INTERNATIONAL STANDARD

IEC 60601-1-2

2001

AMENDMENT 1
2004-09

Amendment 1

Medical electrical equipment –

Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

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FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/462/FDIS	62A/469/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This amendment contains a first series of revisions to IEC 60601-1-2 (second edition, 2001): *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*.

This amendment deals primarily with requirements for EQUIPMENT and SYSTEMS that:

- comply with CISPR 11 Group 2 Class B except for the third harmonic of the fundamental frequency;
- are for use by healthcare professionals;
- are not intended for sale to the general public; and
- are intended for use in domestic establishments or connected to the PUBLIC MAINS NETWORK.

However, this amendment also includes several other corrections and additions to IEC 60601-1-2:2001.

To meet needs for change that were identified by users of this Collateral Standard, it was necessary to amend the standard before the previously approved maintenance cycle date.

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INTRODUCTION

Delete, on page 7, the paragraph beginning "This second edition allows a risk analysis…"

Page 8

2 Terminology and definitions

Replace the existing first paragraph with the following:

For the purposes of this Collateral Standard, the terms and definitions given in IEC 60601-1:1988, IEC 60601-1-1:2000, IEC 60601-1-8:2003 and ISO 14971:2000 and the following apply:

Delete definition 2.210 and change all occurrences of "ESSENTIAL PERFORMANCE" *throughout the document to normal font.*

Replace the existing definition 2.212 with the following:

***2.212**
FUNCTION (of an EQUIPMENT or SYSTEM)
clinically significant operation that the EQUIPMENT or SYSTEM is intended to perform in the diagnosis, treatment or monitoring of a PATIENT

Add the following new definitions:

***2.227**
PROFESSIONAL EQUIPMENT or SYSTEM
EQUIPMENT or SYSTEM for use by healthcare professionals and that is not intended for sale to the general public

[IEV 161-05-05, modified]

2.228
TYPE A PROFESSIONAL EQUIPMENT or SYSTEM
PROFESSIONAL EQUIPMENT or SYSTEM that complies with CISPR 11 Group 2 Class B except for the third harmonic of the fundamental frequency of the EQUIPMENT or SYSTEM, in which case the third harmonic complies with the Group 2 Class A electromagnetic radiation disturbance limit

NOTE See 36.201.1 a) 6).

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3 General requirements

3.201.2 Essential performance

Replace the existing text of this subclause with the following:

Either the essential performance of the EQUIPMENT or SYSTEM shall be identified (see Annex GGG for guidance on identifying the essential performance) or the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM shall be considered essential performance for the purpose of IMMUNITY testing (see 36.202.1 j)). The essential performance shall be disclosed in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS or, if this identification is not performed, by inspection of the documents to verify that the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM has been tested in accordance with 36.202.

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3.201.4 Non-medical electrical equipment

Remove the asterisk from the title and replace the existing text of this subclause with the following:

Non-medical electrical equipment that is supplied as part of a SYSTEM is exempt from the EMC testing requirements of this standard, provided all of the following conditions are met (see also Annex HHH):

a) the non-medical electrical equipment complies with applicable international EMC standards;

b) both the EMISSIONS and IMMUNITY of the non-medical electrical equipment have been determined not to adversely affect the essential performance or safety of the SYSTEM;

c) the EMISSIONS of the non-medical electrical equipment have been determined not to cause the EMISSIONS of the SYSTEM to exceed applicable limits.

Compliance is checked by inspection of the documents for this determination and other appropriate documents or certificates or, if this determination is not performed, by inspection of the documents to verify that the non-medical electrical equipment has been tested in accordance with this standard.

Add the following new subclause:

*3.201.5 General test conditions

For EMC testing, the SINGLE FAULT CONDITION requirements of the General Standard do not apply.

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6.8.201 ACCOMPANYING DOCUMENTS

Renumber this subclause as follows:

6.8 ACCOMPANYING DOCUMENTS

6.8.2.201 Instructions for use

Add the following item:

*d) Requirements applicable to TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS

If a TYPE A PROFESSIONAL EQUIPMENT or SYSTEM is intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 36.201.1 a) 6)), the instructions for use shall include the following warning or equivalent:

Warning
This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [EQUIPMENT or SYSTEM] or shielding the location.

where "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL or TYPE REFERENCE of the EQUIPMENT or SYSTEM.

