IEC 60601-1-2

Edition 4.0 2020-09

INTERNATIONAL STANDARD

colour inside

AMENDMENT 1

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

IEC 60601-1-2:2014-02/AMD1:2020-09(en)

THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2020 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

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

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

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

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

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

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

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

iTeh STANDARD Preview
(standards.iteh.ai)
IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

IEC 60601-1-2

Edition 4.0 2020-09

INTERNATIONAL STANDARD

colour inside

AMENDMENT 1

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01; 33.100.10; 33.100.20

ISBN 978-2-8322-8630-2

Warning! Make sure that you obtained this publication from an authorized distributor.

® Registered trademark of the International Electrotechnical Commission

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/1390/FDIS	62A/1405/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 stability 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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION TO AMENDMENT 1

The fourth edition of IEC 60601-1-2 was published in 2014. Since the publication of IEC 60601-1-2:2014, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fifth edition of IEC 60601-1-2, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 15 items were presented to the National Committees present. All 15 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the fifth edition of IEC 60601-1-2.

The "short list" of issues was documented in the design specification for Amendment 1. MT 23 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-2:2014, the style in force at the time of publication of IEC 60601-1-2 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/43dbaed6-69b0-4955-838b-29a2f7f3d3ec/iec-60601-1-2-2014-amd1-2020

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

1.3.1 IEC 60601-1

Replace, in the second existing paragraph, the first two existing dashes with the following new dashes:

– "the general standard" designates IEC 60601-1 alone, including any amendments;

– "this collateral standard" designates IEC 60601-1-2 alone, including any amendments;

2 Normative references

Replace the existing references to IEC 60601-1 (including footnote 1), IEC 60601-1-8 (including footnote 2), IEC 60601-1-11, IEC 60601-1-12 (including footnote 3), IEC 61000-4-5, IEC 61000-4-11, CISPR 11 (including footnote 6), CISPR 14-1, CISPR 16-1-2 (including footnote 7), CISPR 32 and ISO 14971 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012
Amendment 2:2020

iTeh STANDARD PREVIEW
(standards.iteh.ai)

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
Amendment 1:2020

IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
Amendment 1:2020

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*
Amendment 1:2017

IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measuring techniques – Voltage dips, short interruptions and voltage variations immunity tests*
Amendment 1:2017

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*
Amendment 1:2016
Amendment 2:2019

CISPR 14-1:2016, *Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 1: Emission*

CISPR 16-1-2:2014, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Coupling devices for conducted disturbance measurements*
Amendment 1:2017

CISPR 32:2015, *Electromagnetic compatibility of multimedia equipment – Emission requirements*

ISO 14971:2019, *Medical devices - Application of risk management to medical devices*

Delete the existing normative reference to ISO 7137.

Add the following normative reference to the existing list:

IEC 61000-4-39:2017, *Electromagnetic compatibility (EMC) – Part 4-39: Testing and measurement techniques – Radiated fields in close proximity – Immunity test*

3 Terms and definitions

Replace the existing first paragraph with the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 +A1:2012+A2:2020, IEC 60601-1-8:2006+A1:2012+A2:2020, IEC 60601-1-11:2015+A1:2020, IEC 60601-1-12:2014+A1:2020, IEC 60601-2-2:2009, IEC 60601-2-3:2012 and the following definitions apply.

3.20
SPECIAL ENVIRONMENT

iTeh STANDARD PREVIEW

Replace, in the definition, the words "Table 2 through Table 9" *with* "Table 2 through Table 9 and Table 11".

