different test case types in a TRF, the Testing Laboratory shall pay special attention to the type of the clause in order to correctly complete the TRF.

4.6. Third section of the TRF

4.6.1. The third section contains tables and may contain special remarks. Tables are provided to record the actual measurements taken during the test. It is not allowed to use statements such as "OK", "meets the standard", "more than", "less than", or similar instead of the measured value, unless otherwise specified by CTL.

4.6.2. Tables also provide room for information about test conditions (supplementary information field). When completing measurement tables, traceability of measurement must be ensured. When necessary table rows can be multiplied, however, adding new tables or removing tables is not allowed.

Note: *Examples of measurement tables containing test data for more than one model or part are shown in Annex E.*

4.7. Fourth section of the TRF

4.7.1. The fourth section contains a table describing critical components and/or materials.

4.7.2. The information to be included in the critical components and materials table shall be based on the following:

- a). The CTL clarification: "A safety critical component can only be determined upon a preliminary examination/evaluation of the electrical diagram/design/construction. When the design of the product is such that a determined component, in case of failure, can compromise the safety aspect, this component is defined as "safety critical".
- b). Components, which have specific requirements in the end product standards.
- c). Components, which have requirements in the National Standards included in the evaluation
- d). Materials, which are critical to maintain compliance with the standard (such as corrosion requirements, flammability)
- e). Professional judgment of the CBTL/NCB.

Note: *Additional information can be provided in the free text field of a Description row. An example is shown in Annex E.*



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4.8. Attachments to the CB Test Reports

4.8.1. A complete Test Report shall contain an attachment with photos of the product taken according to CTL-OP 107, Guide on Use of Photographs in CB Test Reports.

4.8.2. An attachment addressing National Differences may be completed when requested by the Applicant. This attachment may be a merge of selected National and Group Differences TRFs into one document. The National Differences attachment shall have its own numbering of pages with a total number of pages indicated. An example of a completed ND TRF is provided in Annex E. The "Summary of compliance with National Differences" field shall only contain the list of countries for which National and/or Group Differences have been addressed.

Optional compliance statement referring to the national or regional standard may also be used:

The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis).

4.8.3. Completed list of used test equipment shall be provided as an attachment to the Test Reports when a Manufacturer Testing Laboratory TMP or WMT has been utilized. (Optional for SMTL and RMTL where quality system verified by the NCB ensures appropriate document control system in place). See Annex E for example of the equipment table.

4.8.4. According to IECEE 02, Clause 4.2.2, Test Reports may contain additional attachments, such as product description and other information necessary for identification of the product, additional test data, schematics, component licenses, and similar



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Part 5

Guidelines on how to prepare Amendment Reports

5.1. General

An Amendment Report can only be issued to the original CB Test Report. The Amendment shall state that it is not valid without the original CB Test Report. The original Test Report reference number shall be clearly identified in the Amendment to allow for logical tracking of product changes.

Amendment Reports to the original CB Test Report can be issued to correct and/or include the following:

- applicant name/address changes;
- manufacturer name/address change;
- factory location name/address changes;
- changes in model/type designation;
- addition of the similar new models/types; - (if none or limited testing is required)
- changes/corrections to electrical rating; - (if none or limited testing is required)
- product modifications; - (if none or only limited testing is required)
- new/alternate components added; - (if none or only limited testing is required).

Note 1: *There are two main reasons for issuing an Amendment Report, technical modifications to the originally tested products (See IECEE 02, Clause 4.2.4) and corrections.*

Note 2: *Misprints and typo errors are treated as corrections. They are not considered a technical modification to the product. Once corrections are processed client/applicant may simply replace the affected pages in the original Test Report. (In order to be traceable, the corrections should have the date of correction typed on the corrected page). There is no limit on the number of allowed corrections.*

5.2. Number of changes allowed to the CB Test Report

5.2.1 It may be necessary to modify the information contained in a CB Test Report several times. However, if these modifications are due to **technical changes to the certified product(s)** they are limited to three, after which a new CB Test Report (and CB Test Certificate) shall be issued. This shall not preclude issuing a new CB Test Reports and Certificates for every technical modification, if the Member NCBs and the Applicant wish to do so.

Note: *It is recommended, however, that for extensive product modifications requiring testing, a new CB Test Report be issued, even if less than three technical modifications were previously processed.*

5.2.2. Engineering judgment should be used regarding the issue of a new CB Test Report versus an Amendment Report, however, upgrading a CB Test Certificate and Report from an old edition of the standard to a newer edition of the standard requires issuing a new CB Test Certificate and a new CB Test Report. The appropriate TRF, matching the new edition of the standard, shall be used. An Amendment Report is not allowed in this case.

5.3. Identification of changes to CB Test Reports:

5.3.1. When a product is subject to **technical modifications**, both, the CB Test Certificate (under "Additional Information") and CB Test Report (under "General product information") shall clearly identify the nature of such modifications, as applicable.

5.3.2. The following rules apply when issuing an Amendment to the original CB Test Report:

5.3.2.1. The reason for the issued Amendment Report shall be explained. All changes made to the original Test Report shall be explained and conducted tests identified.



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Note: For example, if new models are being added, explain the differences and similarities between models and indicate tests that were performed or why tests were not performed.

5.3.2.2. All clauses and/or sub-clauses of the original Test Report that are affected by the changes should be appropriately revised. All pages included in the Amendment Report shall be marked with the correct identifier (e.g. Report Ref. number and the date when the changes to the original Test Report were made).

5.3.2.3. For illustration purposes, a few completed pages from an Amendment Report are shown in Annex F. The example shows Amendment No. 2 Report issued due to the technical modification to the product (critical components were added) with limited testing. However, the original Test Report was already modified once by Amendment 1 Report, which has been issued because new models were added. In this case, after engineering review of the differences and similarities between originally tested models and new models, no tests were considered necessary. In the provided example, the history of all changes and the reasons why the Amendment Reports have been issued are clearly documented. After one more technical modification to the product a new CB Test Report shall be issued. The reissued Test Reports, construction review and the necessary testing shall be completed (see also IECEE 02, Clause 6.3.4).

5.3.2.4 Each Amendment Report shall contain its own “General information section”, which shall be reproduced from the original Report with the necessary changes. If applicable, additional pages containing, revised clauses/sub-clauses and modified test tables for conducted tests, and/or other pages (such as photos, schematics, manuals) that are affected by the product modifications shall be appended.

5.4. Issuing a CBTC and CBTR over another CBTC

5.4.1. When issuing a CBTC over another CBTC (originally issued by NCB “1”) the following conditions of recognition by the NCB “2” shall be followed and documented in the Test Report: For NCB “2” to accept the CBTR/CBTC issued by NCB “1” for its own CB Certification, the Applicant shall provide all relevant details obtained from NCB “1” for the CBTR/CBTC in question. The NCB “2” shall arrange for:

- Obtaining a sample(s) and performing a construction review
- Performing any additional required testing, which will cover any new requirements (e.g. new edition of a standard, national differences, etc.) or address and evaluate changes made to the product.
- Recording the necessary information in the new CB Test Report. The source of the original test data from NCB “1” shall be identified in the new CB Test Report prepared under the responsibility of NCB “2” (Based on ISO/IEC 17025, Sub-clause 4.13.2, “Technical records,”).

5.4.2. The information about the source of the original test data shall be provided in the section “Summary of testing.” The date when sample was received for construction review shall be recorded in the “Date of receipt of test item” field. Additional clarification may also be provided in the “General Product Information section.”

Note 1: The extent of retesting or further partial testing, such as selected clauses of the relevant standard(s), should be up to the professional judgment of NCB “2” as there can be various cases and each case may require a particular approach.

Note 2: As a minimum, the product is required to go through a construction review and any further partial testing deemed appropriate in the judgment of NCB “B” to fully cover any modifications to the product or according to a new edition of a standard, National Differences, etc.