6.8.3.201 Technical description

a) Requirements applicable to all EQUIPMENT and SYSTEMS

Replace, on page 14, the existing item a) 3) with the following:

*3) Table 201, with the modifications specified below.[3), 4)] The flowchart in Figure 201 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 11 EQUIPMENT and SYSTEMS. The flowchart in Figure 202 is the requirement in step-by-step graphical form for completion of Table 201 for CISPR 14 and CISPR 15 EQUIPMENT.

- For CISPR 11 EQUIPMENT and SYSTEMS, "[EQUIPMENT or SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT or SYSTEM.
- For CISPR 14 and CISPR 15 EQUIPMENT, "[EQUIPMENT]" shall be replaced with the MODEL OR TYPE REFERENCE of the EQUIPMENT.
- For CISPR 11 Group 1 EQUIPMENT and SYSTEMS, rows 5, 12 and 13 shall be deleted.
- For CISPR 11 Group 2 EQUIPMENT and SYSTEMS, rows 4, 12 and 13 shall be deleted.
- For EQUIPMENT that complies with CISPR 14-1, rows 4 through 6 and row 13 shall be deleted
- For EQUIPMENT that complies with CISPR 15, rows 4 through 6 and row 12 shall be deleted.
- For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class A, including TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS, "[A or B]" in column 2 of row 6 shall be replaced with "A." For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B, "[A or B]" shall be replaced with "B."
- For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-2, "[Class A, B, C, D, or Not applicable]" in column 2 of row 7 shall be replaced with the class of the EQUIPMENT or SYSTEM according to IEC 61000-3-2. For EQUIPMENT and SYSTEMS that comply with IEC 61000-3-3, "[Complies or Not applicable]" in column 2 of row 8 shall be replaced with "Complies." For EQUIPMENT and SYSTEMS for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, "[Class A, B, C, D, or Not applicable]" and "[Complies or Not applicable]" shall each be replaced with "Not applicable."
- For CISPR 11 EQUIPMENT and SYSTEMS, column 3 of rows 6, 7 and 8 shall be merged into one cell. For CISPR 11 EQUIPMENT and SYSTEMS that comply with Class B and with IEC 61000-3-2 and IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS for which use in a domestic establishment or connection to the PUBLIC MAINS NETWORK is intended and justified (see 6.8.3.201 j) and 36.201.1 a) 6)) and that comply with IEC 61000-3-2 and IEC 61000-3-3, the text in column 3 of row 10 shall be moved into the merged cell. For CISPR 11 EQUIPMENT and SYSTEMS for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable or that comply with Class A but do not meet the requirements for TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS specified in 36.201.1 a) 6), the text in column 3 of row 11 shall be moved into the merged cell.
- For CISPR 14 or CISPR 15 EQUIPMENT, column 3 of rows 7 and 8 shall be merged into one cell. For CISPR 14 or CISPR 15 EQUIPMENT that comply with IEC 61000-3-2 and with IEC 61000-3-3, the text in column 3 of row 9 shall be moved into the merged cell. For CISPR 14 or CISPR 15 EQUIPMENT for which IEC 61000-3-2 and IEC 61000-3-3 are not applicable, the text in column 3 of row 11 shall be moved into the merged cell.

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3) See Annex BBB for examples. These modifications should be performed in the order in which they appear.

4) Row numbers refer to those in Table 201 before modifications are made.

– For EQUIPMENT and SYSTEMS specified for use only in a shielded location and for which the electromagnetic radiation disturbance allowance or the mains terminal disturbance voltage allowance in 36.201.1 a) 4) is used, the text specified by 6.8.3.201 c) 2) shall be added.

– Rows 9, 10 and 11 shall be deleted.

– The row numbers shall be deleted.

Add, on page 15, the following new item a) 7):

7) The performance of the EQUIPMENT or SYSTEM that was determined to be essential performance.