(standards.iteh.ai)

Table 1 – Power input voltages and frequencies during the tests

IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ca2f71333/iec-60601-1-2-2014-amd1-2020

Replace the existing header and first row of Table 1 (1 of 2) with the following new header and first row:

Test	Power input voltage	Power frequency
Conducted DISTURBANCES (conducted EMISSIONS) CISPR 11	Minimum and maximum RATED voltage [c) d)]	Any one frequency [b)]

Replace the existing Table 1 (2 of 2) with the following new table:

Table 1 *(2 of 2)*

Test	Power input voltage	Power frequency
Power frequency magnetic field IMMUNITY IEC 61000-4-8	Any one voltage [a]	Either 50 Hz or 60 Hz. During the test, the frequency of the generated magnetic field and the power frequency of the ME EQUIPMENT or ME SYSTEM shall be the same. [b]
Voltage dips IMMUNITY IEC 61000-4-11	Minimum and maximum RATED voltage [c] [d]	Any one frequency [b]
Voltage short interruptions and voltage variations IMMUNITY IEC 61000-4-11	Any one voltage [a]	Any one frequency [b]
Proximity magnetic fields IEC 61000-4-39	Any one voltage [a]	Any one frequency [b]

[a] The test may be performed at any one power input voltage within the ME EQUIPMENT or ME SYSTEM RATED voltage range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

[b] The test may be performed at any one power frequency within the ME EQUIPMENT or ME SYSTEM RATED frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power frequency, it is not necessary to re-test at additional frequencies.

[c] If the difference between the maximum and the minimum RATED input voltage is less than 25 % of the highest RATED input voltage, then the test may instead be performed at any one RATED voltage.

[d] ME EQUIPMENT and ME SYSTEMS with power input voltage selection by transformer taps shall be tested at only one tap setting.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

7.1.12 PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Replace the existing title of the subclause with the following new title:

7.1.12 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Table 2 – EMISSION limits per environment

Replace, in the third column of the first row of the existing Table 2, "CISPR 11 [c], [d]" *with* "CISPR 11 [c]".

Replace, in the existing Table 2, table footnote [c] *with the following new footnote:*

[c] Standards applicable to modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

Delete, in the existing Table 2, table footnote [d].

8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

8.1 * General

Replace, in the existing first paragraph following Table 3, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11" *in four places.*

Replace, in the existing first paragraph following NOTE 3, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

Replace, in the existing first paragraph following NOTE 4, "Table 4 through Table 9 for the HOME HEALTHCARE ENVIRONMENT" *with* "Table 4 through Table 9 for the HOME HEALTHCARE ENVIRONMENT, and 8.11".

Replace, in the existing second paragraph following NOTE 4, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

Replace, in the existing sixth paragraph following NOTE 4, "Table 1 and Table 4 through Table 9" *with* "Table 1".

Replace, in the existing last paragraph of the subclause, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11, as applicable".

8.6 PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Replace the existing title of the subclause with the following new title:

8.6 * PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS

Replace, in the existing first paragraph following the NOTE, "8.9 and 8.10" *with* "8.9, 8.10 and 8.11".

iTeh STANDARD PREVIEW
(standards.iteh.ai)

8.9 * IMMUNITY TEST LEVELS

Replace, in the existing first paragraph, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11".

IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

Delete the existing NOTE.

Replace, in the existing second paragraph, "Table 4 through Table 9" *with* "Table 4 through Table 9 and 8.11" *in two places*.

Figure 3 – Examples of environments of INTENDED USE

Replace the existing title of Figure 3 with the following new title:

Figure 3 – Examples of locations within EM ENVIRONMENTS

Table 4 – * ENCLOSURE PORT

Replace, in the existing Table 4, the fourth row with the following new rows:

RATED power frequency magnetic fields [d]	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Proximity magnetic fields	IEC 61000-4-39	See 8.11.

Replace, in the existing Table 4, table footnote [e] with the following new footnote:

[e] Void.

Delete, in the existing Table 4, table footnote [g].

Table 5 – * Input a.c. power PORT

Replace, in the first column of the first row of the existing Table 5 (1 of 2), "Electrical fast transients / bursts [a) l) o)]" *with* "Electrical fast transients / bursts [l) o)]".

Replace, in the first column of the second row of the existing Table 5 (1 of 2), "Surges [a) b) j) o)] Line-to-line" *with* "Surges [b) j) o)] Line-to-line".

Replace, in the first column of the third row of the existing Table 5 (1 of 2), "Surges [a) b) j) k) o)] Line-to-ground" *with* "Surges [b) j) k) o)] Line-to-ground".