Note 3: Since some tests may influence the tests that follow, the sequence of tests must always be considered.



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Part 6

Requests for modifications to TRFs

6.1. General

The use of the most recent TRF template is compulsory for all newly developed TRFs. Previously prepared TRFs for standards that are frequently used by the CB Scheme shall also be updated using the new template, however; there is no need for an immediate update of those TRFs that are infrequently used, unless specifically requested by members.

6.2. Modifications required due to an updated TRF Template

6.2.1. Most of template modifications are administrative in nature and simply reflect new CMC decisions. When the TRF template is modified, the IECEE Secretariat shall request the originators of TRFs to incorporate these modifications within the specified time frame. If this is not practical, the IECEE Secretariat shall allow non-originators to make the updates based on template changes (See clause 6.2.3). In either case, the TRFs need to be formally re-distributed to members.

Note: *The updates of TRFs may also be used by the IECEE Secretariat to remove from the list of TRFs those forms that are obsolete and no longer in use. (See also clause 6.4).*

6.2.2. When the originator is not able to provide the updated TRF in the a time frame requested by the Secretariat, and there is an urgent need for the updated TRF, another member appointed by the Secretariat can make the updates, however, the process shall be as follows:

- IECEE Secretariat always sends request to the originator after a new template is approved by the CMC and specifies the time frame for completion of the updates
- If the originator is not able to make that update, the IECEE Secretariat follows clause 6.2.3 and the administrative update path in Annex G.

6.2.3. Rules for administrative TRF changes:

- No reimbursement for administrative modifications to the TRFs
- The originator remains the same, since this is an administrative update only unless otherwise agreed with the IECEE Secretariat
- No technical changes to the TRF allowed when update is based on a new template
- New TRF version (suffix letter) is assigned
- Distribution according to Annex G (all correspondence with a copy to the originator)

Note: *- In special cases, administrative changes may be combined with technical changes when agreed with the TRF originator and the IECEE Secretariat. For the correct procedure see clause 6.3.*

6.3. Requests for technical modifications to published TRFs

Request for technical modifications shall be according to the flowchart in Annex G.

6.3.1. After a new TRF has been developed, the TRF is published on the IECEE website and considered "under comments".

6.3.2. The comment period is maximum 6 months depending on the complexity of the TRF and based on originator's recommendation. All comments are to be sent to the IECEE Secretariat using Annex I modification form.



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6.3.3. During the comment period all members can use the TRF without restrictions, however; all users shall be prepared to replace the TRF in their system, should the TRF be modified due to comments received from members and incorporated in the TRF.

6.3.4. Following the 6-months comment period, the originator shall incorporate received comments in the TRF. In case the provided comments cannot be included, the originator informs members and provides an explanation. In case of a disagreement, members can appeal to WG 9 and ETF, as appropriate. See flowchart in Annex G for details.

***Note:** TRF modification request form is not required when only minor and obvious corrections are needed. The use of the form is recommended when many changes are necessary. However, in all cases, the form helps tracking the implementation of modification requests.*

6.3.5. After the modifications/comments provided by members have been incorporated in the TRF, the TRF is considered a “final form.” Normally, no additional changes are allowed at this stage (exception: only critical issues accidentally overlooked during the 6 months comment period can be processed).

6.3.6. CB Test Certificates issued in conjunction with Test Reports based on the preliminary version of TRFs shall be accepted as equivalent to the certificates provided with the final version of the TRFs.

6.3.7. The “Master TRF date” shall be the TRF publication date. The publication date will be different for the TRFs published on the IECEE website “under comments” and the final version TRFs. Once the TRF is finalized, the publication date is replaced with the new date, which designates the final version.

6.4. Simplified procedure for TRF distribution

The simplified TRF distribution procedure is used when either only the administrative changes to the TRF are made or when TRF updates are due to a simple Amendment to IEC standard. The main difference between the regular and simplified distribution procedure is the 6-months trail and comment period. In case of the simplified TRF distribution procedure, the TRF is immediately published as the final TRF. The TRF originator shall advise the IECEE Secretariat whether the simplified TRF distribution process is applicable. See also Annex G.

6.5. Updates of the IECEE list of TRFs

Only TRFs that are based on standard editions currently in the scope of the CB Scheme shall remain on the IECEE list of TRFs.

Old versions of the TRFs shall be identified as archived on the IECEE Website. Allowing access to old versions of TRFs is for reference only (due to previously issued CB Test Reports that may be still valid in some countries). The archived TRFs shall not be used to generate new Test Reports.

TRFs shall be moved to the archives according to the rule that if there are less than three (3) members using the old edition of the standard, the IEC standard is no longer operational in the CB Scheme.



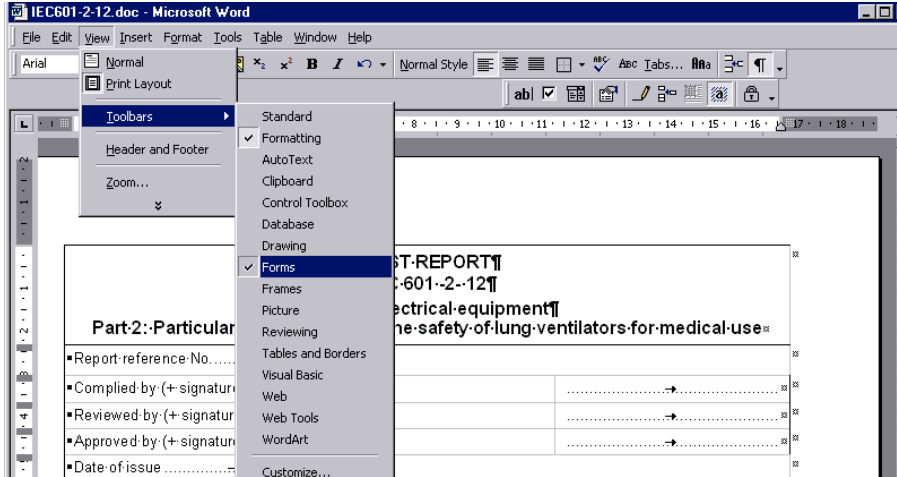
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Annex A

Helpful hints for TRF originators:

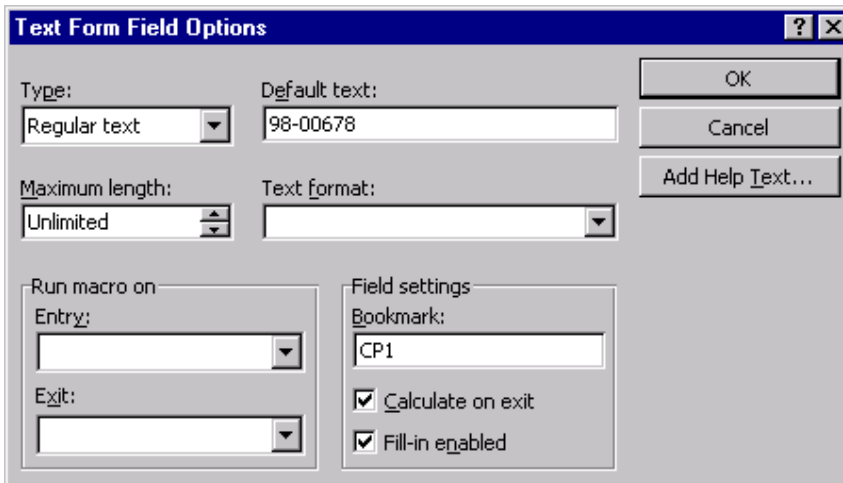
1. In order to add an automatic update for all fields containing the same information, for example the Report Ref. Number, follow these instructions:

Select View, Toolbars, Forms



Move cursor into the space for Report Reference No. on the first page of the Test Report. Then click on Text Form Field icon (ab). Select shading for easier identification of this new field.