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h) Requirements applicable to LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS

Replace the first paragraph of this item with the following:

For LARGE, PERMANENTLY-INSTALLED EQUIPMENT and SYSTEMS for which the exemption specified in 36.202.3 b) 9) is used, the ACCOMPANYING DOCUMENTS shall include the following information:

i) Requirements applicable to EQUIPMENT and SYSTEMS found by a risk analysis to have no essential performance

In the title of item i) and in 1) and 2), delete "by a risk analysis".

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Add the following new item:

*j) Requirements applicable to TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS

For TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK (see 36.201.1 a) 6)), the ACCOMPANYING DOCUMENTS shall include a justification for not complying with the CISPR 11 Group 2 Class B electromagnetic radiation disturbance limit at the third harmonic of the fundamental frequency of the EQUIPMENT or SYSTEM. This justification shall be based on significant physical, technological or physiological limitations that prevent compliance. The ACCOMPANYING DOCUMENTS shall also include a justification why the EQUIPMENT or SYSTEM needs to be used in domestic establishments or connected to the PUBLIC MAINS NETWORK.

Compliance is checked by inspection.

Page 19

Replace the existing Table 201 with the following:

Table 201 – Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYTEMS (see 6.8.3.201 a) 3))

Row			
1	**Guidance and manufacturer's declaration – electromagnetic emissions**		
2	The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment – guidance**
4	RF emissions CISPR 11	Group 1	The [EQUIPMENT or SYSTEM] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Group 2	The [EQUIPMENT or SYSTEM] must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
6	RF emissions CISPR 11	Class [A or B]	
7	Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or Not applicable]	
8	Voltage fluctuations/ flicker emissions IEC 61000-3-3	[Complies or Not applicable]	
9		[See 6.8.3.201 a) 3) and Figure 201]	The [EQUIPMENT or SYSTEM] is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
10		[See 6.8.3.201 a) 3) and Figure 201]	The [EQUIPMENT or SYSTEM] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [EQUIPMENT or SYSTEM] or shielding the location.
11		[See 6.8.3.201 a) 3) and Figure 201]	The [EQUIPMENT or SYSTEM] is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
12	RF emissions CISPR 14-1	Complies	The [EQUIPMENT] is not suitable for interconnection with other equipment.
13	RF emissions CISPR 15	Complies	The [EQUIPMENT] is not suitable for interconnection with other equipment.

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Replace the existing Figure 201 with the following:

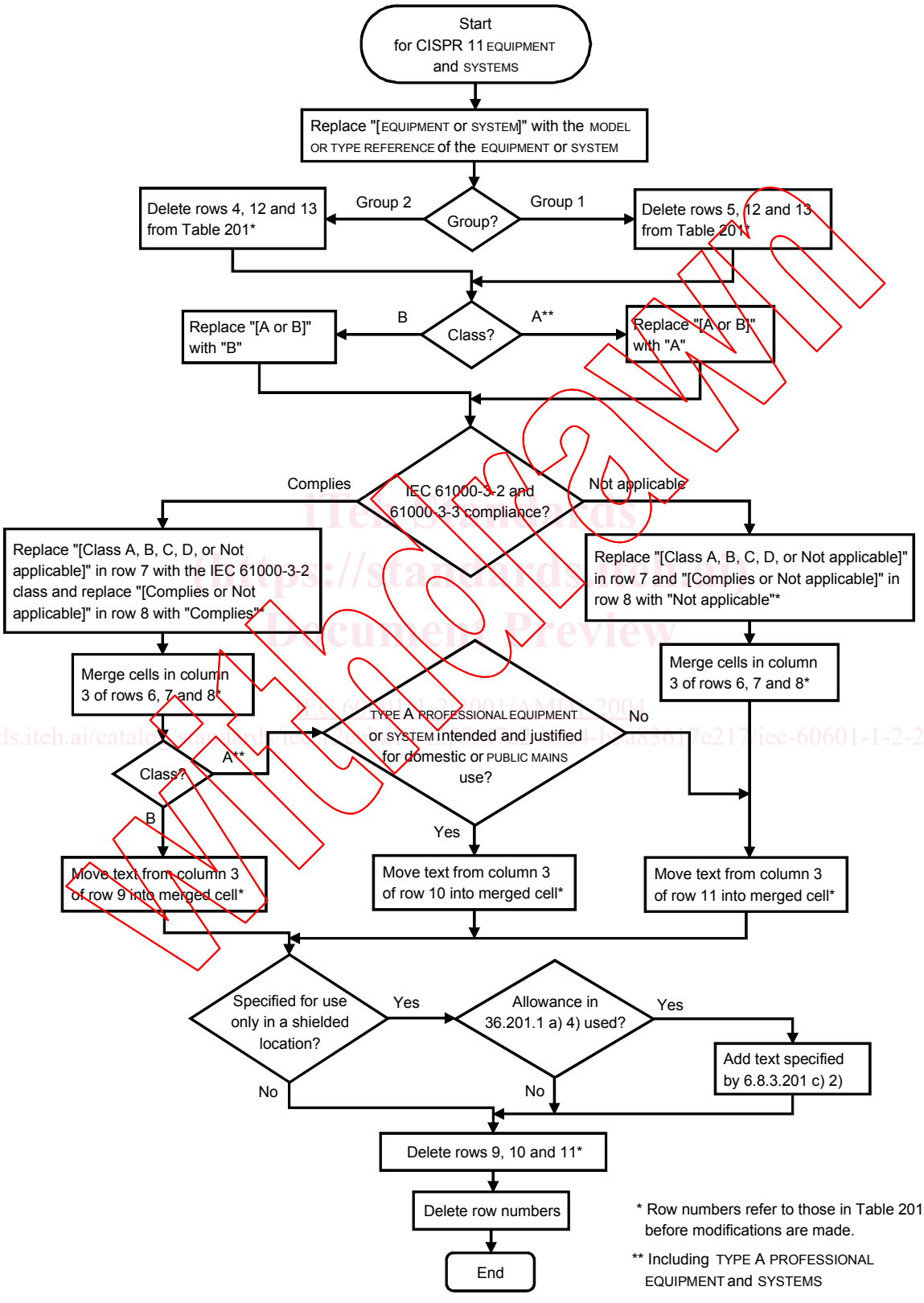

Figure 201 – Instructions for completing Table 201 for CISPR 11 EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 3))

Page 21

Replace the existing Figure 202 with the following:

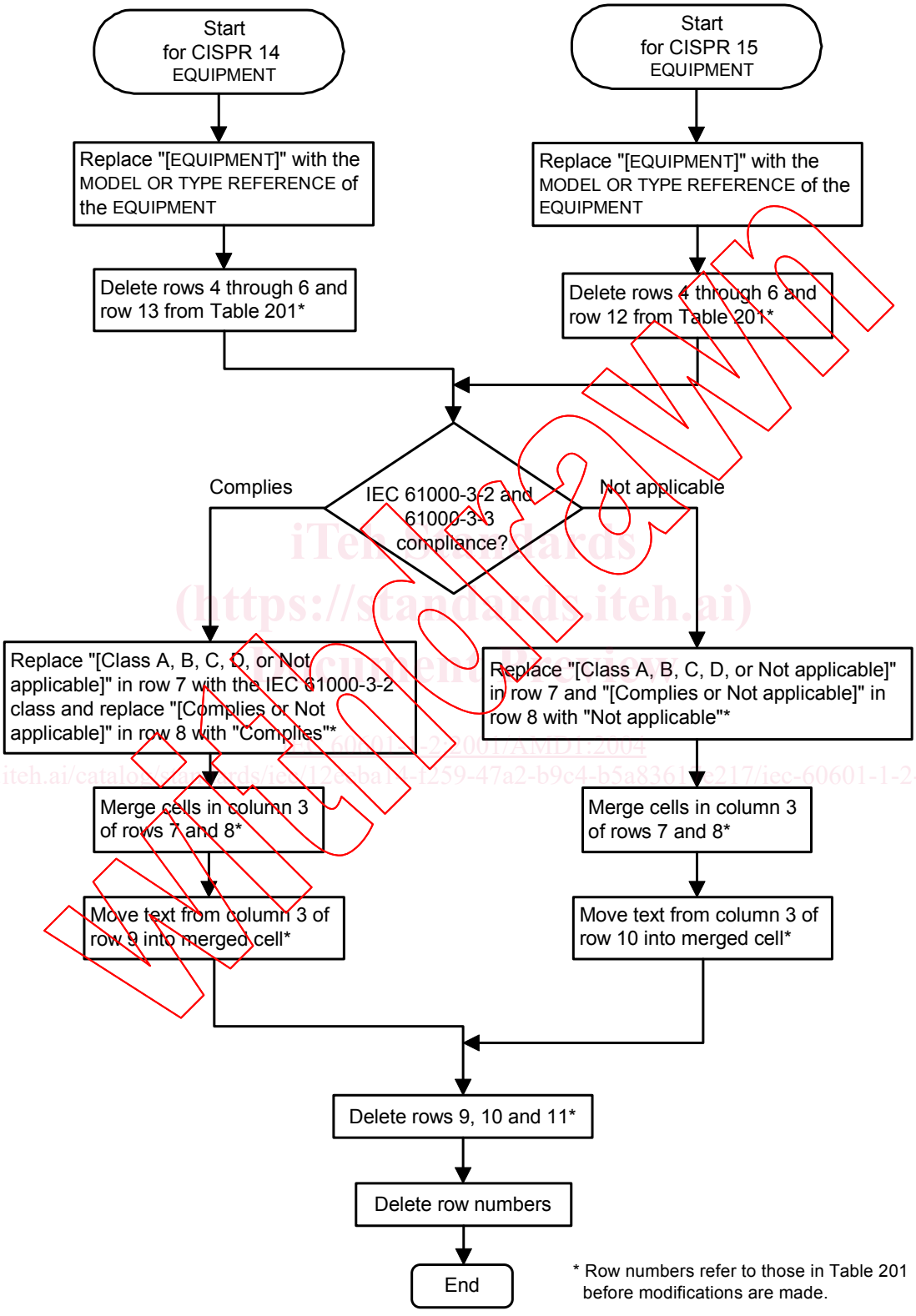

Figure 202 – Instructions for completing Table 201 for CISPR 14 and CISPR 15 EQUIPMENT (see 6.8.3.201 a) 3))

Page 22

In Table 202, replace "differential mode" with "line(s) to line(s)" and "common mode" with "line(s) to earth".

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36 ELECTROMAGNETIC COMPATIBILITY

36.201 Emissions

36.201.1 Protection of radio services

*a) Requirements

Replace, in the last line of the first paragraph of this item, "4) and 5)" with "4), 5) and 6)".

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Renumber the existing item a) 6) as a) 7) and insert the following new item a) 6) in this subclause:

*6) TYPE A PROFESSIONAL EQUIPMENT and SYSTEMS

CISPR 11 Group 2 PROFESSIONAL EQUIPMENT and SYSTEMS that are intended for use in domestic establishments or connection to the PUBLIC MAINS NETWORK shall comply with CISPR 11 Group 2 Class B, with the exception that the third harmonic of the fundamental frequency of the EQUIPMENT or SYSTEM may comply with the CISPR 11 Group 2 Class A electromagnetic radiation disturbance limit, provided this is justified based on:

– significant physical, technological or physiological limitations that prevent compliance with the CISPR 11 Group 2 Class B electromagnetic radiation disturbance limit at the third harmonic of the fundamental frequency of the EQUIPMENT or SYSTEM and
– the need for the use of the EQUIPMENT or SYSTEM in domestic establishments or connected to the PUBLIC MAINS NETWORK.

(See 6.8.2.201 d) and 6.8.3.201 j).)

b) Tests

Replace, in the first paragraph, "1) and 2) below" with "1), 2) and 3) below".

Replace, in Footnote 10, "CISPR 11:1997" with "CISPR 11: 2003".

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36.202 IMMUNITY

36.202.1 General

Replace, on page 35, the existing item d) with the following:

*d) Non-medical electrical equipment

Non-medical electrical equipment that is supplied as part of a SYSTEM is exempt from the IMMUNITY testing requirements of this standard, provided all of the following conditions are met (see also Annex HHH):