



**IECEE OD-2020**

Edition 3.0 2015-06-03

# **IECEE OPERATIONAL DOCUMENT**

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

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**TRF – Development, maintenance and use**





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

**TRF – Development, maintenance and use**

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INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

PRICE CODE **ZZ**

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

## **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 provide instructions to all parties involved in the TRF procedures and to address the certification, data exchange and other IECEE community needs, as appropriate.

### **1.3 Definitions**

For definitions of TRF, TRF Originator and CB Test Report, see Document IECEE Definitions.

### **1.4 Structure of OD-2020**

The OD consists of six Parts and ten Annexes, which complement 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.



## **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: [secretariat@iecee.org](mailto:secretariat@iecee.org)

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 inquires 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) In case when more than one member is willing to originate the TRF, the development of new TRF is assigned to the Organization that offers the best timeframe subject to being accepted for the standard for which the TRF will be based on.

d) 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 of this OD for details).

## **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.

## **2.6 Procedure for the circulation of TRFs to TC/SC Officers**

A weekly e-mail is sent by the IECEE Secretariat to the IEC Central Office Technical Department, the Technical department then forwards the TRFs, excluding Group and National Differences extracted from the provided zip file. The IEC Technical Department sends the TRF files to the IEC TC/SC officers responsible for the standard.

Furthermore, an e-mail addressed to the IEC TC/SC Secretary and Assistant Secretaries, where applicable, with copies to the IEC TC/SC Chairman and IEC CO TO is also sent.

## Part 3 – Instructions 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 and Group Differences TRFs.

**3.1.1** As a basic rule, the starting point is to develop a TRF covering IEC requirements. For the National and Group Differences, if relevant, separate TRFs shall be developed in accordance with Clause 3.5.

3.1.2 The Group Differences TRFs shall be developed by the originator located within the region where the Group Differences are applicable. This may result in a different originator for the IEC TRF and for the Group Differences TRF.

**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 also Clause 3.8.3).

NOTE: The combined CB Test Report Forms may cause undesired consequences, such as when mistakes are found in the body of Part 1 Report, requiring corrections to all affected combination forms. The originators should always consider the pros and cons of merging Part 2 TRFs into one form.

### 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:** Microsoft Word Rich Text Format (\*.rtf)  
(Note: Rich Text format in MS Word 2007, 2010 and 2013 are compatible)

**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 or ISO Standard and its edition, TRF number and Master TRF

**The TRF standard** shall be identified on the first page of the TRF as follows:

IEC Axxxx - yy-yyy: (xx Edition) where A can be 6 or 8, x can be a digit between 0 to 9, and y can be blank or a digit between 0 and 9

ISO Axxxx - yy-yyy: (xx Edition) where A can be 6 or 8, x can be a digit between 0 to 9, and y can be blank or a digit between 0 and 9

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

The Corrigendum is not required to be mentioned in the standard identification field unless it introduces a technical change to the requirements.

### Standard edition

For the purpose of the CB Scheme Test Reports and Certificates do not use consolidated editions in x.y format (e.g. ed.2.1) but rather spell out the edition and its amendments (e.g. ed.2, am1).

Examples:

- IEC60950-1 (ed.2), am1 and am2
- IEC 60601-2-2 (ed.4) for use in conjunction with IEC 60601-1 (ed.2), am1 and am2
- IEC 60601-2-22 (ed.3) for use in conjunction with IEC 60601-1 (ed.3)
- IEC 60335-2-4 (ed.5) and IEC 60335-2-7 (ed.6) for use in conjunction with IEC 60335-1 (ed.4), am1
- IEC 60947-5-1 (ed.3), am1 for use in conjunction with IEC 60947-1 (ed.5)
- IEC 60950-1 (ed.2), am1 with Corr1
- IEC 60335-1 (ed.4), am1 with Corr1

### 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

IEC8xxxx\_x\_xxx followed by suffix letter

ISO8xxxx\_x\_xxx followed by suffix letter

The format of the TRF identification for National Differences shall include the following elements:

Country code\_ND\_ or EU\_GD\_ followed by

IEC6xxxx\_x\_xxx followed by suffix letter, or

IEC8xxxx\_x\_xxx followed by suffix letter, or

ISO8xxxx\_x\_xxx followed by suffix letter

Examples:

- **IEC60950\_1F**: means a TRF for IEC 60950-1 (ed.2), am1 and am2 - TRF version “F”
- **IEC60601\_2\_2F**: means a TRF for IEC 60601-2-2 (ed.5) with C1 – TRF version “F”
- **IEC60601\_2\_22D**: means a TRF for IEC 60601-2-22 (ed.3), TRF version “D”
- **IEC60335\_2\_4&7G** means a TRF for IEC 60335-2-4 (ed.6) and IEC 60335-2-7 (ed.7) - TRF version “G”
- **IEC60947\_5\_1B**: means a TRF for IEC 60947-5-1 (ed.3) – TFR version “B”
- **ISO80601\_2\_61A** means a TRF for ISO80601-2-61:2011, TRF version “A”
- **IEC60335\_2\_23B\_delta**: means a TRF for IEC 60 335-2-23 covering differences between version “A” and version “B” (See Clause 3.8.1.4).

- **IEC60950\_1&IEC60601\_1A**: means a TRF covering two different standards IEC 60950-1 and IEC 60601-1, TRF version “A” (see Clause 3.8.2).
- **EU\_GD\_IEC60335\_2\_14F** means a TRF covering European Group Differences for IEC60335-2-14 version “F” (see Clause 3.5.1)
- **US\_ND\_IEC60065J** means a TRF covering US National Differences for IEC60065 (ed.7) with am.1 (see Clause 3.5.1)
- **MY\_ND\_IEC60065J** means a TRF covering Malaysian National Differences for IEC60065 (ed.7) TRF

NOTE 1: 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).

NOTE 2: Once the suffixes used for TRFs reached letter Z, the next and consecutive suffixes are AA, BB, CC and so on.

**Master TRF:** The date of Master TRF shall be the date of TRF publication. See also Clause 6.3.7 and 6.4.2.

### 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 and clause 3.4.4).

If National Differences are included during product investigation (see clause 3.5.1) 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 the name and address of the 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 four 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.

#### 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.

NOTE 2: it is recommended that the Compliance Checklist is one table with header for each new clause in Capital letters, bold and shaded (12.5%) while each sub-clause has only bold letters.

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. (A4 page width is 21 cm, margins 4 cm and about 0.1 is left for lines width).

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

NOTE 3: 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
<b>30</b>	<b>CONSTRUCTION</b>		

#### Sub-heading

Cl.	Requirement - Test	Result	Verdict
<b>10.5</b>	<b>Markings for Class II appliances</b>		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:

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	<b>Test temperature (°C) .....</b> :	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)**

In product category MED, for TRFs based on the IEC 60601-1:2005, third edition, an exception is allowed as described in a Guideline Document on Medical Products in the CB Scheme according to the IEC 60601-1 and IEC/ISO 80601 Series of Standards. This exception includes an additional verdict N/E (Not evaluated), which is temporarily permitted for Collateral standards that can be excluded from the IECEE CB Scheme investigation. See also OD-2044.

### **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 or test conditions.

An example of a measuring section is shown in Annex E.

NOTE: In product category MED, in TRFs based on the IEC 60601-1 2005, third edition, an additional type of tables, called Risk Management Tables, is required when Risk Management is used for verification of compliance. See OD 2044, Guidelines for risk management in medical electrical equipment and Clause 3.8.4.2 in this OD.

### **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 does not require a 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)
- e) e) Standard => Applicable IEC or National harmonized component standard, or end-product standard if investigated as part of the end-product investigation
- f) Mark(s) of conformity => Evidence ensuring the agreed level of compliance. See OD-2039.

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:

<b>TABLE: List of critical components</b>					
<b>Object/part No.</b>	<b>Manufacturer/ trademark</b>	<b>Type/model</b>	<b>Technical data</b>	<b>Standard (Edition / year)</b>	<b>Mark(s) of conformity<sup>1</sup></b>
<b>- Description:</b>					
<b>Supplementary information:</b>					
<b>1) Provided evidence ensures the agreed level of compliance. See OD-2039.</b>					

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. An example of completed table is provided in Annex E.

### 3.4.5 List of Test Equipment (when applicable)

The Equipment list form is part of the TRF template.

## 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 in the National Differences TRFs (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 of the TRF 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 3.8). In this case the attached National Differences TRFs may need to address National Differences to more than one edition of the standard as applicable for the target countries requested by the Applicant.
- 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 E.

### 3.5.2 Group Differences TRF (when applicable)

This attachment is used for Group Differences requirements.

Note: Currently only EU countries officially declared this type of Differences.



### 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 respectively reserved for requirements and recommendations in the standard. 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 is 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(ed.3).

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.

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

A.6	<b>Flammability tests for classifying materials V-0, V-1 or V-2</b>		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	<b>Flammability tests for classifying materials V-0, V-1 or V-2</b>		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	<i>All samples passed the permitted re-testing.</i>	Pass

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

A.6	<b>Flammability tests for classifying materials V-0, V-1 or V-2</b>		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 submitted TRF using the checklist for TRF Originators (See Annex B).