Double click on the newly created Text Form Field to open the Text Form Field screen:



Type Bookmark name CP1 (use name CP1 for the Report Reference No. for consistency). Type Report Ref. No. in the “default text field” and click OK.

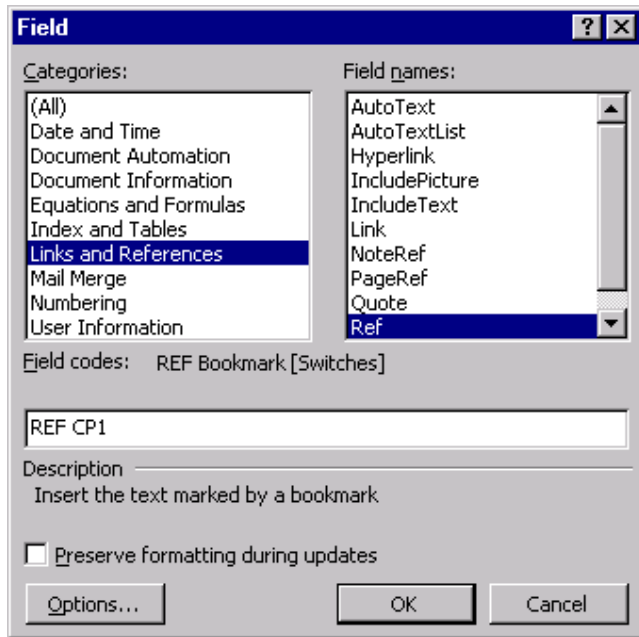
Move cursor to any space where normally the Report Reference No. should be typed (normally in the header).



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Annex A

Select Insert, Field, Links and References and Ref. Then type CP1 and click OK.
If you have several sections with different headers and page layout in the TRF you may need to repeat these steps for each section.



To use the update field feature go to the Text Form Field. Double click on the field, type the information (such as Report Ref. No.) in the “default text field” and click OK.

On each page of the printed document MS Word will automatically enter the text from the “default text field” into the selected locations with the REF CP1 identification.

2. In order to **add a dotted leader** for test cases requiring a specific result or comment in addition to the verdict, follow these instructions:

Cl.	Requirement - Test	Result	Verdict
20.5	Length ≥ 10 m:	12,5	Pass

Move cursor to the second cell (“Requirement – Test”) and click Format then select Tabs.

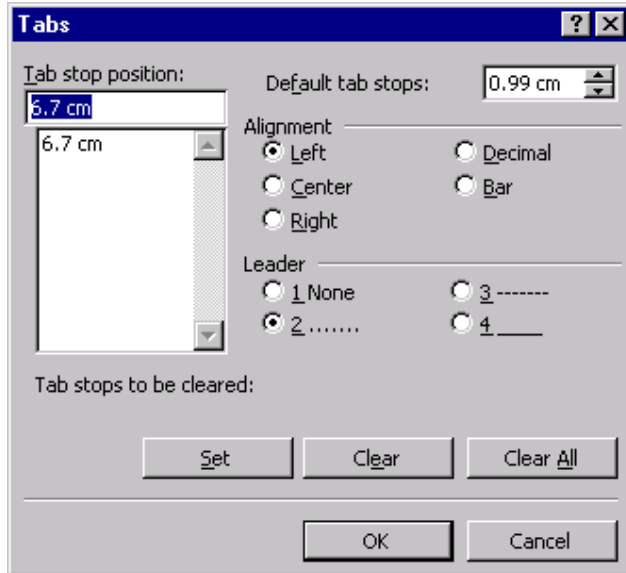
In the “Tab stop position” type 6.7 cm (or as appropriate for the size of the table). Set the alignment on “left”. Select the leader No. 2. Click on “Set” and then OK.

While still in the second cell, move cursor to the end of text in this cell and press “Control” + “Tab”. Add the “:” symbol.

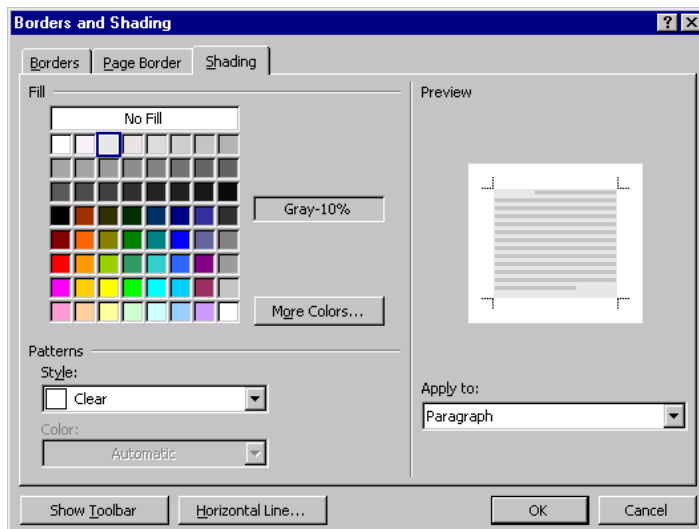


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Annex A



3. In order to **add shading in the cell**, place cursor in that cell; select Format, Borders and Shading. Click on the “Shading” tab and choose the top square for the 12.5% Grey. You may also select Patterns, Style and 12.5% for the shading. This method appears to work better during the conversion from MS Word 6.0 to higher versions of MS Word (the shading is not lost).





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Annex B

Checklist for TRF Originators

No. Requirement	Requirement	Result
1	Formating of the TRF	
1a	Was the latest TRF template used? Was the IECEE Website consulted?	
1b	Are margins set as Top 2 cm, Bottom 2 cm, Left 3 cm, Right 1 cm and paper size set to A4 (210 x 297 mm)?	
1c	Are normal text Arial 10 pt (True Type) font, special characters (e.g. °, β, Ω) and Symbol (True Type) used?	
1d	Is MS Word format "97-2002 + 6.0/95 - RTF" used?	
1e	Is full name of the TRF originator provided?	
1f	Is correct copyright text and current year entered on the first page?	
1g	Does the TR form include no macros, except for the Test Report Ref. Number and the page numbers?	
2	TRF structure	
2a	Is the IEC standards number and edition entered correctly?	
2b	Is correct TRF number entered the footer of each TRF section?	
2c	Is correct standard number entered in the header?	
2d	Does the section titled "Test items particulars" provide information about the product, which is necessary to establish the correct test program (such as special features and characteristics of the product)?	
2e	Does the TRF include all required TRF sections?	
2f	Is Component Table placed at the end of the TRF?	
2g	Is section covering National Differences included, when available?	
2h	Are the different test case types properly used in the TRF?	
2i	Are all pages of each section in the Test Report provided with page number and with the total of pages indicated? Is the page numbering macro working properly?	
2j	Is the number of sub-headers in a sequence (sub-headers following each other without any regular test case entries in-between) avoided and kept to minimum?	
3	Comments and verdicts	
3a	Is the column titled "Requirement – Test" a summary of the requirement and not a repeated full text of the standard?	
3b	Are indicative rather than imperative phrases used when abbreviating the requirements?	
3c	Are words such as "shall" and "should" avoided in the TRF?	



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3d	Is each requirement in the “Requirement – Test” column worded in such a way that it prompts for a clear “Pass”, “Fail” or “N/A” verdict?	
3e	Are regular test cases requiring a specific result or comment in addition to the verdict indicated by a dotted leader?	
3f	Are shaded verdict field identifying only the auxiliary test cases, which do not require a verdict but only additional information?	
3g	For measured values to be recorded in the tables and the main part of the TRF are units of measurement indicated?	
4 G	eneral	
4a	Was spelling checked?	
4b	Was correct language set?	
4c	Was the use of simplified distribution procedure (Annex G) considered?	



