IEC 60601-1

Edition 3.0 2020-08

INTERNATIONAL STANDARD

colour inside

AMENDMENT 2

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

IEC 60601-1: 2005-12/AMD2: 2020-07(en)

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 It also gives information on projects, replaced and withdrawn publications.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.

IEC 60601-1

Edition 3.0 2020-08

INTERNATIONAL STANDARD

colour inside

AMENDMENT 2

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

ISBN 978-2-8322-8632-6

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/1389/FDIS	62A/1404/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.

NOTE The attention of the 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.

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 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. 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 Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 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, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it 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 the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 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. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

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.

INTRODUCTION

Add, after the existing last paragraph, the following paragraph:

Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document.

1.3 * Collateral standards

Replace the existing second paragraph with:

Applicable collateral standards shall apply together with this standard.

Delete the existing third paragraph.

1.4 * Particular standards

Replace the existing first paragraph with:

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in this standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration.

Replace the existing second paragraph with:

A requirement of a particular standard takes priority over this standard and applicable collateral standards.

2 * Normative references

Replace the existing second paragraph with:

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, shall apply together with this standard when applicable. They shall be considered as being included among the normative references below. See 1.3.

Replace the following existing references to IEC 60601-1-2, IEC 60601-1-3 modified by Amendment 1, IEC 60601-1-6 and IEC 60601-1-8 by the following new references:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*
Amendment 1:2020

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013
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

Add the following new reference to the list:

IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers*

Replace, in the existing reference to IEC 60825-1, "2007" *with* "2014".

Replace the existing references to IEC 60950-1 and IEC 62304 by the following new references:

IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
Amendment 1:2009
Amendment 2:2013

IEC 62304:2006, *Medical device software – Software life cycle processes*
Amendment 1:2015

Add the following normative references to the existing list:

IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems*

IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

Replace the existing references to ISO 7000-DB:2004 by the following new reference:
ISO 7000, *Graphical symbols for use on equipment*

Replace, in the existing reference to ISO 7010, "2011" *with* "2019".

Replace, in the existing reference to ISO 14971, "2007" *with* "2019".

Replace, in the existing reference to ISO 15223-1, "2012" *with* "2016".

3 * Terminology and definitions

3.38
*** HARM**

Replace the existing term and definition, modified by Amendment 1, with:

3.38
*** HARM**
injury or damage to the health of people or animals, or damage to property or the environment

[ISO 14971:2019, definition 3.3, modified – "Or animals" added to the definition.]

3.39
HAZARD

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.4]

3.40
*** HAZARDOUS SITUATION**

Replace the existing term and definition, modified by Amendment 1, with:

3.40
*** HAZARDOUS SITUATION**
circumstance in which people, property, or the environment is/are exposed to one or more HAZARDS

[ISO 14971:2019, definition 3.5, modified – Note 1 to entry deleted.]

3.44
INTENDED USE
INTENDED PURPOSE

Replace the existing term and definition, modified by Amendment 1, with:

3.44
INTENDED USE
INTENDED PURPOSE
use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

NOTE 1 The intended medical indication, PATIENT population, part of the body or type of tissue interacted with, user profile, use environment, and operating principle are typical elements of the INTENDED USE.

NOTE 2 INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[ISO 14971:2019, definition 3.6, modified – Note 2 added.]

3.55
MANUFACTURER

Replace the existing term and definition, modified by Amendment 1, with:

3.55
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person himself or on his behalf by another person(s)

NOTE 1 ISO 13485 [30] defines “labelling” as "label, instructions for use, and any other information that is related to identification, technical description, INTENDED PURPOSE and proper use of the ME EQUIPMENT or ME SYSTEM, but excluding shipping documents".

NOTE 2 “Adapting” includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2019, definition 3.9.

3.72
OBJECTIVE EVIDENCE

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.11]

3.88
PROCEDURE

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.13, modified – Note 1 to entry deleted.]

3.89
PROCESS

Replace the existing term and definition, modified by Amendment 1, with:

3.89
PROCESS
set of interrelated or interacting activities that use inputs to deliver an intended result

NOTE 1 Whether the "intended result" of a PROCESS is called output, product or service depends on the context of the reference.

NOTE 2 Inputs to a PROCESS are generally the outputs of other PROCESSES and outputs of a PROCESS are generally the inputs to other PROCESSES.

NOTE 3 Two or more interrelated and interacting PROCESSES in series can also be referred to as a PROCESS.

[ISO 14971:2019, definition 3.14]

3.98
RECORD

Add the following NOTES and replace the existing source statement for definition, modified by Amendment 1, with:

NOTE 1 RECORDS can be used, for example, to formalize traceability and to provide evidence of VERIFICATION, preventive action and corrective action.

NOTE 2 Generally RECORDS need not be under revision control.

[ISO 14971:2019, definition 3.16]

3.100
RESIDUAL RISK

Replace the existing term and definition, modified by Amendment 1, with:

3.100
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been implemented

[ISO 14971:2019, definition 3.17]

3.102
RISK

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.18]

3.103
RISK ANALYSIS

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.19]

3.104
RISK ASSESSMENT

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.20]

3.105
RISK CONTROL

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.21]

3.106
RISK EVALUATION

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.23]

3.107
RISK MANAGEMENT

Replace the existing term and definition, modified by Amendment 1, with:

3.107
RISK MANAGEMENT
systematic application of management policies, PROCEDURES and practices to the tasks of analysing, evaluating, controlling and monitoring RISK

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

[ISO 14971:2019, definition 3.24, modified – NOTE added.]

3.108
RISK MANAGEMENT FILE

Replace the existing NOTE and source statement for definition, modified by Amendment 1, with:

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

[ISO 14971:2019, definition 3.25, modified – NOTE added.]

3.114
SEVERITY

Replace the existing source statement for definition, modified by Amendment 1, with:

[ISO 14971:2019, definition 3.27]

3.136
USABILITY

Replace the existing term and definition, modified by Amendment 1, with:

3.136
USABILITY
characteristic of the OPERATOR interface that facilitates use and thereby establishes effectiveness, efficiency, and OPERATOR satisfaction in the intended use environment

[IEC 62366-1:2015, definition 3.16, modified – Replace "user" with "OPERATOR" in two places and delete Note 1 to entry.]

3.137
USABILITY ENGINEERING

Replace the existing term and definition, modified by Amendment 1, with:

3.137
USABILITY ENGINEERING
HUMAN FACTORS ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of ME EQUIPMENT (including software), systems and tasks to achieve adequate USABILITY

[IEC 62366-1:2015, definition 3.17, modified – Replace "medical devices" with "ME EQUIPMENT" and delete Note 1 to entry.]

3.138
VERIFICATION

Replace the existing NOTES and source statement of definition, modified by Amendment 1, with:

NOTE 1 The OBJECTIVE EVIDENCE needed for a VERIFICATION can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

NOTE 2 The activities carried out for VERIFICATION are sometimes called a qualification PROCESS.

NOTE 3 The word “verified” is used to designate the corresponding status.

[ISO 14971:2019, definition 3.31]

3.146
PRIMARY OPERATING FUNCTION

Replace the existing term and definition, added by Amendment 1, with:

3.146
PRIMARY OPERATING FUNCTION
function that involves OPERATOR interaction that is related to the safety of the ME EQUIPMENT

[IEC 62366-1:2015, definition 3.11, modified – Replace "user" with "OPERATOR" and "medical device" with "ME EQUIPMENT", and delete Note 1 to entry and Note 2 to entry.]

3.147
USABILITY ENGINEERING FILE

For the existing definition, added by Amendment 1, replace "[IEC 62366:2007, definition 3.19]" *with* "[IEC 62366-1:2015, definition 3.18]".

Add, after the existing definition 3.147, added by Amendment 1, the following new terms and definitions:

3.148
ELECTROMAGNETIC DISTURBANCE
EM DISTURBANCE
any electromagnetic phenomenon that could degrade the performance of a device, equipment or system

NOTE An ELECTROMAGNETIC DISTURBANCE can be electromagnetic noise, an unwanted signal or a change in the propagation medium itself.

[IEC 60601-1-2:2014, definition 3.3]

3.149
HIGH PRIORITY
indicating that immediate OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS.

NOTE 2 Immediate implies the interruption of current workflow is expected.

[IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, definition 3.22, modified – Internal reference to IEC 60601-1-8, 6.1.2 in NOTE 1 deleted and bibliographic citations removed from NOTE 2.]

3.150
*** INFORMATION SIGNAL**
any signal that is not an ALARM SIGNAL or a reminder signal

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

NOTE An advisory is a type of INFORMATION SIGNAL.

[SOURCE: IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, definition 3.23]

3.151
LOW PRIORITY
indicating that OPERATOR awareness is required and future action might be needed

NOTE 1 The priority is assigned through RISK ANALYSIS.

NOTE 2 Awareness implies the planning of future workflow is expected.

[IEC 60601-1-8:2006/AMD2:2020, definition 3.27, modified – Internal reference to IEC 60601-1-8, 6.1.2 in NOTE 1 deleted and bibliographic citations removed from NOTE 2.]

3.152
*** MAXIMUM EQUIPMENT PRESSURE**
the maximum gauge pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION

3.153
MEDIUM PRIORITY
indicating that prompt OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS.

NOTE 2 Prompt implies the re-planning of current workflow is expected.

[IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, definition 3.28, modified – Internal reference to IEC 60601-1-8, 6.1.2 in NOTE 1 deleted and bibliographic citations removed from NOTE 2.]

3.154
SAFETY SIGN
sign giving a general safety message, obtained by a combination of a colour and geometric shape and which, by the addition of a graphical symbol, gives a general or particular safety message

[ISO 7010:2019, definition 3.3, modified – Replace "gives a particular safety message" with " gives a general or particular safety message".]

4.2.1 Introduction to RISK MANAGEMENT

Replace, in the existing second paragraph, added by Amendment 1, "ISO 14971" *with* "ISO 14971:2019" *(3 places).*

4.2.2 General requirement for RISK MANAGEMENT

Replace, in the introductory paragraph before the dashes, added by Amendment 1, "ISO 14971:2007" *with* "ISO 14971:2019".

Replace the existing first and second dashes, added by Amendment 1, with:

– the planning for and execution of production and post-production monitoring (subclause 4.1, fourth dash, subclause 4.4, item g), and Clause 10 of ISO 14971:2019), and
– periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (third paragraph of ISO 14971:2019, subclause 4.2).

Figure 6 – Standard test finger (see 5.9.2.1)

Replace, in the existing NOTE 3 of this figure, the reference to "IEC 60950-1" *with* "IEC 60950-1:2005".

6.3 * Protection against harmful ingress of water or particulate matter

Delete, in the existing title, the asterisk (*).

7.1.2 * Legibility of markings

Replace, in the existing first dash, "safety signs" with "SAFETY SIGNS".

7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replace the existing subclause, modified by Amendment 1, with:

When the MANUFACTURER uses consulting the ACCOMPANYING DOCUMENTS as a primary RISK CONTROL measure for a specific RISK (e.g. the instructions for use contain information for safety) and the USABILITY ENGINEERING PROCESS determines that marking the ME EQUIPMENT is required for the effectiveness of the RISK CONTROL, the ME EQUIPMENT shall be marked with the refer to instruction manual/booklet mandatory action SAFETY SIGN ISO 7010-M002 (see Table D.2, SAFETY SIGN 10).

Otherwise, symbol ISO 7000-1641 (2004-01) (see Table D.1, symbol 11) may be used to advise the OPERATOR of the location of the instructions for use or to consult the ACCOMPANYING DOCUMENTS.

7.2.5 ME EQUIPMENT intended to receive power from other equipment

Replace, in the existing second dash modified by Amendment 1, "safety sign" *with* "SAFETY SIGN" *in two places*.

7.2.9 IP classification

Replace the existing second paragraph with:

If the IP classification of the ENCLOSURE of the ME EQUIPMENT or its parts is not specified (i.e. IPXX) or is specified as IP00, IPX0 or IP0X, then the ME EQUIPMENT or its parts need not be marked as such.

7.2.10 * APPLIED PARTS

Replace, in the final paragraph, "safety sign" *with* "SAFETY SIGN" *in two places*.

7.2.13 Physiological effects (safety signs and warning statements)

Replace, in the existing title, "safety signs" *with* "SAFETY SIGNS"*, and in the existing first paragraph,* "safety sign" *with* "SAFETY SIGN" *in two places*.

7.2.17 Protective packaging

Replace, in the existing third paragraph, "safety sign" *with* "SAFETY SIGN".

7.3.2 * HIGH VOLTAGE parts

Replace, in the existing paragraph, modified by Amendment 1, "safety sign" *with* "SAFETY SIGN".

7.3.3 Batteries

Replace the existing third paragraph with:

Where lithium batteries or fuel cells are incorporated and where incorrect replacement (e.g. reversed polarity) would result in a HAZARDOUS SITUATION (such as excessive temperatures, fire or explosion), a warning indicating that replacement by inadequately trained personnel could result in such a HAZARDOUS SITUATION shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.

7.3.7 Supply terminals

Delete, in the existing first paragraph, modified by Amendment 1, "unless it can be demonstrated that no unacceptable RISK can result if connections are interchanged".

7.4.1 * Power switches

Delete, in the existing first paragraph modified by Amendment 1, "or its parts,".

Add, after the third dash of the existing third paragraph modified by Amendment 1, the following paragraphs:

Switches used to control power to parts of ME EQUIPMENT shall have their “on” and “off” positions:

– marked with symbols as specified above; or

– with IEC 60417-5264 (2002-10) and IEC 60417-5265 (2002-10) (see Table D.1, symbols 16 and 17); or

– indicated by an adjacent indicator light; or

– indicated by other unambiguous means.

A switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2015-03) (see Table D.1, Symbol 29).

7.4.2 * Control devices

Delete, in the existing first paragraph, modified by Amendment 1, ", e.g. by use of symbols IEC 60417-5264 (2002-10) and IEC 60417-5265 (2002-10) (see Table D.1, symbols 16 and 17)"

Delete the existing final paragraph, modified by Amendment 1.

7.5 Safety signs

Replace, in the existing title, "Safety signs" *with* "SAFETY SIGNS"*, in the existing first paragraph, modified by Amendment 1,* "safety sign" *with* "SAFETY SIGN" *in three places, and in the existing second paragraph,* "safety sign" *with* "SAFETY SIGN"*.*

Replace, in existing list item a), "safety sign" *with* "SAFETY SIGN" *and* "safety signs" *with* "SAFETY SIGNS"*.*

Replace, in existing list items b), c) and d), "safety sign" *with* "SAFETY SIGN"*.*

Replace, in the existing third paragraph, "safety sign" *with* "SAFETY SIGN"*, and in NOTE 2, replace* "safety signs" *with* "SAFETY SIGNS"*.*

Replace, in the existing fourth and fifth paragraphs, "safety signs" *with* "SAFETY SIGNS"*.*

7.8.1 Colours of indicator lights

Add an asterisk (*) at the beginning of the subclause title.