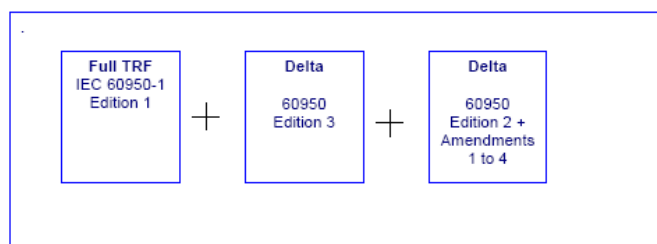
### 3.8 Special case TRFs

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

#### 3.8.1 Generating integrated TRFs covering different editions of the same standard

**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 (for example 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 (IECEE CMC/509/RCMC).

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



b) Full TRF is always 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 repeat 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 that no longer exist in the latest edition.

NOTE: If there are conflicting requirements in the previous and in 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.

Example 1: 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 (or more) 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 an identical device complying with more than one IEC standard.

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 2: 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.

**3.8.2.6** 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.

**3.8.2.7** 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.

**3.8.2.8** Using cross-references, as in the example below, is 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

**3.8.2.9** 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-2020. Only the approved and officially published product combination TRFs shall be used.

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

### 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.

### 3.8.4 Generating TRFs covering IEC 60601-1 third edition series of standards, which include Risk Management

**3.8.4.1** These TRFs shall include a Risk Management Result Table when:

- the compliance statement in the standard make reference to the Risk Management File, and
- the Standard makes reference to the manufacturer’s application of a risk management process, as signified by use of the trigger words: *Risk, Risk Control, Risk Process, Risk Evaluation, Risk Assessment, Risk Analysis, Residual Risk, Acceptable Risk / Unacceptable Risk, Hazard / Hazardous Situation*.

**3.8.4.2** The Risk Management Result Tables should include the following clauses of the appropriate edition of ISO 14971 based on the trigger words used.

Trigger word	Clauses of ISO 14971 to be considered	Comments
Risk	4.2 to 6.5	excluding 6.1
Risk Control	4.2 to 6.5	excluding 6.1
Risk Process	4.2 to 6.5	excluding 6.1
Risk Evaluation	4.2 to 5	
Risk Assessment	4.2 to 5	
Risk Analysis	4.2 to 4.4	
Residual Risk	4.2 to 6.5	Single hazard excluding 6.1
Acceptable Risk / Unacceptable Risk	4.2 to 6.5	where the control measure is applied, excluding 6.1
Acceptable Risk / Unacceptable Risk	4.2 to 5	where the control measure is not applied (just the pass/fail criteria)
Hazard/ Hazardous Situation	4.2 to 4.4	unless the standard does not define the control measure in which case consideration should include up to clause 6.5, excluding 6.1

NOTE 1: The format of the Risk Management Table can be found in Annex E.

NOTE 2: Refer to OD-2044 for further details.

### 3.9 An example of a Test Report Form

For an example of a TRF see Annex E.

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 in the Test Reports**

When abbreviations are used throughout the report, they shall be explained. See examples in Annex E.

## **Part 4 – Instructions on how to fill in TRFs**

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

The standard identified on the first page of TRF including edition and amendments shall match the standard on the CB Certificate to be issued. For examples of completed Test Report pages and instructions on how to complete Test Reports refer to Annex E.

The latest TRF version including the latest TRF Master date shall be used. There is a 6 months grace period before the mandatory use of the latest TRF.

### **4.1 Modifications to the TRFs**

The Test Report Forms shall not be modified.

Adding text in the footer, including watermarks across the pages, adding additional test on each page that is not part of the TRF and can be confusing or annoying when reviewing the reports is considered a modification to TRFs and is not permitted.

However; to protect the environment when compiling and printing hard copy of the Test Report, the whole paragraph with all clauses may be omitted if it is not applicable to the investigated product. See Annex E.

### **4.2 Completing TRFs**

4.2.1 When completing each sub-clause of the TRF, comments indicating why the particular item passed, failed or is not applicable shall 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. Additional specific requirements on how to complete Test Reports are provided in Annex E.

NOTE: Whenever possible and available, the Test Report should also be accompanied by additional information, such as schematics, insulation diagram, test configuration, detailed component information and report on compliance with National Differences.

4.2.2 In addition to identifying the printed name of the signatory, CB Test Certificates and Test Reports shall always be signed by the authorized person(s). Electronic signatures on the CB Test Report are acceptable provided there is a provision to track internally who is responsible for placing the signature on the CB Test Report. Providing just a printed name does not fulfil the accepted understanding of an electronic signature.

### **4.3 A blank Test Report consists of four sections**

Testing Laboratories shall complete, as a minimum, the required four sections (See 3.4). The Test Report shall include photos (see CTL-OP 107). The Report may also contain additional attachments, such as National Differences TRF(s).

### **4.4 First section of the TRF**

4.4.1 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, and copyright and general disclaimer. This page shall be always completed.

4.4.2 On the top of the cover page is the IEC/IECEE logo and room for the NCB logo or name. The statement in the top right corner on the first page: “Test Report issued under the responsibility of” references the NCB responsible for the CB Test Report, which will form the basis for the issuance of the CB Test Certificate. See also Annex E, TRF Cover Page.

NOTE: The name and/or logo of the NCB under the responsibility of which the Test Report is being issued can be placed in the space provided but within a limited fixed size not exceeding 4cm<sup>2</sup>. See also Annex E, TRF Cover Page.

4.4.3 Pages behind the cover page contain: product name, model(s) and rating(s), signature page, testing laboratory information, list of factories (name and address), specific information

related to the product under test, marking details, and other general testing and report information.

**4.4.4** When using the LTR program, the following cases may apply:

- When the LTR is associated only with the NCB or when LTR is part of a CBTL, the appointed “tutor” CBTL’s address shall be used on the TRF signature section (as opposed to the private address of the LTR or its responsible Local Entity). See OD-2034, Clause 4.3.2d.

<b>CB Testing Laboratory .....</b> : The appointed “tutor” CBTL’s name and address
--

#### **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.

However, CTL agreed with the following alternative report method. In case the measured minimum or maximum value is exceeding or is below the limit value by more than 30%, the value given in the TRF shall be  $>[\text{minimum required value} + 30\%]$  or shall be  $<[\text{maximum required value} - 30\%]$  and the accuracy of the used instruments shall be in line with CTL DSH 251B (or the latest version) or better.

**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. For an example see Annex E.

#### **4.8 Test Equipment List used for CTF Stage 1 or 2**

A completed list of test equipment used shall be provided in the CB Test Reports when a Manufacturer Testing Laboratory CTF Stage 1 and Stage 2 has been utilized.

The TRF template and Annex E show an example of the equipment list. Other forms with a different layout but containing corresponding information are also acceptable.

NOTE: The list of test equipment is optional for CTF Stage 3/Stage 4 procedures, where quality system, verified by the NCB during the assessment, ensures appropriate document control system in place.

#### **4.9 Attachments to the CB Test Reports**

**4.9.1** A complete Test Report shall contain an attachment with photos of the product taken according to Annex C, Guide on Use of Photographs in CB Test Reports.

**4.9.2** An attachment addressing National Differences may be completed when requested by the Applicant. 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 in the TRF 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).

**4.9.3** According to IECEE 02:2012, Clause 3.2.2, 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.

**4.9.4** All attachments shall be listed in the “List of Attachments”. The attachments may be merged into one document and renumbered accordingly.



## Part 5 – Instructions 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 change or include but not limited to the following:

- a) applicant name/address changes;
- b) manufacturer name/address change;
- c) factory location name/address changes (PAC Decision PAC/1619/DSH);
- d) changes in model/type designation;
- e) addition of the similar new models/types; - (if none or limited testing is required)
- f) changes/corrections to electrical rating; - (if none or limited testing is required)
- g) product modifications; - (if none or only limited testing is required)
- h) new/alternate components added; - (if none or only limited testing is required).

### 5.2 Type of changes to CB Test Reports

The following changes to CB Test Reports are allowed:

- a). Amendment Report due to technical modification to the originally tested products (See IECEE 02, Clause 3.2.4 and OD 2037, clause 2.0)
- b). Amendment Report due to administrative modification (See IECEE 02, Clause 3.2.4 and OD 2037, clause 2.0).
- c). Corrections

#### 5.2.1 Amendment Report due to technical modification

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 maximum 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 NCBs and the Applicant wish to do so.

NOTE 1: 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.

NOTE 2: The allowed three technical modifications are related to the Test Report and not to the individual models covered by the same Report. The restriction to not allow more than three technical modifications is due to difficulties with review of reports covering considerable number of changes when reports are submitted for Recognition.

Engineering judgment can 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 or amendment of the applied standard, shall be used. An Amendment Report is not allowed in this case.

### 5.2.2 Amendment Report due to administrative modification

Typically, Amendment Reports address changes as specified in 5.1, items a), b), c), d) or similar where no engineering judgment about product compliance is required. There is no limit on the number of allowed Administrative modifications.

### 5.2.3 Corrections

Corrections can cover misprints and typo errors. They are not used to address technical modifications to the product or administrative modifications. Once corrections are processed client/applicant may simply replace the affected pages in the original Test Report. (In order to be traceable, the corrections shall have the date of correction typed on the corrected page). There is no limit on the number of allowed corrections.