Replace, in the first column of the sixth row of the existing Table 5 (1 of 2), "Voltage interruptions [f) i) o) r)]" *with* "Voltage interruptions [f) i) o)]".

Replace, in the existing Table 5 (1 of 2), table footnote [a)] with the following new footnote:

[a)] Void.

Replace, in the existing Table 5 (2 of 2), table footnote [r)] with the following new footnote:

[r)] For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the power input voltage specified in Table 1.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Table 8 – Signal input/output parts PORT

Replace the existing title of Table 8 with the following new title:

IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

Table 8 – SIP/SOP PORT

Replace, in the first column of the fourth row of the existing Table 8, "Conducted disturbances induced by RF fields [b) d) g)]" *with* "Conducted disturbances induced by RF fields [d) g) j) k)]".

Add, in the existing Table 8, the following table footnotes:

[j)] See IEC 61000-4-6:2013, Annex B, for modified start frequency versus cable length and equipment size.

[k)] SIP/SOPS whose maximum cable length is less than 1 m are excluded.

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Replace the existing Table 9 with the following new table:

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5 500				
5 785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50 % duty cycle square wave signal. [c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbeed6-69b0-4953-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

Add, after the existing Subclause 8.10, the following new subclause:

8.11 * IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz shall be evaluated according to steps a) through d) below. MANUFACTURERS may proceed directly to step d). The result of the evaluation for each applicable step shall be documented in the test report or RISK MANAGEMENT FILE, as applicable. See also Figure A.3.

While communication might not be possible when ME EQUIPMENT that includes radio equipment is tested in its passband, the ME EQUIPMENT or ME SYSTEM shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

a) ME EQUIPMENT and ME SYSTEMS that do not contain magnetically sensitive components or circuitry within the ENCLOSURE or as part of an attached ACCESSORY need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

b) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry where a separation distance of those components or circuitry of at least 0,15 m from the field sources specified in Table 11 is ensured by the ENCLOSURE or by the physical design of an attached ACCESSORY during INTENDED USE need not be evaluated further for IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz; otherwise,

c) Perform a RISK ANALYSIS regarding exposure of the ME EQUIPMENT or ME SYSTEM to the frequencies, field strengths, and modulations specified in Table 11 at separation distances less than 0,15 m. If the RISK of exposure (during INTENDED USE) to the frequencies, field strengths, and modulations specified in Table 11 is acceptable, then the tests of Table 11 need not be performed; otherwise,

d) ME EQUIPMENT and ME SYSTEMS containing magnetically sensitive components or circuitry not meeting the separation distance criteria in b) or the RISK acceptability criteria in c) shall be tested for IMMUNITY to magnetic fields as specified in Table 11 using the test methods specified in IEC 61000-4-39. The magnetic field shall be applied only to those surfaces of the ENCLOSURE or attached ACCESSORIES that are accessible during INTENDED USE. The test windows to be used with IEC 61000-4-39 may be selected to illuminate only the area of the magnetically sensitive components or circuitry. The location of application of the magnetic field should be specified in the test plan and shall be documented in the test report.

Table 11 – Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]

a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) r.m.s., before modulation is applied.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
IEC 60601-1-2:2014/AMD1:2020
https://standards.iteh.ai/catalog/standards/sist/b3dbecd6-69b0-4955-838b-29ce2ff71333/iec-60601-1-2-2014-amd1-2020

9 * Test report

Add, in the existing Table 10 (2 of 2), before the last row:

38	The locations of application of proximity magnetic fields.	If the testing according to 8.11 step d) is performed.

A.1 Safety and performance

Replace, in the existing NOTE, the reference "IEC/TS 61000-1-2 in the 2008 edition [8]" *with* "IEC/TS 61000-1-2:2008".

A.3 Rationale for particular clauses and subclauses

Subclause 4.2 – Non-ME EQUIPMENT used in an ME SYSTEM

Add, immediately following the existing third paragraph, the following new text: