

# Technical Information Report

## AAMI/ISO TIR62348: 2012

Assessment of the impact  
of the most significant  
changes in Amendment 1  
to IEC 60601-1:2005 and  
mapping of the clauses of  
IEC 60601-1:2005 to the  
previous edition

# Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

## INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

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# **Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition**

Approved 31 December 2012 by  
**Association for the Advancement of Medical Instrumentation**

Registered 23 December 2012 by  
**American National Standards Institute, Inc.**

**Abstract:** The second edition of this technical report was prepared by the Secretariat of IEC/SC 62A to summarize those changes cited in Amendment 1 that were assessed during the development process as having a moderate to significant impact on users of IEC 60601-1. The tables from the first edition of this technical report were retained in the second edition because there are countries that have not fully transitioned to the third edition of IEC 60601-1. Therefore, the original contents of IEC/TR 62348 remain useful in those countries.

**Keywords:** medical electrical equipment, medical electrical systems, safety, essential performance

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## AAMI Technical Information Report

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Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every five years but at least every 10 years. For a TIR, AAMI consults with a technical committee about five years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

**CAUTION NOTICE:** This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

## ANSI Registration

Publication of this Technical Report that has been registered with ANSI has been approved by the Accredited Standards Developer (AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633). This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the U.S. column, “(R)20xx” indicates the year the document was officially reaffirmed by AAMI. For example, ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

| International designation                                                         | U.S. designation                                                                                                                                                    | Equivalency                                                                                                 |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| IEC 60601-1:2005<br>IEC 60601-1:2005/A1:2012<br>IEC Technical Corrigendum 1 and 2 | ANSI/AAMI ES60601-1:2005/(R)2012<br>ANSI/AAMI ES60601-1:2005/A1:2012<br>ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012 (amdt)<br>ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012 | Major technical variations<br>A1 identical<br>C1 identical to Corrigendum 1 & 2<br>A2 applies to AAMI, only |
| IEC 60601-1-11:2010                                                               | ANSI/AAMI HA60601-1-11:2011                                                                                                                                         | Major technical variations                                                                                  |
| IEC 60601-1-2:2007                                                                | ANSI/AAMI/IEC 60601-1-2:2007/(R)2012                                                                                                                                | Identical                                                                                                   |
| IEC 60601-2-2:2009                                                                | ANSI/AAMI/IEC 60601-2-2:2009                                                                                                                                        | Identical                                                                                                   |
| IEC 60601-2-4:2010                                                                | ANSI/AAMI/IEC 60601-2-4:2010                                                                                                                                        | Identical                                                                                                   |
| IEC 60601-2-16:2012                                                               | ANSI/AAMI/IEC 60601-2-16:2012                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-19:2009                                                               | ANSI/AAMI/IEC 60601-2-19:2009                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-20:2009                                                               | ANSI/AAMI/IEC 60601-2-20:2009                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-21:2009                                                               | ANSI/AAMI/IEC 60601-2-21:2009                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-24:1998                                                               | ANSI/AAMI ID26:2004/(R)2009                                                                                                                                         | Major technical variations                                                                                  |
| IEC 60601-2-25:2011                                                               | ANSI/AAMI/IEC 60601-2-25:2011                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-27:2011                                                               | ANSI/AAMI/IEC 60601-2-27:2011                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-47:2012                                                               | ANSI/AAMI/IEC 60601-2-47:2012                                                                                                                                       | Identical                                                                                                   |
| IEC 60601-2-50:2009                                                               | ANSI/AAMI/IEC 60601-2-50:2009                                                                                                                                       | Identical                                                                                                   |
| IEC/TR 60878:2009                                                                 | AAMI/ISO TIR60878:2003                                                                                                                                              | Identical                                                                                                   |
| IEC/TR 61289:2011                                                                 | AAMI/ISO TIR61289:2011                                                                                                                                              | Identical                                                                                                   |
| IEC/TR 62296:2009                                                                 | AAMI/ISO TIR62296:2009                                                                                                                                              | Identical                                                                                                   |
| IEC 62304:2006                                                                    | ANSI/AAMI/IEC 62304:2006                                                                                                                                            | Identical                                                                                                   |
| IEC/TR 62348:2012                                                                 | AAMI/ISO TIR62348:2012                                                                                                                                              | Identical                                                                                                   |
| IEC/TR 62354:2009                                                                 | AAMI/ISO TIR62354:2009                                                                                                                                              | Identical                                                                                                   |
| IEC 62366:2007                                                                    | ANSI/AAMI/IEC 62366:2007                                                                                                                                            | Identical                                                                                                   |
| IEC 80001-1:2010                                                                  | ANSI/AAMI/IEC 80001-1:2010                                                                                                                                          | Identical                                                                                                   |
| IEC/TR 80001-2-1:2012                                                             | AAMI/ISO 80001-2-1:2012                                                                                                                                             | Identical                                                                                                   |
| IEC/TR 80001-2-2:2012                                                             | AAMI/ISO 80001-2-2:2012                                                                                                                                             | Identical                                                                                                   |
| IEC/TR 80001-2-3:2012                                                             | AAMI/ISO 80001-2-3:2012                                                                                                                                             | Identical                                                                                                   |
| IEC/TR 80002-1:2009                                                               | ANSI/IEC/TR 80002-1:2009                                                                                                                                            | Identical                                                                                                   |
| IEC 80601-2-30:2009 and Technical Corrigendum 1                                   | ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/C1:2009 (amdt) – consolidated text                                                                  | Identical (with inclusion)<br>C1 Identical to Corrigendum 1                                                 |
| IEC 80601-2-58:2008                                                               | ANSI/AAMI/IEC 80601-2-58:2008                                                                                                                                       | Identical                                                                                                   |
| ISO 5840:2005                                                                     | ANSI/AAMI/ISO 5840:2005/(R)2010                                                                                                                                     | Identical                                                                                                   |
| ISO 5840-3:201X <sup>1</sup>                                                      | ANSI/AAMI/ISO 5840-3:2012                                                                                                                                           | Identical                                                                                                   |
| ISO 7198:1998                                                                     | ANSI/AAMI/ISO 7198:1998/2001/(R)2010                                                                                                                                | Identical                                                                                                   |
| ISO 7199:2009 and Amendment 1:2012                                                | ANSI/AAMI/ISO 7199:2009 and Amendment 1:2012                                                                                                                        | Identical                                                                                                   |
| ISO 8637:2010 and A1:201X <sup>1</sup>                                            | ANSI/AAMI/ISO 8637:2010 and A1:2012                                                                                                                                 | Identical                                                                                                   |

| International designation             | U.S. designation                                                | Equivalency                |
|---------------------------------------|-----------------------------------------------------------------|----------------------------|
| ISO 8638:2010                         | ANSI/AAMI/ISO 8638:2010                                         | Identical                  |
| ISO 10993-1:2009                      | ANSI/AAMI/ISO 10993-1:2009                                      | Identical                  |
| ISO 10993-2:2006                      | ANSI/AAMI/ISO 10993-2:2006/(R)2010                              | Identical                  |
| ISO 10993-3:2003                      | ANSI/AAMI/ISO 10993-3:2003/(R)2009                              | Identical                  |
| ISO 10993-4:2002 and Amendment 1:2006 | ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009 | Identical                  |
| ISO 10993-5:2009                      | ANSI/AAMI/ISO 10993-5:2009                                      | Identical                  |
| ISO 10993-6:2007                      | ANSI/AAMI/ISO 10993-6:2007/(R)2010                              | Identical                  |
| ISO 10993-7:2008                      | ANSI/AAMI/ISO 10993-7:2008/(R)2012                              | Identical                  |
| ISO 10993-9:2009                      | ANSI/AAMI/ISO 10993-9:2009                                      | Identical                  |
| ISO 10993-10:2010                     | ANSI/AAMI/ISO 10993-10:2010                                     | Identical                  |
| ISO 10993-11:2006                     | ANSI/AAMI/ISO 10993-11:2006/(R)2010                             | Identical                  |
| ISO 10993-12:2012                     | ANSI/AAMI/ISO 10993-12:2012                                     | Identical                  |
| ISO 10993-13:2010                     | ANSI/AAMI/ISO 10993-13:2010                                     | Identical                  |
| ISO 10993-14:2001                     | ANSI/AAMI/ISO 10993-14:2001/(R)2006                             | Identical                  |
| ISO 10993-15:2000                     | ANSI/AAMI/ISO 10993-15:2000/(R)2006                             | Identical                  |
| ISO 10993-16:2010                     | ANSI/AAMI/ISO 10993-16:2010                                     | Identical                  |
| ISO 10993-17:2002                     | ANSI/AAMI/ISO 10993-17:2002/(R)2012                             | Identical                  |
| ISO 10993-18:2005                     | ANSI/AAMI BE83:2006/(R)2011                                     | Major technical variations |
| ISO/TS 10993-19:2006                  | ANSI/AAMI/ISO TIR10993-19:2006                                  | Identical                  |
| ISO/TS 10993-20:2006                  | ANSI/AAMI/ISO TIR10993-20:2006                                  | Identical                  |
| ISO 11135-1:2007                      | ANSI/AAMI/ISO 11135-1:2007                                      | Identical                  |
| ISO/TS 11135-2:2008                   | ANSI/AAMI/ISO TIR11135-2:2008                                   | Identical                  |
| ISO 11137-1:2006                      | ANSI/AAMI/ISO 11137-1:2006/(R)2010                              | Identical                  |
| ISO 11137-2:2012                      | ANSI/AAMI/ISO 11137-2:2012                                      | Identical                  |
| ISO 11137-3:2006                      | ANSI/AAMI/ISO 11137-3:2006/(R)2010                              | Identical                  |
| ISO 11138-1:2006                      | ANSI/AAMI/ISO 11138-1:2006/(R)2010                              | Identical                  |
| ISO 11138-2:2006                      | ANSI/AAMI/ISO 11138-2:2006/(R)2010                              | Identical                  |
| ISO 11138-3:2006                      | ANSI/AAMI/ISO 11138-3:2006/(R)2010                              | Identical                  |
| ISO 11138-4:2006                      | ANSI/AAMI/ISO 11138-4:2006/(R)2010                              | Identical                  |
| ISO 11138-5:2006                      | ANSI/AAMI/ISO 11138-5:2006/(R)2010                              | Identical                  |
| ISO/TS 11139:2006                     | ANSI/AAMI/ISO 11139:2006                                        | Identical                  |
| ISO 11140-1:2005                      | ANSI/AAMI/ISO 11140-1:2005/(R)2010                              | Identical                  |
| ISO 11140-3:2007                      | ANSI/AAMI/ISO 11140-3:2007/(R)2012                              | Identical                  |
| ISO 11140-4:2007                      | ANSI/AAMI/ISO 11140-4:2007/(R)2012                              | Identical                  |
| ISO 11140-5:2007                      | ANSI/AAMI/ISO 11140-5:2007/(R)2012                              | Identical                  |
| ISO 11607-1:2006                      | ANSI/AAMI/ISO 11607-1:2006/(R)2010                              | Identical                  |
| ISO 11607-2:2006                      | ANSI/AAMI/ISO 11607-2:2006/(R)2010                              | Identical                  |
| ISO 11658:2012                        | ANSI/AAMI/ISO 11658:2012                                        | Identical                  |
| ISO 11663:2009                        | ANSI/AAMI/ISO 11633:2009                                        | Identical                  |
| ISO 11737-1:2006                      | ANSI/AAMI/ISO 11737-1:2006                                      | Identical                  |
| ISO 11737-2:2009                      | ANSI/AAMI/ISO 11737-2:2009                                      | Identical                  |
| ISO/TS 12417:2011                     | ANSI/AAMI/ISO TIR12417:2011                                     | Identical                  |
| ISO 13022:2012                        | ANSI/AAMI/ISO 13022:2012                                        | Identical                  |
| ISO 13408-1:2008                      | ANSI/AAMI/ISO 13408-1:2008/(R)2011                              | Identical                  |
| ISO 13408-2:2003                      | ANSI/AAMI/ISO 13408-2:2003                                      | Identical                  |
| ISO 13408-3:2006                      | ANSI/AAMI/ISO 13408-3:2006/(R)2012                              | Identical                  |
| ISO 13408-4:2005                      | ANSI/AAMI/ISO 13408-4:2005/(R)2012                              | Identical                  |
| ISO 13408-5:2006                      | ANSI/AAMI/ISO 13408-5:2006/(R)2012                              | Identical                  |
| ISO 13408-6:2006                      | ANSI/AAMI/ISO 13408-6:2006                                      | Identical                  |

| International designation    | U.S. designation                                       | Equivalency                 |
|------------------------------|--------------------------------------------------------|-----------------------------|
| ISO 13408-7:2012             | ANSI/AAMI/ISO 13408-7:2012                             | Identical                   |
| ISO 13485:2003               | ANSI/AAMI/ISO 13485:2003/(R)2009                       | Identical                   |
| ISO 13958:2009               | ANSI/AAMI/ISO 13958:2009                               | Identical                   |
| ISO 13959:2009               | ANSI/AAMI/ISO 13959:2009                               | Identical                   |
| ISO 14117:2012               | ANSI/AAMI/ISO 14117:2012                               | identical                   |
| ISO 14155:2011               | ANSI/AAMI/ISO 14155:2011                               | Identical                   |
| ISO 14160:2011               | ANSI/AAMI/ISO 14160:2011                               | Identical                   |
| ISO 14161:2009               | ANSI/AAMI/ISO 14161:2009                               | Identical                   |
| ISO 14708-3:2008             | ANSI/AAMI/ISO 14708-3:2008                             | Identical                   |
| ISO 14708-4:2008             | ANSI/AAMI/ISO 14708-4:2008                             | Identical                   |
| ISO 14708-5:2010             | ANSI/AAMI /ISO 14708-5:2010                            | Identical                   |
| ISO 14937:2009               | ANSI/AAMI/ISO 14937:2009                               | Identical                   |
| ISO/TR 14969:2004            | ANSI/AAMI/ISO TIR14969:2004                            | Identical                   |
| ISO 14971:2007               | ANSI/AAMI/ISO 14971:2007/(R)2010                       | Identical                   |
| ISO 15223-1:2012             | ANSI/AAMI/ISO 15223-1:2012                             | Identical                   |
| ISO 15223-2:2010             | ANSI/AAMI/ISO 15223-2:2010                             | Identical                   |
| ISO 15225:2010               | ANSI/AAMI/ISO 15225:2010                               | Identical                   |
| ISO/TR 15499:2012            | ANSI/AAMI/ISO TIR15499:2012                            | Identical                   |
| ISO 15674:2009               | ANSI/AAMI/ISO 15674:2009                               | Identical                   |
| ISO 15675:2009               | ANSI/AAMI/ISO 15675:2009                               | Identical                   |
| ISO 15882:2008               | ANSI/AAMI/ISO 15882:2008                               | Identical                   |
| ISO 15883-1:2006             | ANSI/AAMI ST15883-1:2009 and A2:2012                   | Major technical variations  |
| ISO 15883-3:2006             | ANSI/AAMI ST15883-3:2012                               | Major technical variations  |
| ISO/TR 16142:2006            | ANSI/AAMI/ISO TIR16142:2005                            | Identical                   |
| ISO 17664:2004               | ANSI/AAMI ST81:2004                                    | Major technical variations  |
| ISO 17665-1:2006             | ANSI/AAMI/ISO 17665-1:2006                             | Identical (with inclusions) |
| ISO/TS 17665-2:2009          | ANSI/AAMI/ISO TIR17665-2:2009                          | Identical                   |
| ISO 18472:2006               | ANSI/AAMI/ISO 18472:2006/(R)2010                       | Identical                   |
| ISO/TS 19218-1:2011          | ANSI/AAMI/ISO TIR19218-1:2011                          | Identical                   |
| ISO/TS 19218-2:2012          | ANSI/AAMI/ISO TIR19218-1:2012                          | Identical                   |
| ISO 20857:2010               | ANSI/AAMI/ISO 20857:2010                               | Identical                   |
| ISO 22442-1:2007             | ANSI/AAMI/ISO 22442-1:2007                             | Identical                   |
| ISO 22442-2:2007             | ANSI/AAMI/ISO 22442-2:2007                             | Identical                   |
| ISO 22442-3:2007             | ANSI/AAMI/ISO 22442-3:2007                             | Identical                   |
| ISO/TR 22442-4:2010          | ANSI/AAMI/ISO TIR22442-4:2010                          | Identical                   |
| ISO 23500:2011               | ANSI/AAMI/ISO 23500:2011                               | Identical                   |
| ISO/TS 23810:2012            | ANSI/AAMI/ISO TIR23810:2012                            | Identical                   |
| ISO 25539-1:2003 and A1:2005 | ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009 | Identical                   |
| ISO 25539-2:2012             | ANSI/AAMI/ISO 25539-2:2012                             | Identical                   |
| ISO 25539-3:2011             | ANSI/AAMI/ISO 25539-3:2011                             | Identical                   |
| ISO 26722:2009               | ANSI/AAMI/ISO 26722:2009                               | Identical                   |
| ISO 27185:2012               | ANSI/AAMI/ISO 27185:2012                               | Identical                   |
| ISO 27186:2010               | ANSI/AAMI/ISO 27186:2010                               | Identical                   |
| ISO 80369-1:2010             | ANSI/AAMI/ISO 80369-1:2010                             | Identical                   |
| ISO 81060-1:2007             | ANSI/AAMI/ISO 81060-1:2007                             | Identical                   |
| ISO 81060-2:2009             | ANSI/AAMI/ISO 81060-2:2009                             | Identical                   |

<sup>1</sup> ISO standard in production

## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Electrical Safety Committee

The adoption of IEC/TR 62348:2012 was initiated by the AAMI Electrical Safety Committee, since this document provides the necessary mapping of the Amendment 1 to the existing ANSI/AAMI ES60601-1:2005. U.S. representatives played an active role in developing the Amendment 1 as well as the main IEC 60601-1 standard.

Committee approval of the technical report does not necessarily imply that all committee members voted for its approval. At the time this document was published, the **AAMI Electrical Safety Committee** had the following members:

*Cochairs:* Jeffrey L. Eggleston  
Michael W. Schmidt

*Members:* Stuart Albert, MBA CBET-E CHSP  
Keith Behnke, Stryker Instruments  
Alan S. Berson, PhD, Bioresearch Funding Group  
Steve Cantwell, Spacelabs Medical Inc.  
Rebecca K. Crossley, CBET, Susquehanna Health System  
Conor Curtin, Fresenius Medical Care Renal Therapies Group  
Yadin David, EdD CCE PE HCSP, Biomedical Engineering Consultants LLC  
Rich Eaton, Medical Imaging & Technology Alliance a Division of NEMA Medical Imaging & Technology Alliance (MITA) a Division of NEMA  
Jeffrey L. Eggleston, MS PE, Covidien  
Richard Gardner, GE Healthcare  
Hamed Ghods, FDA/CDRH  
David L. Green, CBET  
Alex Grob, MECA - Medical Equipment Compliance Associates LLC  
Dale Hallerberg, TUV Rheinland North America Inc.  
Robert Alan Kemerling, PhD, Johnson & Johnson  
Brian Killoran, Welch Allyn Inc.  
Todd Konieczny, Intertek Intertek Testing Services  
Bernie Liebler, Advanced Medical Technology Association  
Alan Lipschultz, CCE PE CSP, HealthCare Technology Consulting LLC  
Joseph P. Murnane, Jr., AAS BSEE, Underwriters Laboratories Inc.  
David G. Osborn, Philips Electronics North America  
Dane Popovski, Baxter Healthcare  
Stefan M. Robert, Cyberonics Inc.  
Steven Rus, Steris Corporation  
Ed Russo, Dranetz  
Michael W. Schmidt, Strategic Device Compliance Services  
Donald Sherratt, Terumo BCT  
James Shults, Hospira Worldwide Inc.  
Richard E. Stein, St Jude Medical Inc.  
James D. Stewardson,  
Anna Varlese, Conmed Corp  
Daidi Zhong, PhD

*Alternates:* Joseph Basta, Spacelabs Medical Inc  
Kenneth E. Gettman, Medical Imaging & Technology Alliance a Division of NEMA National Electrical Manufacturers Association  
Mark Graber, GE Healthcare  
Richard Markle, Philips Electronics North America  
Jim Peterson, Fresenius Medical Care Renal Therapies Group Fresenius Medical Care  
Sheari Rice, Steris Corporation  
Harvey Rudolph, PhD, Underwriters Laboratories Inc

Ted Yantsides, Conmed Corp  
Jianchao Zeng, FDA/CDRH

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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

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## Background of ANSI/AAMI adoption of IEC/TR 62348:2012

The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising of all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this technical report.

International Technical Report IEC/TR 62348 was developed by the IEC Technical Subcommittee (SC) 62A, Common aspects of electrical equipment used in medical practice.

U.S. participation in IEC/SC 62A is organized through the U.S. Technical Advisory Group for IEC/SC 62A, administered by Bernie Liebler of AdvaMed on behalf of the United States National Committee, which is a committee of the American National Standards Institute (ANSI). The U.S. made considerable contributions to IEC 60601-1 and its amendment (Amendment 1). This technical report provides the mapping guidance between the two documents and is a useful guide for anyone using the IEC 60601-1 series.

This second edition cancels and replaces IEC/TR 62348:2006 (AAMI/ISO TIR62348:2006).

AAMI encourages its committees to harmonize their work with international documents as much as possible. The AAMI Electrical Safety Committee reviewed IEC/TR 62348 to formulate the U.S. position while the document was being developed. This close collaboration helped gain widespread U.S. consensus on the document. In collaboration with the U.S. Technical Advisory Group for IEC/SC 62A, the AAMI Electrical Safety Committee voted to adopt the IEC Technical Report as written.

AAMI (and ANSI) have adopted other IEC and ISO documents. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

The concepts incorporated into this technical report should not be considered inflexible or static. This technical information report, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the technical information report. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington VA 22203-1633.

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NOTE—Beginning with the IEC foreword on page “xiv,” AAMI/ISO TIR62348:2012, *Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition* is identical to IEC/TR 62348:2012.

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# INTERNATIONAL ELECTROTECHNICAL COMMISSION

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## **ASSESSMENT OF THE IMPACT OF THE MOST SIGNIFICANT CHANGES IN AMENDMENT 1 TO IEC 60601-1:2005 AND MAPPING OF THE CLAUSES OF IEC 60601-1:2005 TO THE PREVIOUS EDITION**

### FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC 62348, which is a technical report, 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.

This second edition cancels and replaces the first edition published in 2006. The second edition retains the mapping that traces the requirements of IEC 60601-1:2005 and its Amendment A1:2012 (Edition 3.1) from their source in the documents that relate to IEC 60601-1:1998 and its amendments (Edition 2.2). See Clause 7. The second edition adds an assessment of the impact of the most significant changes in Amendment 1:2012 (Clauses 4, 5 and 6).

The text of this technical report is based on the following documents:

|               |                  |
|---------------|------------------|
| Enquiry draft | Report on voting |
| 62A/831/DTR   | 62A/841/RVC      |

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

The committee has decided that the contents of this 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.

A bilingual version of this Technical Report may be issued at a later date.

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

## INTRODUCTION

The first edition of this technical report was created by the Secretariat of SC 62A to assist users of IEC 60601-1 by providing a tool to trace requirements between IEC 60601-1:2005 and their source in the documents that form the basis of the third edition; principally the second edition as amended.

At the Auckland meeting in 2008, IEC Technical Committee (TC) 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

- those issues reported to the Secretariat of IEC Subcommittee (SC) 62A since the publication of IEC 60601-1:2005;
- the way in which risk management has been introduced into IEC 60601-1:2005; and
- the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the Secretariat of SC 62A has received 73 additional issues from National Committees or other interested parties for a total of 182 identified issues with the 2005 edition. Amendment 1 to IEC 60601-1:2005 is intended to address those issues.

The amendment process has resulted in 496 separate changes. Each change was assessed by the experts developing the amendment for its potential impact on users of the standard. Most of the changes are editorial corrections or clarifications and were assessed as having minimal or no impact on the application of the standard. Others were assessed as having moderate or significant impact because they represent a technical change, or they impact a wide range of users, or both.

The second edition of this technical report was prepared by the Secretariat of IEC/SC 62A to summarize those changes that were assessed during the development process as having a moderate to significant impact on users of IEC 60601-1.

The tables from the first edition of this technical report were retained in the second edition because there are countries that have not fully transitioned to the third edition of IEC 60601-1. Therefore, the original contents of IEC/TR 62348 remain useful in those countries.

Table 6 has been updated to include new subclauses added in Amendment 1:2012 (highlighted in blue).

## **ASSESSMENT OF THE IMPACT OF THE MOST SIGNIFICANT CHANGES IN AMENDMENT 1 TO IEC 60601-1:2005 AND MAPPING OF THE CLAUSES OF IEC 60601-1:2005 TO THE PREVIOUS EDITION**

### **1 Scope**

This technical report provides a tool to assist users of IEC 60601-1:2005 to assess the impact of the most significant changes in Amendment 1:2012.

This technical report also provides a tool to assist users of IEC 60601-1 to trace requirements between the third edition and their source in the documents that form the basis of the third edition; principally the second edition as amended.

This report is intended to be used by:

- those who must align standards based on the second edition of IEC 60601-1 with the third edition as amended;
- manufacturers of medical electrical equipment or medical electrical systems;
- health care regulatory authorities, test houses and other organizations responsible for implementing standards for medical electrical equipment and medical electrical systems.

### **2 Normative references**

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

### **3 Terms and definitions**

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 + A1:2012 apply.

### **4 Assessment of the changes in Amendment 1:2012**

Amendment 1 contains 496 separate changes. During the development of the amendment, each change was assessed by the experts involved for its potential impact on users of the standard. Most of the changes are editorial corrections or clarifications and were assessed and having minimal or no impact on the application of the standard.

However, 83 of the changes were assessed as having a moderate to significant impact on the users of the standard. This assessment is based on the likelihood that some alterations to the design documentation, testing, the product itself or its accompanying documents will be required because of the change to a requirement in the amendment.

The changes have been divided into two groups:

- those assessed as having a significant impact (Table 1), and
- those assessed as having a moderate impact (Table 2).

Because any assessment is somewhat subjective, users of the standard are encouraged to review the contents of the amendment and determine its impact on the sections that are relevant to their products.

**Table 1 – Amendment 1 changes assessed as having the potential for a significant impact**

| Clause of IEC 60601-1 | Clause Title                                                                     | Impact many users | Impact particular users | Section of this document |
|-----------------------|----------------------------------------------------------------------------------|-------------------|-------------------------|--------------------------|
| 4.2                   | RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS                           | X                 |                         | 5.3                      |
| 4.3                   | Essential performance                                                            | X                 |                         | 5.4                      |
| 4.5                   | Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS | X                 |                         | 5.5                      |
| 4.6                   | ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT                         | X                 |                         | 5.6                      |
| 5.1                   | TYPE TESTS                                                                       | X                 |                         | 5.8                      |
| 5.5 a)                | Supply voltages, type of current, nature of supply, frequency                    | X                 |                         | 5.9                      |
| 5.7                   | Humidity preconditioning treatment                                               | X                 |                         | 5.10                     |
| 7.2.1                 | Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts    | X                 |                         | 5.13                     |
| 7.2.4                 | ACCESSORIES                                                                      | X                 |                         | 5.13                     |
| 7.2.5                 | ME EQUIPMENT intended to receive power from other equipment                      |                   | X                       | 6.1                      |
| 7.2.21                | Mass of MOBILE ME EQUIPMENT                                                      |                   | X                       | 6.4                      |
| 7.9.1                 | General                                                                          | X                 |                         | 5.17                     |
| 7.9.3.1               | General                                                                          | X                 |                         | 5.20                     |
| 8.5.5.1 a)            | Defibrillation protection                                                        |                   | X                       | 6.7                      |
| 8.5.5.2               | Energy reduction test                                                            |                   | X                       | 6.8                      |
| 8.7.3                 | Allowable values                                                                 | X                 |                         | 5.24                     |
| 8.8.1                 | General                                                                          | X                 |                         | 5.26                     |
| 9.2.3.1               | Unintended movement                                                              |                   | X                       | 6.14                     |
| 9.4.2.3 a)            | Instability from horizontal and vertical forces                                  |                   | X                       | 6.16                     |
| 9.4.2.4.3             | Movement over a threshold                                                        |                   | X                       | 6.17                     |
| 9.4.3.2 b)            | Instability excluding transport position                                         |                   | X                       | 6.20                     |
| 10.3                  | Microwave radiation                                                              |                   | X                       | 6.27                     |
| 11.8                  | Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT                  | X                 |                         | 5.31                     |
| 13.1.2                | Emissions, deformation of ENCLOSURE or exceeding maximum temperature             |                   | X                       | 5.32                     |
| 15.5.3                | Construction of transformers used to provide separation as required by 8.5       | X                 |                         | 5.42                     |

**Table 2 – Amendment 1 changes assessed as  
having the potential for a moderate impact (1 of 2)**

| Clause of<br>IEC 60601-1 | Clause Title                                                                           | Impact<br>many<br>users | Impact<br>particular<br>users | Section<br>of this<br>document |
|--------------------------|----------------------------------------------------------------------------------------|-------------------------|-------------------------------|--------------------------------|
| 2                        | Normative references                                                                   | X                       |                               | 5.1                            |
| 3.28                     | EXPECTED SERVICE LIFE                                                                  | X                       |                               | 5.2                            |
| 4.11                     | Power input                                                                            | X                       |                               | 5.7                            |
| 5.9.2.3                  | Actuating mechanisms                                                                   | X                       |                               | 5.11                           |
| 7.1.2                    | Legibility of markings                                                                 | X                       |                               | 5.12                           |
| 7.3.4                    | Fuses, THERMAL CUT-OUTS and OVER-CURRENT<br>RELEASES                                   | X                       |                               | 5.14                           |
| 7.2.17                   | Protective packaging                                                                   |                         | X                             | 6.2                            |
| 7.2.18                   | External pressure source                                                               |                         | X                             | 6.3                            |
| 7.4.2                    | Control devices                                                                        | X                       |                               | 5.15                           |
| 7.5                      | Safety signs                                                                           | X                       |                               | 5.16                           |
| 7.9.2.1                  | General                                                                                |                         | X                             | 6.5                            |
| 7.9.2.15                 | Environmental protection                                                               | X                       |                               | 5.18                           |
| 7.9.2.17                 | ME EQUIPMENT emitting radiation                                                        |                         | X                             | 6.6                            |
| 7.9.2.18                 | ME EQUIPMENT and ACCESSORIES supplied<br>sterile                                       |                         | X                             | 6.2                            |
| 7.9.2.19                 | Unique version identifier                                                              | X                       |                               | 5.19                           |
| 7.9.3.1                  | General                                                                                | X                       |                               | 5.19                           |
| 8.1 b)                   | Fundamental rule of protection against electric<br>shock                               | X                       |                               | 5.21                           |
| 8.5.1.2                  | MEANS OF PATIENT PROTECTION (MOPP)                                                     | X                       |                               | 5.22                           |
| 8.5.1.3                  | MEANS OF OPERATOR PROTECTION (MOOP)                                                    | X                       |                               | 5.22                           |
| 8.6.4                    | Impedance and current-carrying capability                                              | X                       |                               | 5.23                           |
| 8.7.1 b)                 | General requirements                                                                   |                         | X                             | 6.9                            |
| 8.7.4.5                  | Measurement of the EARTH LEAKAGE CURRENT<br>and current in functional earth connection | X                       |                               | 5.25                           |
| Table 16                 | Minimum CREEPAGE DISTANCES providing MEANS<br>OF OPERATOR PROTECTION                   | X                       |                               | 5.27                           |
| 8.9.4                    | Measurement of CREEPAGE DISTANCES AND AIR<br>CLEARANCES                                | X                       |                               | 5.28                           |
| 8.11.1                   | Isolation from the SUPPLY MAINS                                                        |                         | X                             | 6.10                           |
| 9.2.2.4.4                | Other RISK CONTROL measures                                                            |                         | X                             | 6.11                           |
| 9.2.2.5                  | Continuous activation                                                                  |                         | X                             | 6.12                           |
| 9.2.2.6                  | Speed of movement(s)                                                                   |                         | X                             | 6.13                           |
| 9.2.3.2                  | Overtravel end stops                                                                   |                         | X                             | 6.15                           |
| 9.4.3.1 c)               | Instability in transport position                                                      |                         | X                             | 6.18                           |
| 9.4.3.2 a)               | Instability excluding transport position                                               |                         | X                             | 6.19                           |
| 9.6.1                    | General                                                                                |                         | X                             | 6.21                           |
| 9.6.2.1                  | Audible acoustic energy                                                                |                         | X                             | 6.22                           |
| 9.8.3.2                  | Static forces due to loading from persons                                              |                         | X                             | 6.23                           |
| 9.8.3.3                  | Dynamic forces due to loading from persons                                             |                         | X                             | 6.24                           |
| 10.1.1                   | ME EQUIPMENT not intended to produce<br>diagnostic or therapeutic X-radiation          |                         | X                             | 6.25                           |

**Table 2 (2 of 2)**

| Subclause of IEC 60601-1 | Clause Title                                                           | Impact many users | Impact particular users | Section of this document |
|--------------------------|------------------------------------------------------------------------|-------------------|-------------------------|--------------------------|
| 10.1.2                   | ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation |                   | X                       | 6.26                     |
| 10.4                     | Lasers                                                                 |                   | X                       | 6.28                     |
| 11.1.2.2                 | APPLIED PARTS not intended to supply heat to a PATIENT                 |                   | X                       | 6.29                     |
| 11.6.2                   | Overflow in ME EQUIPMENT                                               |                   | X                       | 6.30                     |
| 11.6.3                   | Spillage on ME EQUIPMENT and ME SYSTEMS                                | X                 |                         | 5.29                     |
| 11.6.6                   | Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS               | X                 |                         | 5.30                     |
| 12.4.5.2                 | Diagnostic X-ray equipment                                             |                   | X                       | 6.31                     |
| 14.1                     | General                                                                | X                 |                         | 5.33                     |
| 14.9                     | Design and implementation                                              | X                 |                         | 5.34                     |
| 14.11                    | PEMS VALIDATION                                                        | X                 |                         | 5.35                     |
| 14.13                    | PEMS intended to be incorporated into an IT-NETWORK                    |                   | X                       | 6.32                     |
| 15.3.1                   | General                                                                | X                 |                         | 5.36                     |
| 15.3.5                   | Rough handling test                                                    |                   | X                       | 6.33                     |
| 15.4.2.1 d)              | Application                                                            |                   | X                       | 6.34                     |
| 14.4.3.5                 | Excessive current and voltage protection                               |                   | X                       | 6.35                     |
| 15.4.6.1 b)              | Fixing, prevention of maladjustment                                    | X                 |                         | 5.37                     |
| 15.4.6.2                 | Limitation of movement                                                 | X                 |                         | 5.38                     |
| 15.4.7.3                 | Entry of liquids                                                       |                   | X                       | 6.36                     |
| 15.5.1.1                 | Transformers                                                           | X                 |                         | 5.39                     |
| 15.5.1.3                 | Overload test                                                          | X                 |                         | 5.40                     |
| 15.5.2                   | Dielectric strength                                                    | X                 |                         | 5.41                     |
| 16.3                     | Power supply                                                           |                   | X                       | 6.37                     |
| 16.6.4.1                 | General conditions for ME SYSTEMS                                      |                   | X                       | 6.38                     |
| 16.8                     | Interruption of the power supply to parts of an ME SYSTEM              |                   | X                       | 5.31                     |
| 16.9.2.1 d)              | MULTIPLE SOCKET-OUTLET                                                 |                   | X                       | 6.39                     |
| 16.9.2.2                 | PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS                             |                   | X                       | 6.40                     |
| Annex A, 4.8             | Components of ME EQUIPMENT                                             | X                 |                         | 5.43                     |

The following clauses break down the changes into two groups based on the breadth of their anticipated impact.

- The first group are those changes that are anticipated to impact many, if not most, of the users of IEC 60601-1 (Clause 5). An example would be the change to the requirements for humidity preconditions testing to align with the IEC Certified Testing Laboratories (CTL) decision to harmonize basic environmental testing conditions for electrical products. Because of the impact on existing test protocols, the impact was assessed as significant.
- The second group are those changes that should impact only some of the users of IEC 60601-1 depending on the nature of the equipment to which they are applying the standard (Clause 6). Examples are the requirements that are applied only to sterile ME EQUIPMENT or ME EQUIPMENT parts or to MOBILE ME EQUIPMENT.

## 5 Changes impacting many users of the standard

### 5.1 Updated normative references (Clause 2) [Moderate impact]

A number of the standards that are referenced in the 3<sup>rd</sup> edition have been revised or have been withdrawn and replaced by different documents (e.g., ISO 14971-1:2000 has been replaced by ISO 14971:2007). These normative references have been updated to reflect current editions.

### 5.2 Definition and rationale for EXPECTED SERVICE LIFE (Definition 3.28 and rationale for 4.4) [Moderate impact]

The application of the term EXPECTED SERVICE LIFE has led to a misunderstanding in some quarters. To address the misunderstanding, the definition and the rationale have been expanded.

### 5.3 Restructuring of RISK MANAGEMENT (Subclause 4.2) [Significant impact]

Subclause 4.2 and its rationale have been significantly modified and expanded. The subclause describes in greater detail the RISK MANAGEMENT PROCESS to be employed in complying with IEC 60601-1.

Subclause 4.2.1 introduces the concepts and the purposes of RISK MANAGEMENT within the framework of a TYPE TEST or design assurance standard. The subclause includes a reminder that, "*verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS.*"

Subclause 4.2.2 is the heart of the subclause and sets out the basic PROCESS requirements, which remain in compliance with ISO 14971 except for the requirements related to product and post-production monitoring and periodic reviews of the suitability of the RISK MANAGEMENT PROCESS.

Subclause 4.2.3 details how the requirements of this standard are to be applied when evaluating RISK. There are four scenarios described. They are:

- a) where IEC 60601-1 or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria;
- b) where IEC 60601-1 or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria;
- c) where IEC 60601-1 or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements; and
- d) where HAZARDS or HAZARDOUS SITUATIONS are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this IEC 60601-1 or its collateral or particular standards.

### 5.4 Application of ESSENTIAL PERFORMANCE (Subclause 4.3) [Significant impact]

The definition of ESSENTIAL PERFORMANCE has been modified from:

performance necessary to achieve freedom from unacceptable risk

in the 3<sup>rd</sup> edition to:

performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

Subclause 4.3 has been revised and extended to discuss the process the MANUFACTURER can use to determine the ESSENTIAL PERFORMANCE of ME EQUIPMENT or an ME SYSTEM. The fundamental goal was not to change the intent of the concept but make it easier to understand and apply. The definition and the process in 4.3 have been changed to focus on clinical functions and to try and exclude "performance" related to BASIC SAFETY, e.g., the performance of insulation. However, remember, regardless of whether we are speaking of BASIC SAFETY or ESSENTIAL PERFORMANCE, both must be managed.

The rationale for Subclause 4.3 has also been updated.

## **5.5 Revision to the concept of equivalent safety (Subclause 4.5) [Significant impact]**

Recognizing that demonstrating "equivalent safety" can be difficult because many of the requirements in IEC 60601-1 do not provide sufficient detail regarding the level of RESIDUAL RISK, this subclause has been modified to allow alternative RISK CONTROL measures or test methods when it can be demonstrated that the RESIDUAL RISK resulting from application of the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard. The RESIDUAL RISK must satisfy the MANUFACTURER'S RISK acceptance criteria and must be comparable to that remaining after applying the requirements of the standard. The MANUFACTURER can demonstrate this by applying:

- scientific data,
- clinical opinion,
- comparative studies, or
- a combination of all three methods.

## **5.6 Requirements for parts that contact the PATIENT (Subclause 4.6) [Significant impact]**

The requirement for such parts was moved from 8.3 d). The RISK MANAGEMENT PROCESS is still required to assess the parts that fall outside of the definition of APPLIED PARTS that need to be subject to the requirements for APPLIED PARTS. However, the revision to 4.6 clarifies that applicable requirements of the collateral standards also apply to these parts.

## **5.7 Steady-state measurement of input of the ME EQUIPMENT or ME SYSTEM (Subclause 4.11) [Moderate impact]**

The provision in the IEC 60601-1:2005 that allowed a supplier certification to be used in place of the power input measurements required by 4.11 has been replaced by a note that supplier information can be used to supplement those measurements.

## **5.8 Simultaneous fault testing (Subclause 5.1) [Moderate impact]**

Subclause 5.1 was modified to clarify the requirement that the combination of simultaneous independent faults that could result in a HAZARDOUS SITUATION be documented in the RISK MANAGEMENT FILE. The original text of IEC 60601-1:2005 required that the results of the RISK ANALYSIS be used to determine which combination(s) of simultaneous faults were to be tested. Since the RISK ANALYSIS is documented in the RISK MANAGEMENT FILE, this is not a new requirement. When testing is necessary to demonstrate that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations. Because of the potential for additional documentation, this was judged to be of moderate impact.

## **5.9 SUPPLY MAINS test characteristics** (Subclause 5.5 a)) [Significant impact]

The requirement in 5.5 a) was modified to include other characteristics of the SUPPLY MAINS other than just supply voltage. As this could involve additional testing, the impact was assessed as significant.

## **5.10 Humidity preconditioning** (Subclause 5.7) [Significant impact]

The requirements for humidity preconditions testing have been aligned with the IEC Certified Testing Laboratories (CTL) decision to harmonize basic environmental testing conditions for electrical products. The minimum time for soaking ME EQUIPMENT enclosures with an IPX0 rating is set to 48 h and for higher IP rating to 168 h. Because of the impact on existing test protocols, the impact was assessed as significant.

## **5.11 Actuating mechanisms** (Subclause 5.9.2.3) [Moderate impact]

The reference to RISK MANAGEMENT was removed. Any conductive parts of actuating mechanisms are not to be considered ACCESSIBLE PARTS if removal of the handles, knobs, etc. requires the use of a TOOL.

## **5.12 Legibility of markings** (Subclause 7.1.2) [Moderate impact]

The test procedure for legibility of markings has been modified so the test is run from the intended OPERATOR position, or, if that is not specified, a distance of 1 m. Also, the description of the visual acuity of the observer is extended to include a near-vision specification.

## **5.13 Identification of ME EQUIPMENT, parts and ACCESSORIES** (Subclauses 7.2.1 and 7.2.4) [Significant impact]

The requirements for Identification of ME EQUIPMENT and ACCESSORIES have been expanded to include several new items. These include:

- contact information of the MANUFACTURER (for example, this could be a mailing address, a web site, or a telephone number);
- a serial number or lot or batch identifier; and
- the date of manufacture or use by date, if applicable.

The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID.

Detachable components of the ME EQUIPMENT shall be marked with:

- the name or trademark of the MANUFACTURER; and
- a MODEL OR TYPE REFERENCE;

unless misidentification does not result in an unacceptable RISK.

## **5.14 Marking of fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES** (Subclause 7.3.4) [Moderate impact]

The requirements for marking of these protective devices have been clarified and an allowance to use the nomenclature described in IEC 60127-1 has been added.

### **5.15 Marking of stand-by control** (Subclause 7.4.2) [Moderate impact]

The switch marking commonly used in IT equipment () to indicate a control that activates a stand-by mode is now permitted on ME EQUIPMENT.

### **5.16 Use of safety signs** (Subclause 7.5) [Moderate impact]

The requirements have been modified to clarify:

- a) that the general warning sign () is not required when a safety sign with an established meaning is appropriately used; and
- b) that when supplementary text is placed together with safety signs, the supplementary text shall be in a language that is acceptable to the intended OPERATOR.

### **5.17 General requirements for ACCOMPANYING DOCUMENTS** (Subclause 7.9.1) [Significant impact]

The general requirements have been revised to replace the "address" of the MANUFACTURER with contact information for the MANUFACTURER. This aligns with the changes made to Subclauses 7.2.1 and 7.2.4). The contact information could include information beyond the postal address such as a Web site address or telephone number(s).

The requirement to use RISK MANAGEMENT to determine what information needs to be provided as hard copy or marking if the ACCOMPANYING DOCUMENTS are provided electronically has been eliminated. The USABILITY ENGINEERING PROCESS in Subclause 12.2 must consider which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT.

### **5.18 Disposal of waste** (Subclause 7.9.2.15) [Moderate impact]

The requirement to identify the RISKS associated with the disposal of waste products and the ME EQUIPMENT and ACCESSORIES at the end of life has been replaced with a simpler requirement. The MANUFACTURER must provide advice on proper disposal.

### **5.19 Unique version identification** (Subclauses 7.9.2.19 and 7.9.3.1) [Moderate impact]

The instructions for use must contain a unique version identifier such as its date of issue. If the technical description is provided as a separate document, then it must also contain a unique version identifier.

### **5.20 Disclosure of ESSENTIAL PERFORMANCE** (Subclause 7.9.3.1) [Significant impact]

The technical description needs to contain information pertaining to ESSENTIAL PERFORMANCE and the absence or degradation thereof and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency.

### **5.21 Change to the fundamental rule of protection against electric shock** (Subclause 8.1 b)) [Moderate impact]

The reference to RISK MANAGEMENT has been removed from the dash dealing with interruption of power-carrying conductor between parts of a separate ENCLOSURE. This can be done by a plain engineering calculation and is not a RISK MANAGEMENT issue.

The dash dealing with unintended movement was simplified because the issue is dealt with in Subclause 8.10.1.

#### **5.22 Use of Y capacitors as a MEANS OF PROTECTION** (Subclauses 8.5.1.2 and 8.5.1.3) [Moderate impact]

The requirements allowing use of Y capacitors as a MEANS OF PROTECTION have been substantially revised to clarify when Y1 or Y2 capacitors can be used as either a MEANS OF PATIENT OR MEANS OF OPERATOR PROTECTION.

#### **5.23 Requirements for impedance and current-carrying capabilities** (Subclause 8.6.4) [Moderate impact]

In those cases where DETACHABLE POWER SUPPLY CORD is neither supplied nor specified by the MANUFACTURER, testing shall be done with a 3 m long cord of appropriate cross-sectional area based on 8.11.3.3 and Table 17. This may involve some retesting of equipment.

In addition, provision is made for using a d.c. current when making earth impedance measurements. This should facilitate testing as IEC 60950-1 allows either a.c. or d.c. to be used and has done for some years without problem.

#### **5.24 Allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR** (Subclause 8.7.3) [Substantial impact]

A new requirement has been added for the LEAKAGE CURRENT that can flow in a FUNCTIONAL EARTH CONDUCTOR in non-PERMANENTLY INSTALLED ME EQUIPMENT. The maximum current allowed is 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

#### **5.25 Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection** (Subclause 8.7.4.5) [Moderate impact]

The requirement for measuring EARTH LEAKAGE CURRENT for CLASS II ME EQUIPMENT with a functional earth connection has been clarified. This equipment is tested as if it were CLASS I ME EQUIPMENT.

#### **5.26 Clarification of the insulation to be tested** (Subclause 8.8.1) [Significant impact]

The requirement has been clarified. Only insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION is to be subjected to the insulation testing in Subclauses 8.8. This change also allowed for the deletion of Table 11, *Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART*. The removal of Table 11 does not mean that the requirements for minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART have been eliminated. These CREEPAGE DISTANCE and AIR CLEARANCE requirements are defined in 8.9.1.1, which refers to the tables for MEANS OF OPERATOR PROTECTION.

#### **5.27 Spacing for one MEANS OF OPERATOR PROTECTION for a WORKING VOLTAGE of 25 V r.m.s.** (Table 16) [Moderate impact]

A slightly smaller CREEPAGE DISTANCE providing a MEANS OF OPERATOR PROTECTION was added to Table 16 for a WORKING VOLTAGE of 25 V r.m.s or d.c. This change may benefit some MANUFACTURERS by allowing slightly smaller CREEPAGE DISTANCES at WORKING VOLTAGES under 25 V r.m.s or d.c.

**5.28 Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES** (Subclause 8.9.4) [Moderate impact]

The minimum spacing for CREEPAGE DISTANCE can now be adjusted depending on the pollution degree associated with the intended environment of use. As the majority of applications are for pollution degree 2, it is unlikely that this proposed change will affect many existing products.

**5.29 Spillage on ME EQUIPMENT and ME SYSTEMS** (Subclause 11.6.3) [Moderate impact]

The requirement was modified to use RISK MANAGEMENT to identify use environments where spillage on the ME EQUIPMENT or ME SYSTEM would be likely to occur. Once the liquid is applied, BASIC SAFETY and ESSENTIAL PERFORMANCE are to be maintained in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION.

**5.30 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS** (Subclause 11.6.6) [Moderate impact]

The requirement was clarified that it is the effect of number of cleaning/disinfection cycles stated in the instructions for use that is evaluated. Following these PROCESSES, there is to be no loss of BASIC SAFETY and ESSENTIAL PERFORMANCE.

**5.31 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT or ME SYSTEM** (Subclauses 11.8 and 16.8) [Significant impact]

Subclauses 11.8 and 16.8 were modified to require that following interruption and restoration of the power supply to ME EQUIPMENT or all or part of an ME SYSTEM, BASIC SAFETY and ESSENTIAL PERFORMANCE need to be maintained. This replaced the requirement that the interruption and restoration of power supply must not result in an unacceptable RISK.

**5.32 Emissions, deformation of ENCLOSURE or exceeding maximum temperature** (Subclause 13.1.2) [Significant impact]

The additions to this subclause will significantly reduce the situations where a fire ENCLOSURE may be required. The original text was unclear and the new text allows the use of the most conservative values combined with construction restrictions in, IEC 60950-1 for limited energy circuits.

**5.33 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)** (Subclause 14.1) [Moderate impact]

IEC 60601-1:2005 already required a development process for all PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS) including software. It also has informative references to IEC 62304 for information on software. IEC 62304 was under development when the FDIS of IEC 60601-1:2005 was circulated for ballot.

If IEC 62304 was used for software development to meet the requirements of IEC 60601-1, there will be no additional cost. IEC 62304 does provide additional detailed software requirements beyond the requirements of Clause 14, and if IEC 60601-1:2005 was implemented without considering these additional requirements, a moderate amount of effort will be necessary to bring an existing process into compliance with the additional requirements included by referencing IEC 62304.

#### **5.34 Design and implementation** (Subclause 14.9) [Moderate impact]

The reference to the RISK MANAGEMENT FILE WAS removed and replaced with “shall be documented. This is consistent with the way the documentation requirements are written in IEC 62304.

#### **5.35 PEMS VALIDATION** (Subclause 14.11) [Moderate impact]

A new requirement was introduced regarding documentation of the methods used for PEMS VALIDATION.

#### **5.36 Mechanical strength** (Subclause 15.3.1) [Moderate impact]

The reference to unacceptable risk was replaced by a requirement that ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE due to molding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

A new major row was inserted in Table 28 to deal with push, impact, drop and molding stress relief.

#### **5.37 Actuating parts of controls of ME EQUIPMENT** (Subclause 15.4.6.1 b) [Moderate impact]

The portion of the requirement that limited its applicability to controls, the adjustment of which can result in a HAZARDOUS SITUATION for the PATIENT or OPERATOR while ME EQUIPMENT is in use has been removed. The requirement now applies to all controls that indicate any scale, which includes “on” or “off” position, scale markings or other indications of position.

#### **5.38 Limitation of movement** (Subclause 15.4.6.2) [Moderate impact]

The requirement to provide stops of adequate mechanical strength to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter has been extended to all rotating or movable parts of controls. The limitation that the requirement be applied only when an unexpected change could produce a HAZARDOUS SITUATION has been removed.

In addition, when an axial pull is likely to be applied in NORMAL USE there is to be no unexpected change of the controlled parameter.

#### **5.39 Transformers** (Subclause 15.5.1.1) [Moderate impact]

The wording of Subclause 15.5.1.1 in IEC 60601-1:2005 might be understood to say that only one MEANS OF OPERATOR PROTECTION is required between opposite polarity of the secondary output contacts in the area between secondary windings and the subsequent protection component (e.g. the fuse). If this would be true, the device would not be SINGLE FAULT SAFE as required by Subclause 4.7. This change clarifies that requirement.

#### **5.40 Overload test** (Subclause 15.5.1.3) [Moderate impact]

A permissive requirement was added to allow that the overload test may be applied after rectification. This may be advantageous in some situations.

#### **5.41 Dielectric strength** (Subclause 15.5.2) [Moderate impact]

A new requirement was added to clarify how to deal with dielectric strength testing of insulation in transformers other than mains transformers. For transformers operating at frequencies above 1 KHz, the insulation is tested according to the requirement in 8.8.3.

#### **5.42 Construction of transformers used to provide separation as required by 8.5** (Subclause 15.5.3) [Significant impact]

IEC 60601-1:2005 cited the requirements for transformers in Subclause 5.12 or IEC 61558-1:1997. That standard was modified during the development of 60601-1 making it obsolete and referring the user to IEC 61558-2-15. IEC 61558-2-15 is for transformers between 3 and 10 kVA. These requirements are not appropriate for most transformers in ME EQUIPMENT. New text was added containing specific requirements that are based on the principles of the second edition of IEC 60601-1. With reference to spacing and dielectric strength, the requirements of the third edition are employed. Where only MEANS OF OPERATOR PROTECTION is required, transformers constructed for use in IEC 60950-1 equipment should be considered acceptable.

#### **5.43 Resistors bridging a MEANS OF PROTECTION** (Rationale for Subclause 4.8) [Moderate impact]

During the development of Amendment 1, it was observed that the third edition still does not offer a means of providing requirements for resistors that are bridging safety insulation (MOP). Often product design engineers are not sure what is required. As a step forward, the experts in Maintenance Team 28 developed this guidance.

## **6 Changes impacting particular users of the standard**

### **6.1 ME EQUIPMENT intended to receive power from other equipment** (Subclause 7.2.5) [Significant impact]

For ME EQUIPMENT intended to receive power from other equipment where compliance with this standard is dependent on that other equipment, the marking requirement is expanded. The MANUFACTURER must:

- place the name or trademark of the manufacturer of the other electrical equipment with a MODEL OR TYPE REFERENCE of the specified other equipment adjacent to the relevant connection point; or
- place a safety sign () adjacent to the connection point and include the required information in the instructions for use; or
- use a special connector style that is not commonly available on the market and listing of the required details in the instructions for use.

The change also eliminated any reference to RISK MANAGEMENT, so the MANUFACTURER is obligated to use one of these RISK CONTROL measures.

### **6.2 ME EQUIPMENT or ACCESSORIES supplied sterile** (Subclauses 7.2.17 and 7.9.2.18) [Moderate impact]

For ME EQUIPMENT or ACCESSORIES supplied sterile, the marking and instructions for use must indicate the method of sterilization.

The instructions for use must include the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization.

### **6.3 ME EQUIPMENT supplied from an external pressure source** (Subclause 7.2.18) [Moderate impact]

In addition to the maximum supply pressure, ME EQUIPMENT that depends on an external pressure source is now required to label each input connector with the RATED flow rate if a certain flow rate is required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

### **6.4 Mass of MOBILE ME EQUIPMENT** (Subclause 7.2.21) [Significant impact]

MOBILE ME EQUIPMENT is to be marked with its mass including its SAFE WORKING LOAD in kilograms.

### **6.5 General requirements for the instructions for use when the PATIENT is an OPERATOR** (Subclause 7.9.2.1) [Moderate impact]

Where the PATIENT is an intended OPERATOR, the instructions for use are to indicate:

- the PATIENT is an intended OPERATOR;
- a warning against servicing and maintenance while the ME EQUIPMENT is in use;
- which functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and
- which maintenance the PATIENT can perform (e.g. changing batteries).

### **6.6 ME EQUIPMENT emitting radiation** (Subclause 7.9.2.17) [Moderate impact]

When ME EQUIPMENT emits radiation for medical purposes, the instructions for use are to disclose the nature, type, intensity and distribution of this radiation.

### **6.7 ME EQUIPMENT with DEFIBRILLATION-PROOF APPLIED PARTS** (Subclause 8.5.5.1 a)) [Significant impact]

The test requirement was modified to require the measurement of stray voltage during the defibrillation test at any unused or disconnected connections of the APPLIED PART under test or any function of the same APPLIED PART. There is a distinct danger of electric shock to an OPERATOR in the case of an APPLIED PART with multiple functions, where one or more of those functions is unused or is disconnected during defibrillation. There are two distinct situations to be considered:

- a) The unused connection is located at the main body of the ME EQUIPMENT (i.e. directly at the ENCLOSURE) where the likelihood of being touched by a second OPERATOR during defibrillation is deemed to be high; and
- b) An adapter cable is connected to the main body of the ME EQUIPMENT where the likelihood of a second OPERATOR touching any pins at the remote end of the cable during defibrillation is deemed to be low.

The rationale for 8.5.5.1 attempts to clarify how the requirement should be applied in these two situations.

Note 1 in subclause 8.5.5.1 IEC 60601-1:2005 emphasized that the MANUFACTURER needed to consider the possibility of an OPERATOR receiving a shock from such parts should be considered in the RISK MANAGEMENT PROCESS due to the high RISK of a 4 kV electric shock.

This change could have an impact on the testing previously done by MANUFACTURERS of ME EQUIPMENT with such APPLIED PARTS. ME EQUIPMENT that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.

#### **6.8 Energy reduction test for ME EQUIPMENT with DEFIBRILLATION-PROOF APPLIED PARTS** (Subclause 8.5.5.2) [Significant impact]

The test requirements have been modified to more clearly specify how the test voltage is applied to each PATIENT CONNECTION of the APPLIED PART under test. The test is now repeated with the polarity of the test voltage reversed. This change may require retesting of some DEFIBRILLATION-PROOF APPLIED PARTS.

#### **6.9 Measurement of LEAKAGE CURRENT for sterile equipment** (Subclause 8.7.1 b)) [Moderate impact]

The general conditions for the measurement of LEAKAGE CURRENT have been extended to require that, when applicable, these measurements be made following any required sterilization PROCEDURES.

#### **6.10 Isolation of PERMANENTLY INSTALLED ME EQUIPMENT from the SUPPLY MAINS** (Subclause 8.11.1) [Moderate impact]

A new requirement was added that means needs to be provided to isolate PERMANENTLY INSTALLED ME EQUIPMENT from the SUPPLY MAINS. When appropriate, the means for isolating the equipment from the supply mains needs to be capable of being locked in the off position. The actuator of a SUPPLY MAINS switch needs to comply with IEC 60447.

#### **6.11 Protective measures** (Subclause 9.2.2.4.4) [Moderate impact]

The term “protective measures” was changed to “RISK CONTROL measures” and the compliance paragraph was changed from checking the RISK MANAGEMENT FILE TO examination of the construction and circuits, and conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.

#### **6.12 Continuous activation** (Subclause 9.2.2.5) [Moderate impact]

The compliance paragraph was changed from checking the RISK MANAGEMENT FILE to examination of the construction and circuits, and conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.

#### **6.13 Speed of movement(s)** (Subclause 9.2.2.6) [Moderate impact]

The compliance paragraph was changed from checking the RISK MANAGEMENT FILE to inspection of the overtravel (stopping distance) calculations and evaluation and any functional tests.

#### **6.14 Unintended movement** (Subclause 9.2.3.1) [Significant impact]

Inspection of the RISK MANAGEMENT FILE has been replaced by inspection of the USABILITY ENGINEERING FILE when the control limiting unintended movement is part of a PRIMARY OPERATING FUNCTION.

#### **6.15 Overtravel end stops** (subclause 9.2.3.2) [Moderate impact]

The use of RISK MANAGEMENT was replaced by a specific test procedure based on UL 187.

**6.16 Overbalancing from horizontal and vertical forces** (Subclause 9.4.2.3 a)) [Significant impact]

In the test procedure, the lateral force to be applied to the ME EQUIPMENT has been reduced from 25 % of the weight of the unit to 15 % of the weight. The maximum force to be applied has been reduced from 220 N to 150 N.

**6.17 Movement over a threshold** (Subclause 9.4.2.4.3) [Significant impact]

The height of the threshold barrier was reduced from 20 mm to 10 mm. The compliance measure was changed from assessment of unacceptable RISK to maintenance of BASIC SAFETY and ESSENTIAL PERFORMANCE.

**6.18 Instability of MOBILE ME EQUIPMENT in transport position** (Subclause 9.4.3.1 c)) [Moderate impact]

MOBILE ME EQUIPMENT is to be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position.

**6.19 Instability of MOBILE ME EQUIPMENT on an incline surface and in other than transport position** (Subclause 9.4.3.2 a)) [Moderate impact]

MOBILE ME EQUIPMENT is to be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 5° when in any position excluding transport position.

**6.20 Instability of MOBILE ME EQUIPMENT from lateral forces in other than transport position** (Subclause 9.4.3.2 b)) [Significant impact]

In the test procedure, the lateral force to be applied to the ME EQUIPMENT has been reduced from 25 % of the weight of the unit to 15 % of the weight. The maximum force to be applied has been reduced from 220 N to 150 N.

**6.21 Acoustic energy and vibration** (Subclause 9.6.1) [Moderate impact]

This change reduces but does not entirely eliminate the reference to RISK MANAGEMENT in this subclause. Compliance with the general requirement is demonstrated by the tests in Subclauses 9.6.2 and 9.6.3. Reference is made to RISK MANAGEMENT only “when necessary”.

**6.22 Audible acoustic energy measurements** (Subclause 9.6.2.1) [Moderate impact]

This new requirement allows ME EQUIPMENT that is too large to fit in a test room to be tested in place.

**6.23 Static forces due to loading from persons** (Subclause 9.8.3.2) [Moderate impact]

In paragraphs a) and b), the requirement that any deflection that could result in an unacceptable RISK would constitute a failure was replaced by a firm requirement that any permanent deflection from normal of greater than 5° would constitute a failure. In additions, BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

#### **6.24 Dynamic forces due to loading from persons** (Subclause 9.8.3.3) [Moderate impact]

The requirement that the dynamic forces resulting from sitting down, standing up, or other movements of the PATIENT are not to result in an unacceptable RISK was modified to require that BASIC SAFETY and ESSENTIAL PERFORMANCE are to be maintained after a dynamic load is applied.

#### **6.25 ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation** (Subclause 10.1.1) [Moderate impact]

The second paragraph contains a new requirement if the INTENDED USE of the ME EQUIPMENT requires it to be in permanent proximity to a PATIENT. If this is the case, then the resulting annual exposure should be made acceptable taking into account the irradiated body part and national regulations and/or international recommendations.

#### **6.26 ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation** (Subclause 10.1.2) [Moderate impact]

Any unintended X-radiation from ME EQUIPMENT designed to produce diagnostic or therapeutic X-radiation is to be reduced as far as possible by application of applicable particular and collateral standards, or in the absence of these standards by application of RISK MANAGEMENT PROCESS.

#### **6.27 Microwave radiation** (Subclause 10.3) [Significant impact]

The general requirement to apply RISK MANAGEMENT to unintended microwave radiation was replaced by specific requirement and a test procedure. However, a MANUFACTURER is allowed to present calculations to support a claim of compliance. Therefore, the test is only required if calculations are insufficient to demonstrate compliance.

#### **6.28 Lasers and light-emitting diodes (LEDs)** (Subclause 10.4) [Moderate impact]

LEDs are no longer covered by IEC 60825-1. This subclause is restricted to equipment that produces or amplifies electromagnetic radiation in the wavelength range from 180 nm to 1 mm. There is no requirement for LEDs in the general standard. There is an IEC standard (IEC 62471) that could be used to evaluate the safety of LED light sources. However, the testing in that standard is extensive and does not appear to be relevant to typical LEDs used in ME EQUIPMENT.

#### **6.29 APPLIED PARTS not intended to supply heat to a PATIENT** (Subclause 11.1.2.2) [Moderate impact]

For APPLIED PARTS that can exceed 41 °C, the disclosure requirements in this subclause have been extended to include the conditions for safe contact, e.g. duration or condition of the PATIENT.

#### **6.30 Overflow in ME EQUIPMENT** (Subclause 11.6.2) [Moderate impact]

A more severe test has been added unless the fill level is marked on the ME EQUIPMENT. Having the fill level in the instructions was not judged sufficient. Therefore, the reference to the instructions for use was removed. MOBILE ME EQUIPMENT exceeding 45 kg is required to pass over the threshold in Subclause 9.4.2.4.3 without overflowing.

#### **6.31 Diagnostic X-ray equipment** (Subclause 12.4.5.2) [Moderate impact]

The general requirement for RISK MANAGEMENT was replaced by a direct reference to IEC 60601-1-3.