## 5.3 Identification of changes to CB Test Reports

**5.3.1.** A CB Amendment Test Report shall clearly identify the nature of modifications under the General Product Information section of the TRF, as applicable.

**5.3.2.** All changes made to the original Test Report shall be clarified and conducted tests stated in the Summary of tests.

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.

**5.3.3.** 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 shall be included in the Amendment, Other pages (such as photos, schematics, manuals) that are affected by the product modifications shall be appended.

**5.3.4** All pages included in the Amendment Report shall be marked with the correct identifier for traceability (e.g. Report Ref. number and the date when the changes to the original Test Report were made).

## 5.4 Amendment Report example

For an example of an Amendment Report refer to Annex F

NOTE: For illustration purposes, only a few completed pages from an Amendment Report are shown.

The provided example, shows Amendment No. 2 Report that has been issued due to the technical modification to the product (new critical components were added, the size of enclosure was changed and limited testing was performed. 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. Either the entire history of changes is repeated in each subsequent Amendment Report or only the changes specific to the new Amendment Report are provided.

In the given example, after one more technical modification to the products, a new CB Test Report will be issued. For the reissued Test Reports, construction review and the necessary testing will need to be completed.

## 5.5 Issuing a CBTC and CBTR over another CBTC

**5.5.1.** When issuing a CBTC over another CBTC (originally issued by the NCB “1”) the following conditions of recognition by the NCB “2” shall be followed and documented in the Test Report:

For the NCB “2” to accept the CBTR/CBTC issued by the NCB “1” for its own CB Certification, the Applicant shall provide all relevant details obtained from the 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 additionally required testing, which needs to address new requirements (e.g. new edition of a standard, national differences, etc.) or to address and evaluate changes made to the product since the last evaluation.
- Recording the necessary information in the new CB Test Report. The source of the original test data from the NCB “1” shall be identified in the new CB Test Report prepared under the responsibility of the NCB “2” (In accordance with ISO/IEC 17025, Sub-clause 4.13.2, “Technical records,”).

**5.5.2.** 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 the 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 the NCB “2” 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.

## **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 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 may be considered “under comments”. (See Annex G)

**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.

**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 to be the “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. See also clause 6.4.

**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 Requests for corrections to published TRFs**

6.4.1 When changes are made to the Test Report Forms by the originator to correct mistakes which are not related to new editions or amendments of the Standard, the originator making corrections must provide a copy of the corrected TRF, which includes Track Changes. This marked up copy should be provided with a clean Test Report Form during the weekly TRF distribution by IECEE Secretariat.

It is the responsibility of the TRF originator to keep track of all corrections until the new TRF version is published.

6.4.2 The Test Report Form Number stays the same until the editions or amendments of the Standard have changed however; the Master TRF date must be changed with each correction.

#### **6.5 Simplified procedure for TRF distribution**

The simplified TRF distribution procedure is used when either only the administrative changes to the TRF were made or when TRF updates are due to a simple Amendment or reissue of the IEC standard. The main difference between the regular and simplified distribution procedure is the need for 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.

#### **6.6 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.

## Annex A - Helpful hints for TRF originators

### **Important Note:**

*The Text Form Fields are the legacy field types that were available in earlier versions of Word 97– 2003. You can continue to use them in Word 2007-2013, and you **must** use them for forms to be saved in Word 97– 2003 format.*

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

### **MS Word 2000-2003**

---

From the **View** Menu select **Toolbars** and enable the **Forms** Toolbar

Click in your Word document wherever you wish to insert a Form Field.

On the Forms Toolbar click on the first button to insert a Form Field into your document:



A Text Form Field will be inserted at the cursor location.

Go to page 3 of this document.

### **MS Word 2007**

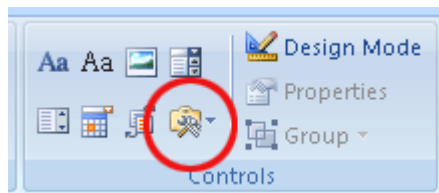
---

Click on the Menu button and select **Word Options**

In the **Popular** section, select *Show Developer Tab in the Ribbon*

Click in your Word document wherever you wish to insert a Form Field.

On the Developer Menu select the **Legacy Tools** icon which is in the Controls section



On the Legacy Forms menu click the first icon to insert a Form Field.

A Text Form Field will be inserted at the cursor location.

### **Important Note:**

**In Word 2007-2013, the document must be saved as "Word 97-2003 Document"**

Go to page 3 of this Annex.

### **MS Word 2010/2013**

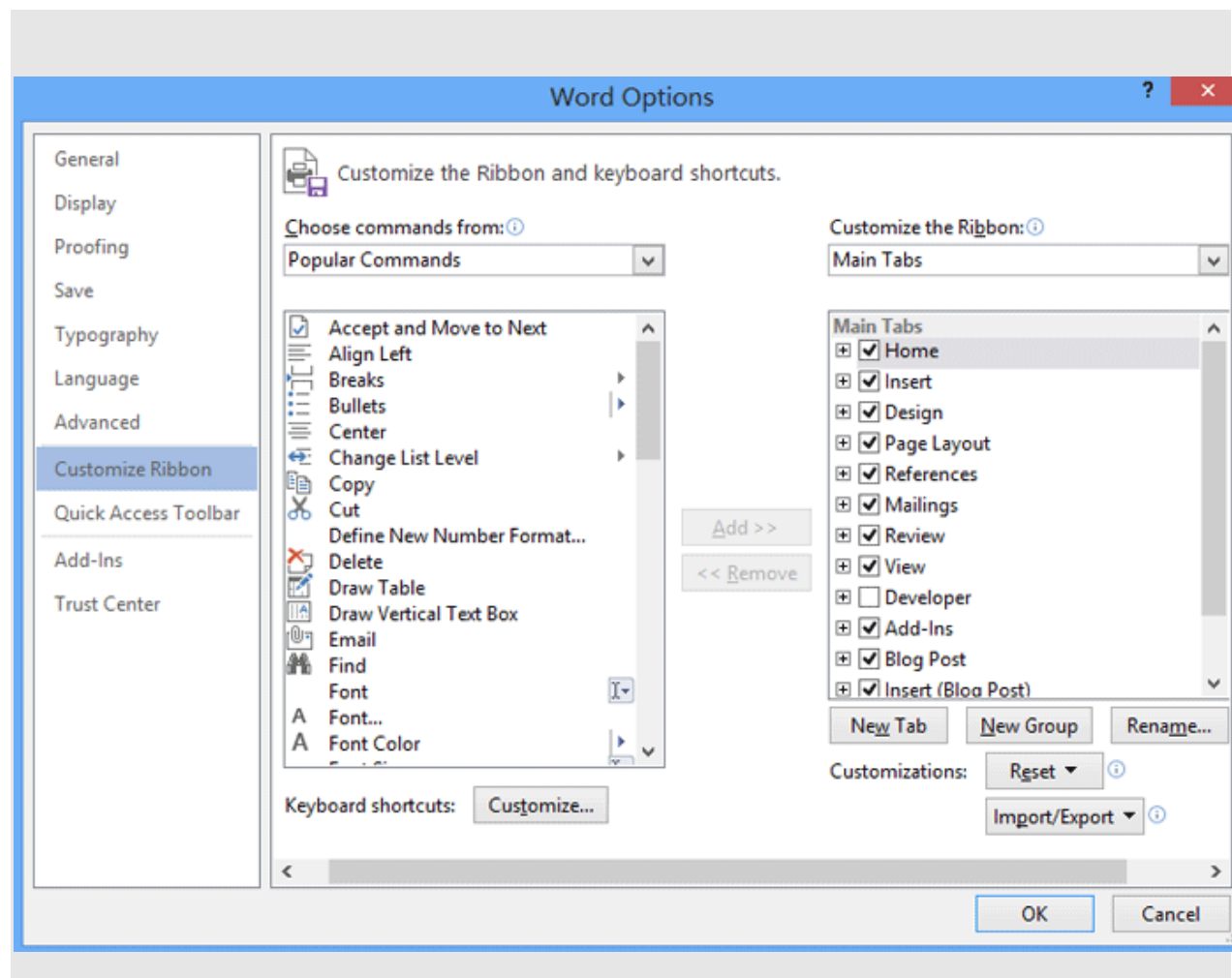
---

Click the **File**

Click the **Options** button at left bar

Click the **Customize Ribbon** button at left bar

Locate the "**Developer**" on the right side, and please check it and click OK.

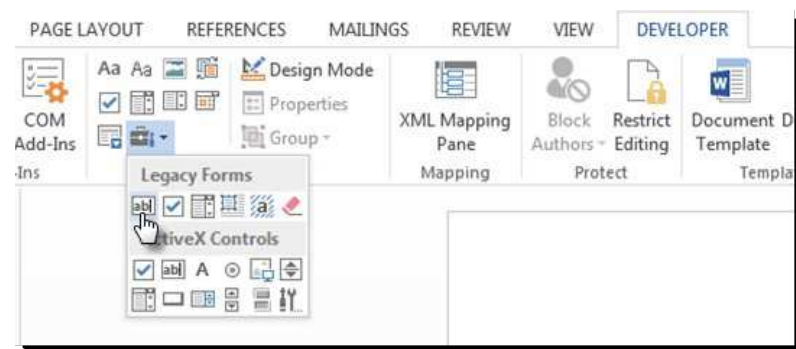


Click inside your Word document, wherever you wish to insert a Form Field.

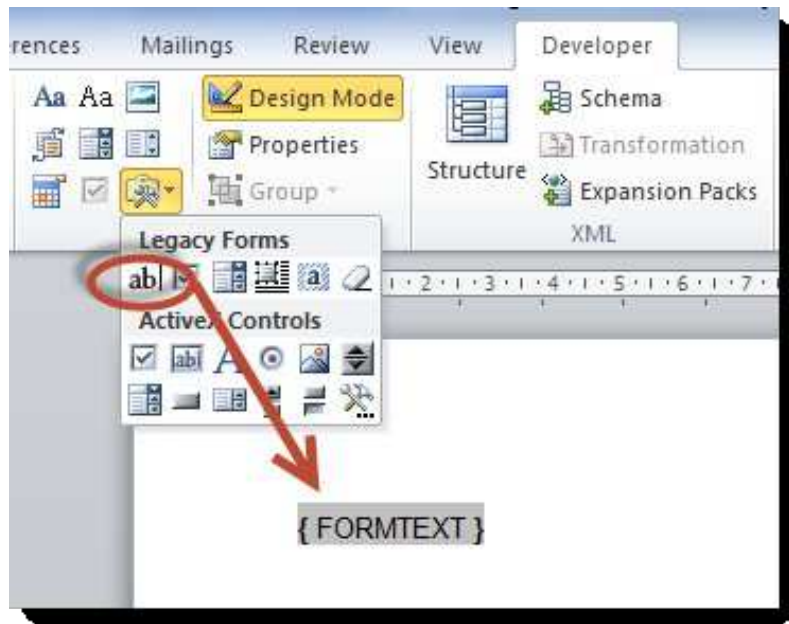
Click on the Developer tab

On the Developer tab, click on the Legacy Tools button:

### Word 2013



## Word 2010



Click on the Text Form Field button

A Text Form Field will be inserted at the cursor location.

**Important Note:**

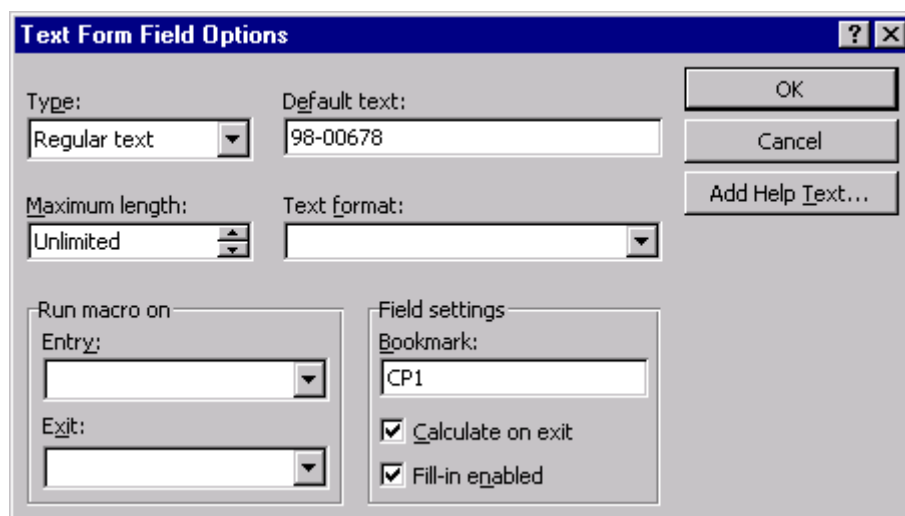
**In Word 2007-2013, the document must be saved as "Word 97-2003 Document"**

Go to page 3 of this document.

## All versions of the MS Word

---

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.

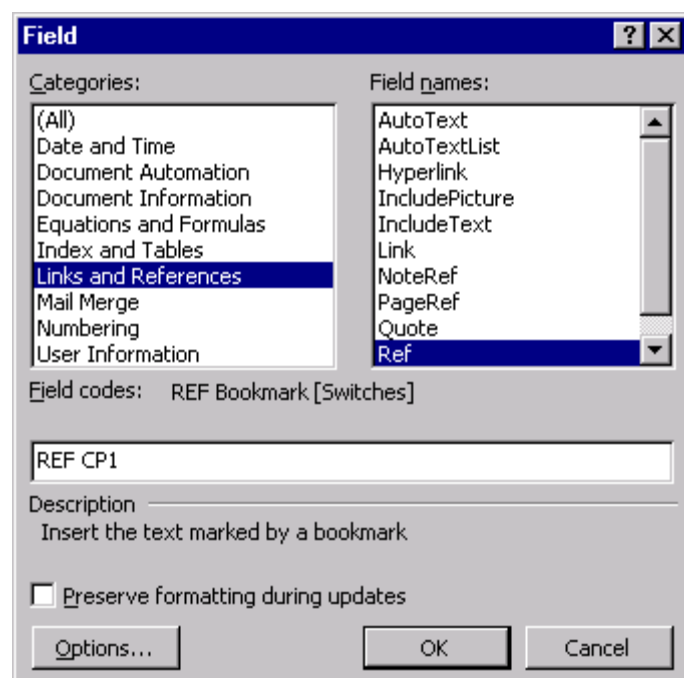
Move cursor to any space **where normally the Report Reference No. should be typed** (normally in the header).



## MS Word 2000-2003

---

Select “Insert” field, “Links and References” and “Ref.” Then type CP1 and click OK.



## MS Word 2007-2013

---

From the MENU bar:

Select INSERT

Click on the Quick Parts

Click on the Field

Under ‘Field Names’ click on Ref

Under ‘Bookmark Name’ click on CP1

Click OK.

## All versions of the MS Word

---

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.

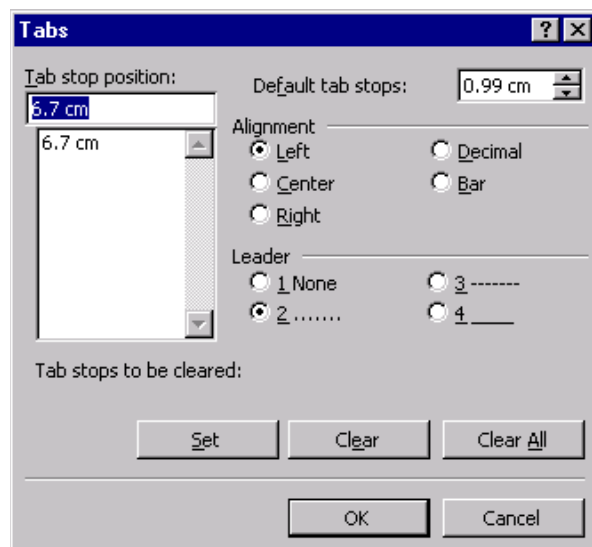
**2. In order to add a dotted leader** for test cases requiring a specific result or comment in addition to the verdict, follow these instructions:

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

Move cursor to the second cell (“Requirement – Test”) and:

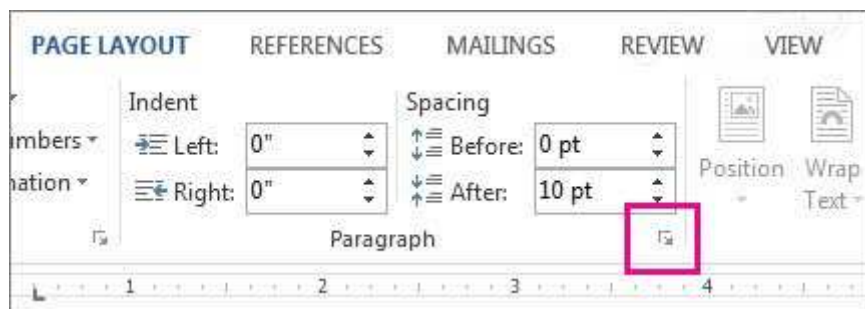
### MS Word 2000-2003

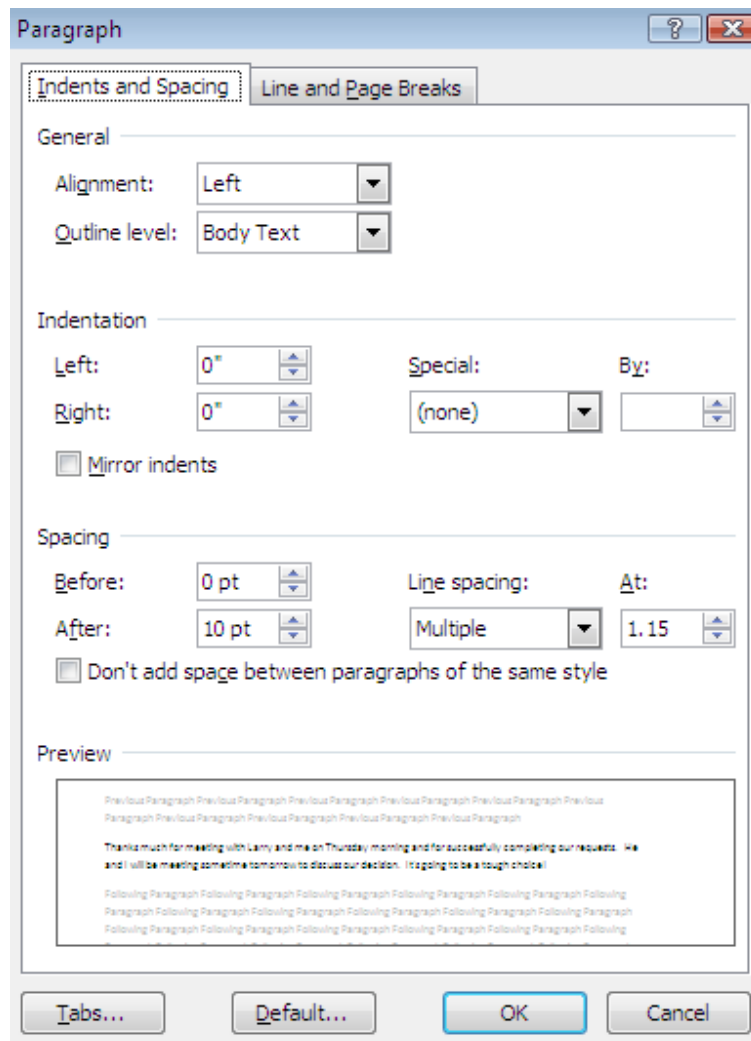
Click Format then select Tabs.



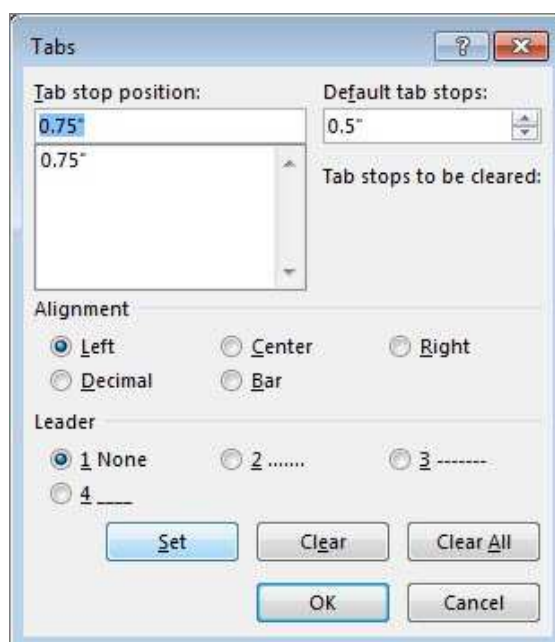
### MS Word 2007-2013

Click **Page Layout**, and then click the **Paragraph** Dialog Box Launcher.





Click on the **Tabs...** button.



## All versions of the MS Word

In the “Tab stop position” type 6.7 cm (or as appropriate for the size of the table and cell).  
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.

3. In order to **add shading in the cell**, place cursor in that cell

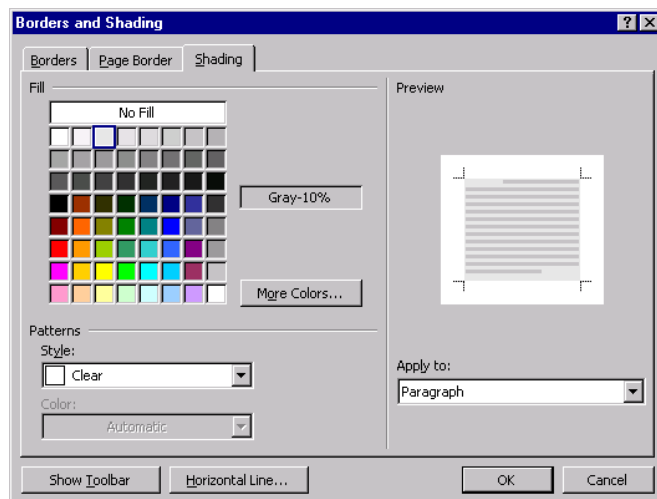
## MS Word 2000-2003

Select Format, Borders and Shading.

Click on the “Shading” tab and choose the top square for the 12.5% Grey.

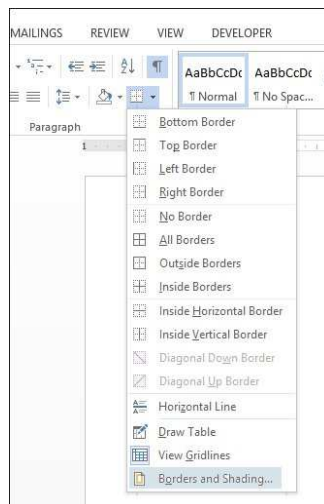
You may also select Patterns, Style and 12.5% for the shading. This method appears to work better during the conversion from MS Word 6.0 to higher versions of MS Word (the shading is not lost).

**Important Note:** Do not select Styles in Patterns. Leave it clear:



## MS Word 2007-2013

Select HOME, click on the arrow at the Borders icon and select ‘Borders and Shading’



Select Patterns, Style and 12.5% for the shading.

**Annex B – Checklist for TRF Originators**

<b>No.</b>	<b>Requirement</b>	<b>Result</b>
<b>1</b>	<b>Formatting of the TRF</b>	
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 "97-2002 + 6.0/95 - RTF" or "97-2003 + 6.0/95 - RTF" used?	
1e	Is the name of the TRF originator provided?	
1f	Is correct copyright text and current year entered on the first page of the TRF?	
1g	Does the TR form include no macros, except for the Test Report Ref. Number and the page numbers?	
<b>2</b>	<b>TRF structure</b>	
2a	Is the IEC standards number and edition entered correctly?	
2b	Is correct TRF number entered in 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	Are the different test case types properly used in the TRF?	
2h	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?	
2i	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?	
2j	For MED TRFs: Are the required Risk Management Result Tables included according to clause 3.8.4?	
<b>3</b>	<b>Comments and verdicts</b>	
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?	
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?	

No.	Requirement	Result
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?	
<b>4</b>	<b>General</b>	
4a	Was correct spelling checked?	
4b	Was correct language set?	
4c	Was the use of simplified versus regular distribution procedure (Annex G) considered?	

## Annex C - Guide on use of photographs in CB Test Reports

### Contents

C.1 General requirements .....	35
C.2 Specific requirements .....	35
C.3 Photographs to be taken.....	35
C.4 Storage and distribution .....	36

### C.1 General requirements

CB test reports shall include photographs of the test sample. Photographs are required for modified reports only when the photographs provided with the original test report are no longer representative of the product covered by the addendum report. Sufficient photographs shall be taken to clearly identify the test sample and its components as well as safety relevant design details. The photographs shall be suitable to fulfil also the requirements of OD-4002 (PID) and shall show the finally certified sample as reference for the factory inspection.

The CB test report shall clearly identify the product shown in the photographs (manufacturer, model number, type designation, etc.) by either labelling the photographs with the product identification or including the product identification in references to the photographs in the text of the report.

### C.2 Specific requirements

The number of photographs will depend on the complexity of the test sample. A minimum number of 2 exterior and 2 interior photographs is preferred, where practical.

If printed in a test report, the preferred format is not more than 2 photographs on each page.

The quality of the photographs and prints shall be such that all necessary features can be clearly identified.

The photographs may include a ruler to show proportion.

Note: Scaling of dimensions from photographs should not be done.

It is recommended that the background is a colour that contrasts with the features of the test sample.

It is recommended that the camera be tripod mounted.

Lighting should be arranged to minimise shadows.

Colour photographs are required with a minimum resolution of 800x600 dpi.

### C.3 Photographs to be taken

The photographs shall clearly identify the tested product including the safety critical components listed in the CB test report.

The following views are recommended:

- External view of the assembled product (or component where a component is being tested) showing different views including the front, rear, top and base. One photograph may show more than one side.
- Marking, warning and designation labels, if a copy of the original is not part of the report.
- Labelling of controls and indication lights.
- Internal construction including safety critical features.
- Supply terminations and cord anchorage.

- Earthing connections.
- Printed circuit boards critical to product safety– component side.
- Printed circuit boards critical to product safety – solder/pattern side.
- Details of safety critical components, both electrical and mechanical.
- Detachable parts critical to product safety.

Additional photographs and special features:

- Where a range of products has been tested, use photographs to show the different versions.
- Where modifications have been made show the details in the photographs.
- Special features, such as a marginal creepage distance, should be detailed. Use arrows or other visual aids to clearly identify special features.

#### **C.4 Storage and distribution**

It is preferred that a printed copy of the photographs is included with each printed copy of the CB test report. As an alternative, a CD with the photographic image files may be included with the printed report.

If the CB test report is issued electronically, then, electronic file copies of the photographs shall be included with the electronic file copy of the report.

It is recommended that the file for the photographs (in the report or on CD) is in secure format.

PDF format recommended.



**Annex D - Example of a TRF page in landscape orientation**

Page 30 of 35

Report No. \_\_\_\_\_

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

10A	<b>TABLE: flammability test for classifying materials 5V</b>						
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:							

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

TRF No.: IEC60xxxxA

## Annex E - Instructions on how to complete Test Report pages

Annex E comprise the following subsections:

E.1 - TRF Cover Page .....	39
E.2 Test item description Testing procedure and testing location .....	40
E.3 List of attachments.....	41
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E.15 Component information:.....	45
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Note: For the purpose of Annex E the following color code is used.

**Black font** = requirements

**Blue font** = examples from TRF

**Black font, small size** = notes

**E.1 - TRF Cover Page**

NOTE 1: Cover page example based on TRF for IEC 60601-2-44 and additionally on TRF for IEC 60950-1.

**In the right top corner of the cover page:**

**Test Report issued under the responsibility of:** Paste NCB logo or type the name of the NCB responsible for the CB Test Report and issuing the CB Test Certificate

**TEST REPORT****IEC 60601-2-44****Medical electrical equipment****Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography**


---

<b>Report Number:</b>	Type Test Report reference number
<b>Date of issue:</b>	Type Test Report issue date
<b>Total number of pages:</b>	Imbedded macro or type the number of pages
<b>Name of Testing Laboratory preparing the Report :</b>	Provide the name of CBTL taking responsibility for the Test Report
<b>Applicant's name:</b>	Type name of Applicant as it appears on the CBTC
<b>Address:</b>	Type Applicant's address

---

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

Note 2: 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 60601-2-44 (ed.3) am1, with Corr.1 for use in conjunction with IEC 60601-1 (ed.3)

**Test procedure :** **CB Scheme**

Note 3: Remove reference to the CB Scheme if not issuing a CB Test Certificate according to IECEE 02.

**Non-standard test method:** **N/A**

Note 4: Describe any non-standard test methods used or type N/A.

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\_2\_44F** (Not to be modified)

**Test Report Form Originator:** Not to be modified

**Master TRF :** **Dated 2015-05** (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.**

---

**General disclaimer:**

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 CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

---

**- End of Cover Page -**

Note 5: Remove reference to the CB Scheme if not issuing a CB Test Certificate according to IECEE 02.

The copyright statement and additional information is always required and shall not be modified or removed from the TRF.

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; however, the copyright statement shall be retained.

## E.2 Test item description Testing procedure and testing location

- Test item description** : Describe the product (computer, modem, hand-held lamp, electric oven, .....). Use IEC standard terminology.
- Trademark** : Describe or paste a copy of the trademark used
- Manufacturer** : Type name and address of the manufacturer  
(See IECEE Definitions & Acronyms, item 8)
- 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

### Testing procedure and testing location

Select applicable program and identify testing location.

When CBTL or ACTL is used:

- CB Testing Laboratory:** Type name of the responsible CB Testing Laboratory
- Testing location/ address:** Type address of the CB Testing Laboratory
- Associated Laboratory :** Type Name of ACTL, when used
- Testing location/ address:** Type address of ACTL, when used
- Tested by (name, function, signature):** Type name & function Sign here
- Approved by (name, function, signature):** Type name & function Sign here

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 CBTL, with which it is associated, to handle tests outside its limited capabilities. Tests conducted by ACTL and CBTL shall be listed accordingly, in the “Summary of testing.” For reporting the use of LTR procedure, see Clause 4.4.4.

---

When Stage 1 Procedure is used:

- Testing procedure CTF Stage 1: Type name of CTF Stage 1 Laboratory
- Testing location/ address: Type address of CTF Stage 1 Laboratory
- Tested by (name, function, signature): Type name (CBTL staff) & function Sign here
- Approved by (name, function, signature): Type name (CBTL or NCB) & function Sign here

---

When CTF Stage 2 Procedure is used:

- Testing procedure: WMT/ Stage 2 : Type name of CTF Stage 2 Laboratory
- Testing location/ address: Type address of WMT/ Stage 2 Laboratory
- Tested by (name, function, signature): Type name (CTF Staff) & function, Sign here
- Witnessed by (name, function, signature): Type name (CBTL or NCB) & function, Sign here
- Approved by (name, function, signature): Type name (CBTL or NCB) & function, Sign here

---

When CTF Stage 3 or 4 Procedure is used:

- Testing procedure: Stage 3 or 4: Type name of CTF Stage 3/ Stage 4 Laboratory
- Testing location/ address: Type address of CTF Stage 3/ Stage 4 Laboratory
- Tested by (name, function, signature): Type name (Stage 3/ Stage 4) & function, Sign here
- Approved by (name, function, signature): Type name (Stage 3/ Stage 4) & function, Sign here
- Supervised by (name, function, signature): Type name (CBTL or NCB) & function, Sign here

---

NOTE: Until 2015, blank TRFs still contain all MTL/CTF programs and signature fields.

### **E.3 List of attachments**

The list below includes typical examples of attachments:

- a) Photo (x pages) - required
- b) National Differences (xx pages) – when applicable
- c) Other attachments as needed

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

### **E.4 Summary of testing**

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

Provide information on testing location (CBTL, Client's laboratory, Subcontractor's laboratory).

The "Summary of testing" field shall contain the list of all tests conducted by the CBTL or CTF 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.

### **E.5 Summary of compliance with National Differences (List of countries addressed):**

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.

If applicable, insert standard number and edition, such as EN standard, leave blank or delete the whole sentence:

The product fulfils the requirements of \_\_\_\_\_.

### **E.6 Copy of marking plate**

Include a copy of marking plates of all models included in the type testing showing model designation, rating, manufacturer, and other information, as appropriate and/or required in the standard. If samples were selected representing the entire range of models included in the type testing, marking plates of the representative models are to be provided. For a series of models a reduced number marking plates may be acceptable as long as there is sufficient information in the report to reconstruct the information for all required marking plates.

NOTE 1: See OD-2041 for examples of product families and sample selection criteria.

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"

Unless otherwise specified in the respective product standard marking shall be of permanent type.

NOTE 2: Marking provided as an "electronic paper" is not acceptable as it relies on the supply of power to be viewed.

### E.7 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.

An example of “Test item particular” section:

<b>Test item particulars</b> .....	:
Classification of installation and use .....	See IEC 60601-1 Test Report
Supply Connection .....	:

### E.8 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: The verdict may be spelled out (Pass, Fail) or abbreviated (P, F). No abbreviation is used for N/A verdict. See also sub-clause 3.4.2.2., Results and verdicts, for the exception used in MED category for collateral standards.

### E.9 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: Date(s) of performance of test may be a time frame “from – to” or the last day of testing.

### E.10 General remarks

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

"(See Enclosure #)" refers to additional information appended to the report.

"(See appended table)" refers to a table appended to the report.

The tests 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 testing laboratory.

List of test equipment must be kept on file and available for review.

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

This Test Report Form is intended for the investigation of the safety of X-ray equipment for computed tomography in accordance with IEC 60601-2-44. It can only be used together with the IEC 60601-1: 2005 (Third Edition) Test Report.

### E.11 Manufacturer’s Declaration per Sub-clause 4.2.5 of IECEE 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 4.2.5, IECEE 02).

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 .....	<input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>Not applicable</b>
---	---

Select “Yes” when more than one factory is listed on the CB Test Certificate or “Not applicable” when only one factory is used.

When differences between products from various factories exist, they shall be identified in the General product information section.

### **E.12 Name and address of factory(ies)**

The CB Test Report shall include the name and address of each factory in the designated area of the TRF.

### **E.13 General product information**

(Optional)

Provide product information, intended use, explanation of the test program, model differences, differences between products from different factories, and similar information, as needed.

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

The test report shall provide clear description and selection criteria of the models tested representing the "family range".

NOTE: 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 (whether initial 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 should be as required by clause 5.2.

Identification of product changes, preferably in comparison to the original model tested. See also Part 5 of this OD.

### E.14 Different test cases and clause types require different type of input

Types of Clause in a TRF:

**Heading:**

Cl.	Requirement - Test	Result	Verdict
<b>30.</b>	<b>CONSTRUCTION</b>		Verdict optional

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

**Sub-heading:**

Cl.	Requirement - Test	Result	Verdict
<b>10.5</b>	<b>Markings for Class II appliances:</b>		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 verdicts 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 (for example $23^{\circ}$ C) or comment required	—

NOTE: Example of completed clauses from the TRF for IEC 60950-1.

<b>4</b>	<b>PHYSICAL REQUIREMENTS</b>		Pass
<b>4.1</b>	<b>Stability</b>		Pass
	Angle of $10^{\circ}$	Sample didn't fall over	Pass
	Test: force (N) .....	200 N	Pass

<b>4.6</b>	<b>Openings in enclosures</b>		Pass
4.6.1	Top and side openings		Pass
	Dimensions (mm) .....	Openings do not exceed 3 mm in any direction	—
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	—

<b>5</b>	<b>ELECTRICAL REQUIREMENTS AND SIMULATED ABNORMAL CONDITIONS</b>		
<b>5.1</b>	<b>Touch current and protective conductor current</b>		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	—

### E.15 Component information:

NOTE: Example of completed Critical Component table.

The evidence used to verify component compliance may be included as an attachment in the CB Test Report or available in the project folder. See also OD 2039.