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Annex C

**Example of a blank Test Report Form
and National Differences Form**



Test Report issued under the responsibility of:

TEST REPORT IEC 60601-2-33 Medical electrical equipment Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis	
Report Reference No	:
Date of issue	:
Total number of pages	:
CB Testing Laboratory	:
Address	:
Applicant's name	:
Address	:
Test specification:	
Standard	IEC 60601-2-33: 2007 (Second Edition) + A 1: 2005 + A 2: 2007 for use with IEC 60601-1:1988 + A1:1991 + A2: 1995
Test procedure	CB Scheme
Non-standard test method.....	N/A
Test Report Form No	IEC60601_2_33F
Test Report Form(s) Originator	Underwriters Laboratories Inc.
Master TRF	Dated 2009-05
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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.	
Test item description	:
Trade Mark.....	:
Manufacturer	:
Model/Type reference	:
Ratings	:

Testing procedure and testing location:	
<input checked="" type="checkbox"/>	CB/CCA Testing Laboratory: Testing location/ address:
<input type="checkbox"/>	Associated CB Laboratory: Testing location/ address: Tested by (name + signature): Approved by (name + signature) ..:
<input checked="" type="checkbox"/>	Testing procedure: TMP Tested by (name + signature): Approved by (name + signature) ..: Testing location/ address:
<input type="checkbox"/>	Testing procedure: WMT Tested by (name + signature): Witnessed by (name + signature):. Approved by (name + signature) ..: Testing location/ address:
<input type="checkbox"/>	Testing procedure: SMT Tested by (name + signature): Approved by (name + signature) ..: Supervised by (name + signature): Testing location/ address :
<input type="checkbox"/>	Testing procedure: RMT Tested by (name + signature): Approved by (name + signature) ..: Supervised by (name + signature): Testing location/ address:

TRF No.: IEC60601_2_33F

Note 1: In the example above, the Testing Laboratory marked testing procedure and location as CBTL and TMP. In this case only the signature fields that are relevant for testing at the CBTL and TMP are required.

List of Attachments (including a total number of pages in each attachment):

Summary of testing:

Tests performed (name of test and test clause):

Testing location:

Summary of compliance with National Differences

List of countries addressed:

The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable).

Copy of marking plate:

“The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks”

TRF No.: IEC60601_2_33F

Test item particulars :
FIRST LEVEL CONTROLLED OPERATING MODE capability :
SECOND LEVEL CONTROLLED OPERATING MODE capability..... :
Equipped with superconducting magnets :
Equipped with resistive magnets..... :
Type of gradient system :
Options included :
..... :
Possible test case verdicts:
- test case does not apply to the test object : N/A
- test object does meet the requirement : P (Pass)
- test object does not meet the requirement : F (Fail)
Testing :
Date of receipt of test item..... :
Date (s) of performance of tests :
General remarks:
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. Throughout this report, a point (comma) is used as the decimal separator. This Test Report Form is intended for the investigation of magnetic resonance equipment for medical diagnosis in accordance with IEC 60601-2-33. It can only be used together with IEC 60601-1 Report. Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.
Manufacturer's Declaration per Sub-clause 6.2.5 of IEC 60601-2-33:
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided : Yes/Not applicable
When differences exist; they shall be identified in the General Product Information section.
Name and address of factory (ies) :
General product information:

TRF No.: IEC60601_2_33F

IEC 60601-2-33			
Clause	Requirement + Test	Result - Remark	Verdict
6	IDENTIFICATION, MARKING AND DOCUMENTS		
6.8.1	ACCOMPANYING DOCUMENTS provide sufficient information to the USER		
6.8.2	aa) INSTRUCTIONS FOR USE provide recommendations for and indicate the need for a pre-screening program to identify PATIENTS and MR WORKERS at risk	See Attachment #	
	- provide recommendations to adequately safeguard PATIENTS and MR WORKERS from injury taking into consideration risk due to past professional activity which might have caused accidental implantation of ferromagnetic materials for MR WORKER		
	All three specific classes of PATIENTS are mentioned in the INSTRUCTIONS FOR USE		
	bb) INSTRUCTIONS FOR USE provide clear recommendations to the USER to establish a program for the supervision appropriate to the classes of PATIENTS described in 6.8.2 aa) and to the controlled mass of operation of the MR EQUIPMENT		
Note: Remaining sub-clauses from Clause 6 were removed to save space in this OD.			
26	VIBRATION AND NOISE		
	The MR EQUIPMENT does not produce noise having an unweighted peak sound pressure level (L_p) higher than 140 dB referenced to 20 μ Pa in any accessible area.....:	See appended Table 26	
36	ELECTROMAGNETIC COMPATIBILITY		
	Outside the CONTROLLED ACCESS AREA the magnetic stray field is smaller than 0.5 mT and the electromagnetic interference level complies with Collateral Standard IEC 60601-1-2		
	Inside the CONTROLLED ACCESS AREA the requirements as stated in 6.8.2 ee) were applicable		
45	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		
45.101	The helium vessel is designed as a pressure vessel and was tested in compliance with clause 45 of IEC 60601-1, or with national regulations.....:		

TRF No.: IEC60601_2_33F

IEC 60601-2-33			
Clause	Requirement + Test	Result - Remark	Verdict
49	INTERRUPTION OF THE POWER SUPPLY		
49.101	The MR EQUIPMENT comprises a superconducting magnet or resistive magnet and is provided with an EMERGENCY SHUT DOWN UNIT		
49.102	The equipment is provided with a facility to allow the OPERATOR to immediately stop a scan by interrupting the power to the gradient system and that to the RF transmit coil as required		
51	PROTECTION AGAINST HAZARDOUS OUTPUT		
51.101	Operating modes		
51.101.1	The MR EQUIPMENT complies with the requirements in sub-clauses from a) to c):		
	a) Means are provided in order to ensure, that the limit(s) of the selected operating mode cannot be exceeded. This control is independent of OPERATOR input or is checked by the MR EQUIPMENT in order to detect any OPERATOR input error		
	b) A reset to the NORMAL OPERATING MODE with respect to SAR and dB/dt is performed automatically with change of the PATIENT		
	c) The MR EQUIPMENT provides information upon request about the relevant SAR and relevant GRADIENT OUTPUT		
Note: Remaining sub-clauses from Clause 51 were removed to save space in this OD.			
52	ABNORMAL OPERATION AND FAULT CONDITIONS		
52.1	Safety of the MR EQUIPMENT was assessed against the requirements of clause 52 in the Collateral Standard IEC 60601-1-4		
	All relevant information regarding residual risk is included in the INSTRUCTIONS FOR USE		
	Means are provided to secure the software and firmware control programs against unauthorised access or modification		
59	CONSTRUCTION AND LAYOUT		
59.101	MR equipment equipped with a superconducting magnet, has means to monitor the cryogen level(s)		

TRF No.: IEC60601_2_33F

IEC 60601-2-33			
Clause	Requirement + Test	Result - Remark	Verdict
26	TABLE: measurements of acoustic noise		
Location of the microphone..... :			
MR EQUIPMET mode producing the worst case situation acoustically..... :			
Accessible area	Measured unweighted peak sound pressure level L_p (dB)	Measure A-weighted r.m.s. sound pressure level $L_{Aeq, 1h}$ (dB)	Remarks
Supplementary information:			

51.105.2 TABLE: measurements of maximum GRADIENT OUTPUT for PATIENT							
Dimensions of the compliance volume (m)..... :							
Coordinates the compliance volume boundaries (m)..... :							
MAXIMUM GRADIENT SLEW RATE per GRADIENT UNIT (mT/m/ms)..... :							
SEARCH COIL sensitivity factor S..... :							
GRADIENT UNIT	Max. GRADIENT strength $G_{+,max}$ (mT/m)	Max. GRADIENT strength $G_{-,max}$ (mT/m)	Ramp time (ms)	Coordinates of location (m)	Peak value V_{out} of SEARCH COIL voltage (V)	GRADIENT OUTPUT dB/dt (T/s)	Remarks
Supplementary information:							

TRF No.: IEC60601_2_33F

Note 2: This is an example and only selected pages from the TRF were copied.

IEC60601_2_22C - ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-2-22 EUROPEAN GROUP DIFFERENCES AND NATIONAL DIFFERENCES (Medical electrical equipment, diagnostic and therapeutic laser equipment)	
Differences according to	IEC 60601-2-22: 2007 (Third Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition)
Attachment Form No.	EU_GD_IEC60601_2_22C
Attachment Originator	Name of originator
Master Attachment	date
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CENELEC COMMON MODIFICATIONS (EN 60601-2-22)		

ZB	ANNEX ZB, SPECIAL NATIONAL CONDITIONS (EN 60601-2-22)		

ZC	ANNEX ZC, NATIONAL DEVIATIONS (EN 60601-2-22)		

Note 4: This is an example only, not an actual TRF for National Differences.

IEC60601_2_22C - ATTACHMENT			
Clause	Requirement + Test	Result - Remark	Verdict

<p>ATTACHMENT TO TEST REPORT IEC 60601-2-22 US NATIONAL DIFFERENCES Medical electrical equipment Part 22: Particular requirements for safety of diagnostic and therapeutic laser equipment</p>
<p>Differences according to..... : IEC 60601-2-22</p>
<p>Attachment Form No..... : US_ND _IEC60601_2_22C</p>
<p>Attachment Originator : Name of originator</p>
<p>Master Attachment..... : date</p>
<p>Copyright © 2008 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.</p>

National	Differences	

	Special national conditions (if any)	

Note 5: *This is an example only, not an actual TRF for National Differences.*



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Annex D

Example of a TRF page in landscape orientation



IEC 60xxx-2-1			
Clause	Requirement - Test	Result - Remark	Verdict

10A	TABLE: flammability test for classifying materials 5V							
Sample	test bars			test plaques				
No./ref.	thickness (mm)	flaming time (s)	burning distance (mm)	thickness (mm)	position	flaming & glowing time (s)	burning distance (mm)	
Supplementary information:								

TRF No.: IEC60xxxA

Note: This is an example only, not an actual TRF.



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Annex E

Instructions on how to complete Test Report pages

Annex E comprise the following subsections:

CONTENTS	Page
<u>TRF Cover Page</u>	42
<u>Testing procedure and testing location</u>	44
<u>List of attachments</u>	45
<u>Summary of testing</u>	45
<u>Summary of compliance with National Differences</u>	45
<u>Copy of marking plate</u>	45
<u>Test items particulars</u>	45
<u>Possible test case verdicts</u>	46
<u>Testing dates</u>	46
<u>General remarks</u>	46
<u>Manufacturer's Declaration</u>	46
<u>Name and address of factory(ies)</u>	46
<u>General product information</u>	47
<u>Different test cases & clause types require different type of input</u>	48
<u>Component Information</u>	50
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<u>List of test equipment used</u>	55



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TRF Cover Page

Note1: Cover page example based on TRF for IEC 60601-1-6

IEC 60601 - 1- 6 **Medical electrical equipment** **Part 1-6: General requirements for safety - Collateral Standard: Usability**

Report Reference No: Type Test Report reference number
Date of issue: Type Test Report issue date
Total number of pages: Macro or type number of pages

CB Testing Laboratory: Type name of responsible Testing Laboratory
Address: Type address of Testing Laboratory

Applicant's name: Type name of Applicant
Address: Type Applicant's address

Test specification: Do not modify standard(s) identified by the TRF Originator

Make sure to select the TRF corresponding to the edition of the standard (including Amendments) that was used for the investigation of the product.

Standard : IEC 60601 1-6: 2006, Second Edition

Test procedure : CB Scheme
(Remove reference to the CB Scheme if not issuing a CB Test Certificate according to IECEE 02).

Non-standard test method: N/A
Describe any non-standard test methods used or type N/A.

Note 2: When it is necessary to use methods not covered by standard methods, these shall be documented according to ISO/IEC 17025:2005, Clause 5.4.4..

Test Report Form No. : IEC60601_1_6B (Not to be modified)

Test Report Form Originator : Not to be modified

Master TRF : Dated 2008-01 (Not to be modified)

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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.



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Note 3: *The copyright text and additional information is a standard text and shall not be modified or removed from the TRF.)*

Test item description	: Describe the product (computer, modem, hand-held lamp, electric oven,)
Trademark	: Describe or paste a copy of the trademark used
Manufacturer	: Type name and address of the manufacturer (See IECEE 02, Clause 3.7)
Model/type reference	: Type, model, type reference as it appears on the marking plate
Rating(s)	: Provide rating values corresponding to the ratings on which the testing has been based and as identified on the marking plate.



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Testing procedure and testing location:

Select applicable program and identify testing location.

CB Testing Laboratory : Type name of the Main Testing Laboratory
Testing location/ address : Type address of the Main Testing Laboratory

Associated Laboratory : Type name of ACB Testing Laboratory
Testing location/ address : Type address of Associated Laboratory
Tested by (name + signature) : Type name Sign here
Approved by (name + signature) : Type name Sign here

Note 4: An Associated CB Testing Laboratory is a testing facility that has a limited testing capability within its recognized scope of specific Product Categories or standards, and may need to rely upon the Main CBTL, with which it is associated, to handle tests outside its limited capabilities. A qualified staff of the Main CBTL is responsible for carrying out a review of test reports and/or partial test reports prepared by the Associated CB Testing Laboratory for which it is responsible. See OD-CB2015, Clauses 2.2 and 3.2.

When TPM Procedure used:
Testing procedure: TMP : Type name of TMP Laboratory
Tested by (name + signature) : Type name (CBTL) Sign here
Approved by (name + signature) : Type name (CBTL or NCB) Sign here
Testing location/ address : Type address of TMP Laboratory

When WMT Procedure used:
Testing procedure: WMT : Type name of WMT Laboratory
Tested by (name + signature) : Type name (WMT) Sign here
Witnessed by (name + signature) : Type name (CBTL or NCB) Sign here
Approved by (name + signature) : Type name (CBTL or NCB) Sign here
Testing location/ address : Type address of WMT Laboratory

When SMT Procedure used:
Testing procedure: SMT : Type name of SMT Laboratory
Tested by (name + signature) : Type name (SMT) Sign here
Approved by (name + signature) : Type name (SMT) Sign here
Supervised by (name + signature): Type name (CBTL or NCB) Sign here
Testing location/ address : Type address of SMT Laboratory

When RMT Procedure used:
Testing procedure: RMT : Type name of RMT Laboratory
Tested by (name + signature) : Type name (RMT) Sign here
Approved by (name + signature) : Type name (RMT) Sign here
Supervised by (name + signature) : Type name (NCB) Sign here
Testing location/ address : Type address of RMT Laboratory

Note 5: All blank Test Report Forms contain all programs and signature fields for: (1) "Tested by"; (2) "Supervised by"; (3) "Witnessed by"; and (4) "Approved by" as required by the CB Operational Documents (OD-CB2027, -CB2028, -CB2029, -CB2030, -CB2031).



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List of attachments:

The list below includes typical examples of attachments:

- a) Photo (x pages) - required
- b) National Differences (xx pages) – when applicable
- c) List of test equipment (xx pages) – required when TMP or WMT programs are used
- d) Other attachments as needed

List of Attachments shall include a total number of pages in each attachment.

Summary of testing:

Provide list of tests performed (name of the test and test clause number), as applicable.
Provide information on testing location.

The “Summary of testing” field shall contain the list of all tests conducted by the CBTL or MTL according to the testing program agreed with the responsible NCB.

The reason why any of the normally applicable tests were not conducted shall be explained in the “General product information” field.

It is important to clarify the differences between models covered by the Report when testing a family (series) of products.

Summary of compliance with National Differences:

Provide list of countries, for which compliance with National Differences has been verified. Include any additional relevant information in the National Differences TRF included in the CB Test Report.

Copy of marking plate:

Include a copy of the marking plate showing model designation, rating, manufacturer, and other information, as appropriate and/or required by the standard.

If the marking plate artwork contains certification marks, the use of these certification marks on the actual product must be authorized by the respective NCBs. The following statement shall be included in the “Copy of marking plate” field of the Test Report:

“The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks”

Test items particulars:

Provide information about the product needed to establish a correct test program, such as product mobility, type of power connections, and similar.

Select information applicable to the product, add values provided in technical documentation.

Example:

Test item particulars :	
Classification of installation and use..... :	See IEC 60601-1 Test Report
Mode of operation..... :	Intermediate
Surface temperature of APPLIED PART	40°C



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Possible test case verdicts:

Test case does not apply to the test object:	N/A
Test item does meet the requirement:	Pass (P)
Test item does not meet the requirement:	Fail (F)

Note 6: *The verdict may be spelled out (Pass, Fail) or abbreviated (P, F).*

Testing dates:

Date of receipt of test item	:	Complete as appropriate (YYYY-MM-DD)
Date(s) of performance of test	:	Complete as appropriate and when required by the test procedure used.

Note 7: *Date(s) of performance of test may be a time frame from – to or the last day of testing.*

General remarks:

The text below shall not be modified, except as noted.

The test results presented in this report relate only to the item(s) tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.

Clause numbers between brackets refer to clauses in EN 60598-1 (optional remark for EN standards).

"(see remark #)" refers to a remark appended to the report.

"(see Annex #)" refers to an annex appended to the report.

"(see appended table)" refers to a table in the Test Report.

When using a comma or point as the decimal separator in data entered in the Test Report, select as appropriate:

Throughout this report a comma / point is used as the decimal separator.

Manufacturer's Declaration (per Sub-clause 6.2.5 of IECCE 02):

When the application for obtaining a CB Test Certificate includes more than one factory location, the Applicant shall include a declaration from the Manufacturer(s) stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory (Sub-clause 6.2.5, IECCE 02).

Name and address of factory(ies):

The CB Test Report shall include the name and address of each factory.



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General product information:

(Optional)

Provide product information, intended use, explanation of the test program, model differences, and similar information, as needed.

Provide the rationale for selection of samples for testing, when applicable.

Note 8: *It is not necessary to explain sample selection, when sample selection is already addressed by the standard.*

Additional examples of information that may be included in this field:

1. The reason why any of the applicable tests were not conducted shall be explained.
2. Definition of variables used in the type/model designation

For new Test Reports the following may be useful:

Detailed product information;
Type of product;
Intended user (if prior training is necessary);
Intended operating environment (if different from normal/typical as defined by the standard);
Readiness for use (end product, sub-assembly or component);
Accessories;
Modules and interconnection (if equipment under test is of a modular design);
Other aspects as highlighted by the corresponding standard.

For modifications to the existing Test Reports the following may be useful:

Clear explanation of the nature of such modifications as required by clause 5.2;
Identification of product changes, preferably in comparison to the original model tested.



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Different test cases and clause types require different type of input:

Types of Clause in a TRF:

Heading:

Cl.	Requirement - Test	Result	Verdict
30.	CONSTRUCTION		Verdict optional

Verdict recommended but can be omitted when all verdicts in related sub-clauses are provided.

Sub-heading:

Cl.	Requirement - Test	Result	Verdict
10.5	Markings for Class II appliances:		Verdict required

Test case types:

Regular test cases

Cl.	Requirement - Test	Result	Verdict
21.1.1	Marking on main part	Result/comment optional	Verdict required

When regular test case requires a specific result or comment in addition to the verdict, it is indicated by a dotted leader as in the example below. In this case both, the comment (or measured value) and verdict are required.

Cl.	Requirement - Test	Result	Verdict
20.5	Length \geq 10 m..... :	Result/comment required	Verdict required

A shaded verdict field identifies Auxiliary test case, not requiring a verdict but additional information only. In this case the verdict is not needed only the result shall be provided.

Cl.	Requirement - Test	Result	Verdict
3.2.1	Test temperature ($^{\circ}$C) :	Result/comment required	—

Note 9: *Example of completed clauses from the TRF for IEC 60950-1)*



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4	PHYSICAL REQUIREMENTS		
4.1	Stability		Pass
	Angle of 10°	Test sample did not fall over	Pass
	Test: force (N).....	200 N	Pass

4.6	Openings in enclosures		Pass
4.6.1	Top and side openings		Pass
	Dimensions (mm)	Openings do not exceed 3 mm in any dimension	—
4.6.2	Bottoms of fire enclosures		Pass
	Construction of the bottom.....	Openings in the bottom are protected by a screen	—
4.6.3	Doors or covers in fire enclosures	The door is interlocked	Pass
4.6.4	Openings in transportable equipment		N/A
4.6.5	Adhesives for constructional purposes		N/A
	Conditioning temperature (°C)/time (weeks)	N/A	—

5	ELECTRICAL REQUIREMENTS AND SIMULATED ABNORMAL CONDITIONS		
5.1	Touch current and protective conductor current		Pass
5.1.1	General		Pass
5.1.2	Equipment under test (EUT)		Pass
5.1.3	Test circuit		Pass
5.1.4	Application of measuring instrument		Pass
5.1.5	Test procedure		Pass
5.1.6	Test measurements		Pass
	Test voltage (V)	1500 V	—
	Measured touch current (mA)	0.3 mA	—
	Max. allowed touch current (mA)	3.5 mA	—
	Measured protective conductor current (mA)	20 mA	—
	Max. allowed protective conductor current (mA) :	N/A	—



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Component information:

Note 10: Example of completed Critical Component table

TABLE: Critical components information						Pass
Object / part No.	Manufacturer/ trademark	Type / model	Technical data	Standard	Mark(s) of conformity ¹⁾	
AC Inlet	Makao Enterprise Ltd.	MA-224	250 V ac, 2.5 A	IEC 60320-1	VDE UL Recognized	
Fuse (F1)	Fusecom Co.	F-240S	T2A, 250 V	IEC 60127-1 IEC 60127-3	VDE UL Recognized	
Fuse Holder	Fusehod Co.	F-240SAP	10 A, 250 V	IEC 60127-6	CSA UL Recognized	
- Description	Secured through the double "D" shaped hole in the enclosure by a lock washer and a nut					
Enclosure	GE Plastics	Designated SE1	V-1, 105°C, 2.5 mm thick	UL 94	UL	
X-Capacitor (CX3)	Darin Co. Ltd	MPX2	0.33µF, 275V, 100°C	IEC 60384-14	VDE	
Line Filter (LF1)	Wells Industry Ltd	HNN-B1	300 V, 130°C	-	-	
Triple insulation wire used in LF1	Furukawa Co.	TEX-E2	130°C See license attached	IEC 60950-1	VDE UL	
Transformer T1	Wells Industry Ltd	HNN-2	300 V, 130°C	IEC 60950-1	TUV Rh	
Bobbin of T1	Chang Plastics Co.	Designated 7-37	Nylon, V-0, 150°C	UL 94	UL	
Switch S1	Astronam Ltd.	LPPD-33	300 V, 2.5 A	IEC 61058-1	KEMA	
- Description	Single throw, double pole switch used as main disconnect device Number of operations 10,000; contact gap 4 mm					
Supplementary information:						
¹⁾ Provided evidence ensures the agreed level of compliance. See OD-CB2039.						



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Annex E

Test Measurement section

(Tables, specific test conditions, test remarks and additional information)

Measured values shall be recorded in the tables.

2.10.3 and 2.10.4	TABLE: Clearance and creepage distance measurements						
Clearance (cl) and creepage distance (cr) at/of/between:	U peak (V)	U r.m.s. (V)	Required cl (mm)	cl (mm)	Required cr (mm)	cr (mm)	
Functional:							
	350 V	230 V	1.5	2.0	2.5	2.7	
Basic/supplementary:							
Reinforced:							
Supplementary information:							

Note 11: It is not allowed to use statements such as “OK”, “meets the standard”, “more than”, “less than”, or similar instead of the measured value unless otherwise specified by CTL.

5.1	TABLE: temperature rise measurements					Pass
	Test voltage (V)	:	190			—
	t1 (°C)	:	25			—
	t2 (°C)	:	26			—
Temperature rise ΔT of part/at:				ΔT (K)	Allowed ΔT (K)	
Fuse holder				55	65	
Terminal				30	55	
Temperature rise ΔT of winding:		R_1 (Ω)	R_2 (Ω)	ΔT (K)	Allowed ΔT (K)	Insulation class
Supplementary information:						
Heating Test conducted in an enclosure sized 4 by 3 by 12 cm.						

Note 12: The supplementary information field is provided for describing any specific test conditions or testing clarifications.



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19.7	TABLE: Abnormal operation, locked rotor/moving parts					
	Test voltage (V).....:	220/120			—	
	Ambient, t ₁ (°C)	22/30			—	
	Ambient, t ₂ (°C)	24/30			—	
	Temperature of winding	R ₁ (Ω)	R ₂ (Ω)	dT (K)	T (°C)	Max. T (°C)
	Winding (1) - Model 234	0.097	0.127	77.34	101.34	105
	Winding (1) - Model 4566	0.108	0.153	110.21	140.21	155
	Winding (2) - Model 234					
	Winding (2) - Model 4566					
	Model 234					
	Winding (1)	0.142	0.196	80.75	101.75	105
	Winding (2)					
	Model 4566					
	Winding (1)	0.108	0.153	110.21	140.21	155
	Winding (2)					
Supplementary information						
Motor Model 234 tested at 220 V and in the range of ambient temperature of 22°C-24°C						
Motor Model 4566 tested at 120 V and at 30°C						

Note 13: Two examples that ensure traceability of measurements when completing a measurement table for multiple models are shown above.



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Annex E

National Differences

(Section contains information and test results according to declared national differences).

Note 14: Provided example, based on the standard EN 60598-2-10, 2003 Edition, shows Group/CENELEC Common Differences.

ANNEX TO TEST REPORT IEC 60598-2-10 EUROPEAN GROUP DIFFERENCES AND NATIONAL DIFFERENCES Luminaries Part 2: Particular requirements: Section Ten – Portable luminaries for children	
Differences according:	EN 60598-2-10:2003 used in conjunction with EN 60598-1:2004+A1:2006
Annex Form No:	EU_GD_IEC60598_2_10B
Annex Form Originator	Intertek Semko AB
Master Annex Form	2007-10
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Clause	Requirement + Test	Result - Remark	Verdict
--------	--------------------	-----------------	---------

CENELEC COMMON MODIFICATIONS (EN 60598-2-10)			Pass
10.5 (3)	MARKING		Pass
10.5 (3.3.101)	Adequate warning on the package		Pass
10.10 (5)	EXTERNAL AND INTERNAL WIRING		Pass
10.10 (5.2.1)	Connecting leads		Pass
	- without a means for connection to the supply		N/A
	- terminal block specified		Pass
	- relevant information provided		Pass
	- compliance with 4.6, 4.7.1, 4.7.2, 4.10.1, 11.2, 12 and 13.2 of Part 1		Pass
10.10 (5.2.2)	Cables equal to HD21 S2 or HD22 S2		Pass

ANNEX ZB, SPECIAL NATIONAL CONDITIONS (EN)			Pass
(3.3)	DK: power supply cord with label		Pass
	IT: warning label on Class 0 luminaries		N/A
(4.5.1)	DK: socket-outlets		Pass
(5.2.1)	CY, DK, FI, SE, GB: type of plug		Pass



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Annex E

Additional options:

When completing the Test Report for a product for which the whole chapter of the standard is not applicable due to the nature of the product then, as an option, only the chapter's header may be printed in the final Report. (For example, modems and electric pencil sharpeners fall under the scope IEC 60950. The telecommunication requirements apply to a modem but are irrelevant for electric pencil sharpener.)

For pencil sharpener the Test Report may look as in the example below:

IEC 60950			
Clause	Requirement + Test	Result - Remark	Verdict
6	CONNECTION TO TELECOMMUNICATION NETWORKS		N/A

Note 15: Example based on the TRF for IEC 60950, Third edition. Clauses 6.1 through 6.3 are not printed.

For additional clarity, the header may also be followed by a supplementary note.

6	CONNECTION TO TELECOMMUNICATION NETWORKS		N/A
	Telecommunication requirements not applicable to the evaluated product.		—

If this time and paper saving option of compiling the TRF is selected, then the header with the N/A verdict is always required. This is to indicate that the chapter was considered during the investigation but was found to be not applicable. The printed header shows that the chapter was not accidentally omitted in the final Test Report.



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**Annex F
Example of Amendment to the original Test Report**



Test Report issued under the responsibility of:

TEST REPORT IEC 60601 - 2- 49 Medical electrical equipment	
Part 2: Particular requirements for the safety of multifunction patient monitoring equipment	
Report No. :	TR-12345a (Note: The NCB rules for numbering system shall be used – Original Report Ref. No may include a suffix or it can be a new number, or it may be unchanged number as long as the Amendment Report can be link to the Original report without ambiguity).
Date of issue..... :	2005 February 8, Amendment No. 2: 2007 March 16
Total number of pages..... :	Enter number of pages
CB Testing Laboratory	Name of Testing Laboratory (for LTR procedure see Clause 4.4)
Address	Testing Laboratory address
Applicant's name	Company name
Address	Company address
Test specification:	
Standard	IEC 60601-2-49, First Edition (2001)
Test procedure	CB Scheme
Non-standard test method..... :	N/A
Test Report Form No. :	IEC60601_2_49A
Test Report Form(s) Originator..... :	Underwriters Laboratories Inc.
Master TRF..... :	Dated April 2003
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Test item description	Monitoring System
Trade Mark	None
Manufacturer	Same as Applicant
Model/Type reference	Models ABC-123, AP139 and AP154
Ratings	12 V dc, 500 mA

Annex F**List of Attachments (including a total number of pages in each attachment):**

This Amendment to the original Report Ref. No. TR-12345a contains 8 Report Pages and one new photograph.

Summary of testing:**Tests performed (name of test and test clause):**

(Provide information about testing conducted for this Amendment, as appropriate.)

Input test
Heating test

Testing location:

Testing location: ACTL name

Summary of compliance with National Differences

List of countries addressed:

Instruction: Provide information about verified/tested to National Differences.

In case of technical modifications to the product, state if modified products still complies with previously evaluated National Differences.

The product fulfils the requirements of _____ (insert standard number and edition and delete the text in parenthesis or delete the whole sentence if not applicable).

Copy of marking plate:

“The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBS that own these marks”

Instruction: Provide copy of a new marking plate (or artwork) for new models added, or when marking plate changed due to modified ratings, trademark, and other changes, as applicable.

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Annex F

Test item particulars :			
Classification of installation and use..... :	See IEC 60601-1 Test Report		
Device type	MULTIFUNCTION PATIENT MONITORING EQUIPMENT - having more than one APPLIED PART		
Contact Surface Temperature (T_R)	36 °C		
Accessories and detachable parts included	N/A		
Other options included	N/A		
Possible test case verdicts:			
- test case does not apply to the test object	N/A		
- test object does meet the requirement	Pass (P)		
- test object does not meet the requirement.....	Fail (F)		
Testing:			
Date of receipt of test items	2007 March 2		
Date(s) of performance of tests	2007 March 7-9		
Abbreviations used in the report:			
- normal condition:	N.C.	- single fault condition:	S.F.C.
- operational insulation:	OP	- basic insulation:	BI
- double insulation:	DI	- supplementary insulation:	SI
- basic insulation between parts of opposite polarity:	BOP	- reinforced insulation:	RI
General remarks:			
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. List of test equipment must be kept on file and available for review.			
This Test Report contains the general safety requirements as related to the usability of Medical Electrical Equipment. It can only be used together with IEC 60601-1 Test Report.			
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.			
Manufacturer's Declaration per Sub-clause 6.2.5 of IEC 60601-1:			
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... : Yes			
When differences exist; they shall be identified in the General Product Information section.			

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<p>Name and address of factory (ies) : Provide factory information</p>
<p>General product information:</p> <p>The multifunction patient monitoring equipment consists of a patient control console with two applied parts, data store module and a serial port adapter. The system serves as a means of transferring data from the monitoring system console to a PC. The Data Store system is Class III and powered by a direct plug-in power supply with a 12 V dc, 500 mA, SELV, Limited Power, output. Instructions are provided for choosing a suitable supply.</p> <p>Amendment 1 Report:</p> <p>The original Test Report Ref. No. TR-12345a, dated 2005 February 8 was modified on June 22, 2005 to include the following changes and/or additions, which were considered technical modifications:</p> <p>New models added: The two new Models AP139 and AP154 are multifunction patient monitoring equipment identical to the previous Model ABC-123, except for minor variations in the SELV circuitry and markings. After review of the construction, no additional tests were considered necessary.</p>
<p>Amendment 2 Report:</p> <p>The original Test Report Ref. TR-12345a, dated 2005 February 8 was additionally modified on March 16, 2007 to include the following changes and/or additions, which were considered technical modifications:</p> <p style="padding-left: 40px;">New critical component xxx was added</p> <p>Two tests were considered necessary. See the "Summary of testing". A photo of modified printed wiring board with new component layout was added.</p>

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Note 2: *In this example, additional pages (such as pages with test tables for conducted tests, component table) or pages that are affected by the product modifications should follow pages shown above. A photo-documentation needs be attached to this Amendment Report.*

Note 3: *The example shows Amendment 2 Report issued due to the technical modification to the product (critical components were added) with limited testing. However, the original Test Report was already modified once by Amendment 1 Report, which has been issued because new models were added. In this case, after engineering review of the differences and similarities between originally tested models and new models, no tests were considered necessary. In the provided example, the history of all changes and the reasons why the Amendment Reports have been issued are clearly documented.*

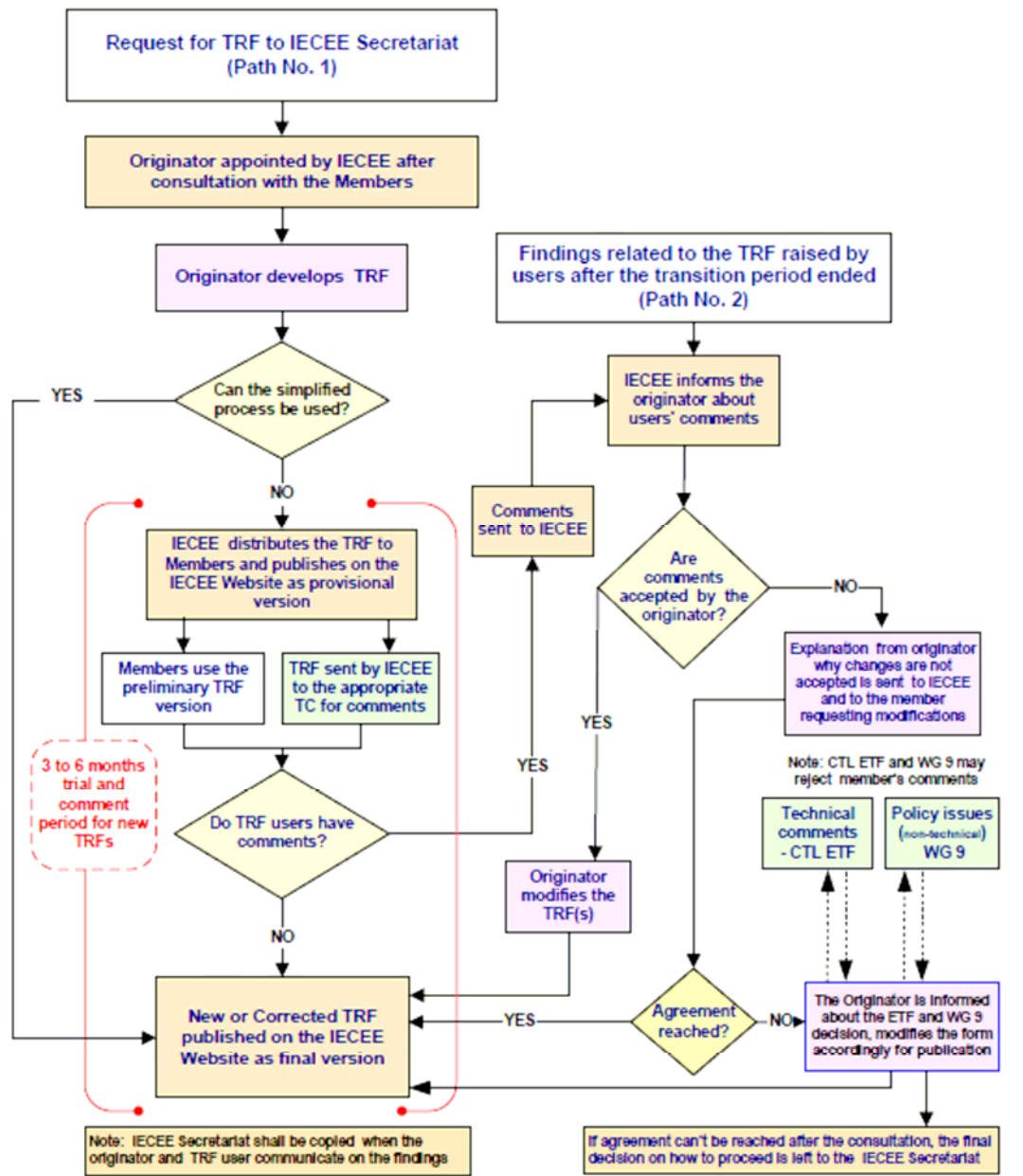
Note 4: *Only one more technical modification to the product is still allowed in the example given above before a new CB Test Reports shall be issued. (Refer also to IEC60601-1, Clause 4.2.4.).*



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Annex G

TRF Flowchart for Originators, Administrator and Users





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Annex H

Distribution of TRFs

The IECEE Secretariat maintains a list of completed TRFs and TRFs in preparation, which includes the expected completion date.

The assigned TRF Originator shall always inform the IECEE Secretariat on completion of the relevant TRF(s). The completed Master TRF(s) shall be sent by e-mail to the IECEE Secretariat in Geneva for distribution.

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Suggestions about changes/improvements to the TRF template(s) and Operational Document CB 2020 shall be communicated to the IECEE Contact Persons identified above.

The IECEE Secretariat shall provide the collected input to the WG 9 (TRFs) Convener for review and discussion at the next WG meeting, and later report to the CMC, when found appropriate.



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Annex J

The originator shall always use the latest TRF template available at the IECEE Website at <http://www.iecee.org/cbscheme/html/cbtrep.htm>. This applies to the TRF itself, to the National Differences templates and standardized attachments.

The list of available Test Report Forms as well as the list of Test Report Forms in preparation (including the expected completion date) can also be found on the IECEE Website.

Link to the [TRF and National Differences templates, and List of available TRFs](#)