TABLE: Critical components information					Pass
Object / part No.	Manufacturer/ trademark	Type / model	Technical data	Standard	Mark(s) of conformity <sup>1)</sup>
AC Inlet	Makao Enterprise Ltd.	MA-224	250 V ac, 2.5 A	IEC 60320-1 (2007)	VDE, UL Recognized
Fuse (F1)	Fusecom Co.	F-240S	T2A, 250 V	IEC 60127-1 (2011)	VDE, TUV, UL Recognized
Fuse Holder	Fusehod Co.	F-240SAP	10 A, 250 V	IEC 60127-6 (2002)	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 (Sixth Edition)	UL
X-Capacitor (CX3)	Darin Co. Ltd	MPX2	0.33µF, 275V, 100°C	IEC 60384-14 (2005)	VDE

TABLE: Critical components information					Pass
Object / part No.	Manufacturer/ trademark	Type / model	Technical data	Standard	Mark(s) of conformity <sup>1)</sup>
Line Filter (LF1)	Wells Industry Ltd	HNN-B1	300 V, 130°C	-	-
Triple insulation wire in LF1	Furukawa Co.	TEX-E2	130°C; See license attached	IEC 60950-1 (2001)	VDE UL
Transformer T1	Wells Industry Ltd	HNN-2	300 V, 130°C	IEC 60950-1 (2005)	TUV Rh
Bobbin of T1	Chang Plastics Co.	Designated 7-37	Nylon, V-0, 150°C	UL 94 (Sixth Edition)	UL
Switch S1	Astronam Ltd.	LPPD-33	300 V, 2.5 A	IEC 61058-1 (2001)	DEKRA
- Description	Single throw, double pole switch used as main disconnect device Number of operations 10,000; contact gap 4 mm				
Optical Disk Drive	Panasonic Corp	UJDA780	5 V dc, 1.8 A, Class I laser	UL60950-1, IEC60950-1 (2005)	UL, TUV-R
Optical Disk Drive	Interchangeable	—	5 V dc, 1.8 A, Class I laser	IEC60950-1 (2005)	—
Supplementary information: <sup>1)</sup> Provided evidence ensures the agreed level of compliance. See OD-2039.					

### E.16 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:						

5.1	<b>TABLE: temperature rise measurements</b>			Pass		
	Test voltage (V) .....	:	190 V <sup>(13)</sup>	—		
	t1 (°C) .....	:	25	—		
	t2 (°C) .....	:	26	—		
Temperature rise $\Delta T$ of part/at:			$\Delta T$ (K)	Allowed $\Delta T$ (K)		
Fuse holder			55	65		
Terminal			30	55		
Temperature rise $\Delta T$ of winding:		$R_1$ ( $\Omega$ )	$R_2$ ( $\Omega$ )	$\Delta T$ (K)	Allowed $\Delta T$ (K)	Insulation class
Supplementary information: Heating Test conducted in an enclosure sized 4 by 3 by 12 cm.						

NOTE 1: The supplementary information field is provided for describing any specific test conditions or testing clarifications. Repeating the measurement unit is optional when the TRF has already identified it (e.g. 190 V can be entered as 190).

19.7	<b>TABLE: Abnormal operation, locked rotor/moving parts</b>					
	Test voltage (V) .....	:	220/120	—		
	Ambient, t <sub>1</sub> (°C) .....	:	22/40	—		
	Ambient, t <sub>2</sub> (°C) .....	:	25/40	—		
Temperature of winding		$R_1$ ( $\Omega$ )	$R_2$ ( $\Omega$ )	dT (K)	T (°C)	Max. T (°C)
Motor winding (1) - Model 234						
Motor winding (1) - Model 4566						
Motor winding (2) - Model 234						
Motor winding (2) - Model 4566						
Model 234						
Motor winding (1)						
Motor winding (2)						
Model 4566						
Motor winding (1)						
Motor winding (2)						
Supplementary information Motor Model 234 tested at 220 V and in the range of ambient temperature of 22°C-25°C Motor Model 4566 tested at 120 V and at 40°C						

NOTE2: Two examples that ensure traceability of measurements when completing a measurement table for multiple models are shown above.

The results of Risk Management process and review of the Risk Management file shall be recorded in the Risk Management Results Tables.

<b>IEC 60601-1</b>			
<b>9.2.4</b>	<b>Risk Management Results Table: Emergency stopping devices</b>		
<b>Clause ISO 14971</b>	<b>Document Ref. in RMF (Document No. &amp; paragraph)</b>	<b>Result- Remark</b>	<b>Verdict</b>
4.2	Document XYZ2 – rev 3	Refer to clause 2.1b	Pass
4.3			
5			
6.2			
6.3			
6.4			
6.5			

NOTE 3: An example of Risk Management Table referring to the documents identified in the Risk Management File. Refer to OD-2044 for further details.

### E.17 National Differences section

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

NOTE: Provided example, based on the standard EN 60598-2-10, 2003 Edition, shows Group/CENELEC Common Differences. The attachment addressing National Differences may be a merging of selected National and Group Differences TRFs into one document with correctly numbered pages.

<b>ANNEX TO TEST REPORT IEC 60598-2-10 EUROPEAN GROUP DIFFERENCES AND NATIONAL DIFFERENCES</b>	
Luminaries	
Part 2: Particular requirements: Section Ten – Portable luminaries for children	
<b>Differences according</b> .....	EN 60598-2-10:2003 used in conjunction with EN 60598-1:2004+A1:2006
<b>Annex Form No.</b> .....	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
	<b>CENELEC COMMON MODIFICATIONS (EN 60598-2-10)</b>		Pass
<b>10.5 (3)</b>	<b>MARKING</b>		Pass
10.5 (3.3.101)	Adequate warning on the package		Pass
<b>10.10 (5)</b>	<b>EXTERNAL AND INTERNAL WIRING</b>		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

<b>ZB</b>	<b>ANNEX ZB, SPECIAL NATIONAL CONDITIONS (EN)</b>		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

### E.18 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
<b>6</b>	<b>CONNECTION TO TELECOMMUNICATION NETWORKS</b>		N/A

NOTE: 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.

<b>6</b>	<b>CONNECTION TO TELECOMMUNICATION NETWORKS</b>		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.

### E.19 List of test equipment used

A completed list of used test equipment shall be provided in the Test Reports when a Manufacturer Testing Laboratory according to CTF stage 1 or CTF stage 2 procedures has been used.

This page may be removed when CTF stage 1 or CTF stage 2 are not used. See also TRF Template.

Clause	Measurement / testing	Testing / measuring equipment / material used, (Equipment ID)	Range used	Last Calibration date	Calibration due date

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



Test Report issued under the responsibility of:

<p><b>TEST REPORT</b>  <b>IEC 60601-2-6</b>  <b>Medical electrical equipment</b>  <b>Particular requirements for the basic safety and essential performance</b>  <b>of X-ray equipment for computed tomography</b></p>	
<b>Report Number.</b> .....	TR-12345B <small>(Note 1: The NCB rules for numbering system shall be used – The 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)</small>
<b>Date of issue</b> .....	2015 May 18, Amendment No. 2: 2015 June 16
<b>Total number of pages</b> .....	Enter number of pages in the Amendment Report
<b>Applicant's name</b> .....	Applicant's name
<b>Address</b> .....	Applicant's address
<b>Test specification:</b>	
<b>Standard</b> .....	IEC 60601-2-44 (ed.3) am1, with Corr.1 for use in conjunction with IEC 60601-1 (ed.3)
<b>Test procedure</b> .....	CB Scheme
<b>Non-standard test method</b> .....	N/A
<b>Test Report Form No.</b> .....	IEC60601_2_44F
<b>Test Report Form(s) Originator</b> :	UL(US)
<b>Master TRF</b> .....	Dated 2015-05
<p><b>Copyright © 2015 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved.</b></p> <p>This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.</p> <p>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.</p> <p><b>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.</b></p>	
<b>General disclaimer:</b>	
<p>The test results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.</p>	

<b>Test item description</b> .....	Positron Emission Computed Tomography/Computed Tomography (PET/CT) Combination Systems	
<b>Trade Mark</b> .....	None	
<b>Manufacturer</b> .....	Same as Applicant	
<b>Model/Type reference</b> .....	Models AP-123, AP139 and AP154	
<b>Ratings</b> .....	480 V~, 50/60 Hz, 80 kVA, 3 phase	
<b>Testing procedure and testing location:</b>		
<input checked="" type="checkbox"/>	<b>CB Testing Laboratory:</b>	Name of the responsible CB Testing Laboratory
<b>Testing location/ address</b> .....		Address of responsible CBTL
<input type="checkbox"/>	<b>Associated CB Testing Laboratory:</b>	Name of Associated Testing Laboratory, when used
<b>Testing location/ address</b> .....		Address of ACTL
<b>Tested by (name, function + signature) ....</b>		Name, function                      signature
<b>Approved by (name, function + signature) :</b>		Name, function                      signature
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 1</b>	When applicable, select CTF Stage and complete appropriate section
<b>Testing location/ address</b> .....		
<b>Tested by (name, function + signature) ....</b>		
<b>Approved by (name, function + signature) :</b>		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 2</b>	
<b>Testing location/ address</b> .....		
<b>Tested by (name, function + signature) ....</b>		
<b>Witnessed by (name, function + signature):</b>		
<b>Approved by (name, function + signature) :</b>		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 3 or 4:</b>	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 3 or 4:</b>	
<b>Testing location/ address</b> .....		
<b>Tested by (name, function + signature) ....</b>		
<b>Witnessed by (name, function + signature):</b>		
<b>Approved by (name, function + signature) :</b>		
<b>Supervised by (name, function + signature):</b>		

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

This Amendment Report, Ref. No. TR-12345B to the original Report Ref. No. TR-12345 contains x Report Pages and a new photograph.

**Summary of testing:**

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

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

Clause 4.11 - Input test  
 Clause 11 - Heating test

**Testing location:**

The name of the CBTL, ACTL, client's laboratory or subcontractor's laboratory that conducted testing

**Summary of compliance with National Differences (List of countries addressed):**

***Instruction:*** Provide information about verified compliance with National Differences requirements.

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

**The product fulfils the requirements of \_\_\_\_\_ (insert standard number and edition and delete the text in parenthesis, leave it blank or delete the whole sentence, if not applicable)**

***Instruction:***

*In case of technical modifications to the product, state whether modified products still comply with previously evaluated National or Regional standards.*



**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.*

<b>Test item particulars .....</b>	
<b>Classification of installation and use .....</b>	See Part 1 Report
<b>Supply Connection .....</b>	non-detachable cord
Possible test case verdicts:	
- test case does not apply to the test object.....	N/A
- test object does meet the requirement.....	P (Pass)
- compliance with the requirement not evaluated.:	N/E (applicable only to collateral standards)
- test object does not meet the requirement.....	F (Fail)
<b>Testing.....</b>	
<b>Date of receipt of test item .....</b>	2015 June 02
<b>Date (s) of performance of tests .....</b>	2015 June 05
<b>General remarks:</b>	
<p>"(See Enclosure #)" refers to additional information appended to the report.                  "(See appended table)" refers to a table appended to the report.  <b>The tests results presented in this report relate only to the object tested.</b>  <b>This report shall not be reproduced except in full without the written approval of the testing laboratory.</b>  <b>List of test equipment must be kept on file and available for review.</b>  <b>Throughout this report a <input checked="" type="checkbox"/> comma / <input type="checkbox"/> point is used as the decimal separator.</b>  <b>This Test Report Form is intended for the investigation of the safety of X-ray equipment for computed tomography in accordance with IEC 60601-2-44. It can only be used together with the IEC 60601-1: 2005 (Third Edition) Test Report.</b></p>	
<b>Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:</b>	
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 .....	<input type="checkbox"/> <b>Yes</b> <input checked="" type="checkbox"/> <b>Not applicable</b>
<b>When differences exist; they shall be identified in the General product information section.</b>	
<b>Name and address of factory (ies) .....</b> : <i>Instruction:</i> Provide list of names of factories and addresses or refer to original report.	

**General product information:*****Instruction:***

*Describe any product changes or other relevant information.*

Original CB Test Report dated 2015 May 18, Amendment No. 2: 2015 June 26

**Amendment 1 Report:**

The original Test Report Ref. No. TR-12345, dated 2015 May 18 was modified on 2015 May 28 to include the following changes and/or additions:

New models added:

The two new Models AP139 and AP154 are identical to the previous Model AP-123, except for minor variations in the SELV circuitry and markings. After construction review and verification of electrical spacing, no additional tests were considered necessary.

**Amendment 2 Report:**

The original Test Report Ref. No. TR-12345, dated 2015 May 18 was additionally modified on 2015 June 26 to include the following changes and/or additions, which were considered technical modifications:

All three models AP123, AP139 and AP154 have changes to electronic components and circuitry.

Due to changes in the component layout, the modified units have reduced size casing.

Additional testing was conducted as reported under Summary of testing.

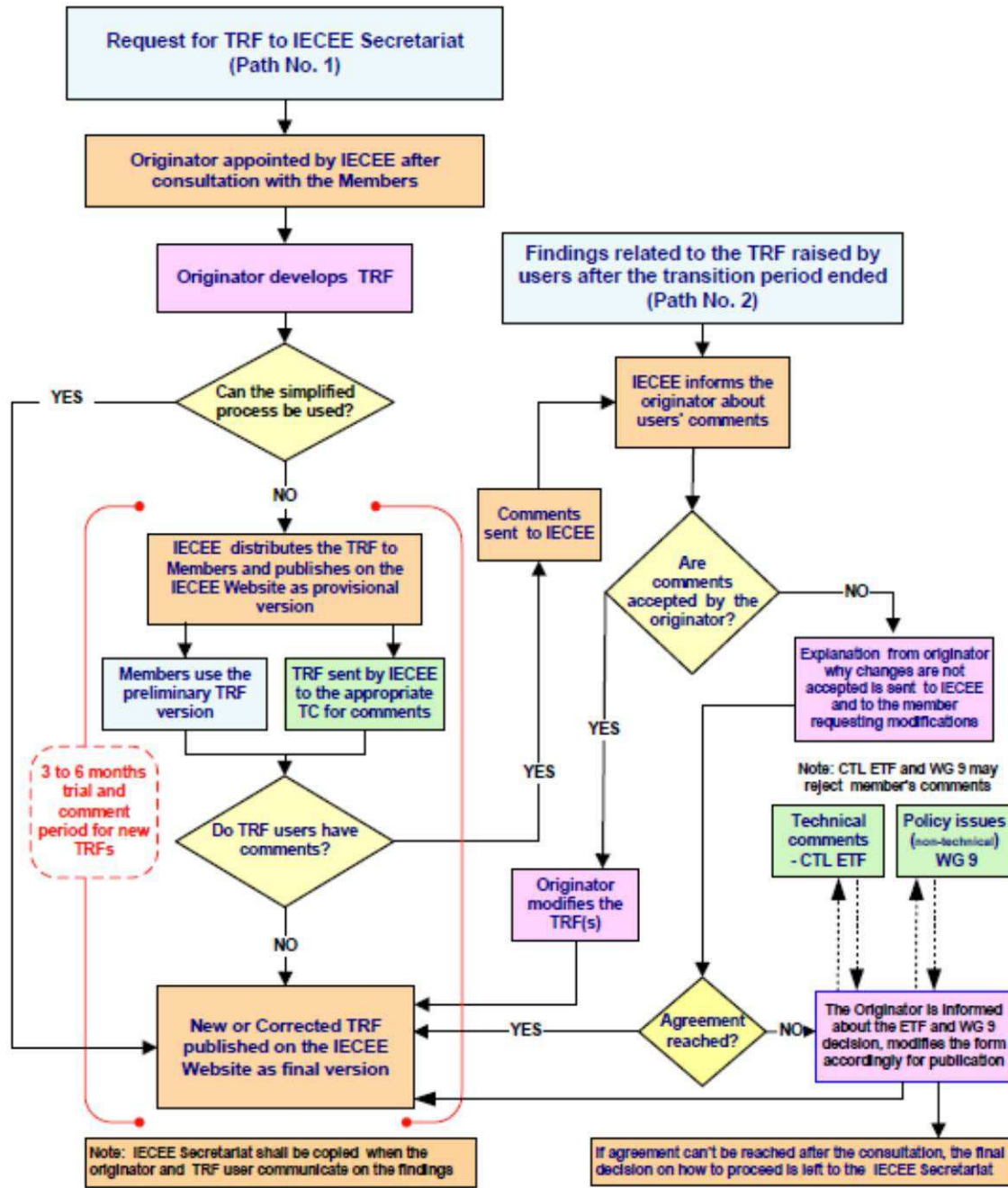
A photo of modified printed wiring board with new component layout was added in this Amendment Report.

Additional pages (a total of x pages, such as additional test tables for conducted tests, component table) or pages from the original Report that are affected by the product modifications shall follow pages shown above. A photo-documentation needs be also attached to this Amendment Report.

NOTE 2: The example shows Amendment No. 2 Report issued due to the technical modification to the product (critical components were added and case size changed) 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 model 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 is clearly documented. The entire history of changes may be repeated in each Amendment Report as illustrated in the above example.

NOTE 3: Both Amendment Report 1 and 2 involved changes that required engineering evaluation, therefore; only one more technical modification to the product is still allowed in the example given above before a new CB Test Report will become necessary

**Annex G - TRF Flowchart for Originators, Administrator and Users**



NOTE: The IECEE Secretary may also send each TRF to the appropriate TC for comments or for clarification of the requirements. See also clause 2.6., Procedure for the circulation of TRFs to TC/SC Officers.

## **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.

Contact Person at the IECEE Secretariat is:

Ms. Sonia Alves-Polidori  
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PO Box 131  
CH-1211 GENEVA 20  
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E-mail: [secretariat@iecee.org](mailto:secretariat@iecee.org)  
Tel: +41 22 919 0223

Suggestions about changes/improvements to the TRF template(s) and Operational Document OD-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.



**Annex J – TRFs on IECEE Website**

TRFs shall be published on IECEE Website and accessible to members under a password. A designated area on the Website shall be reserved for standardized attachments.

The originator shall always use the latest TRF template available on 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**

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