



Medical electrical equipment

Part 2.54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601- 2-54:2018 (ED. 1.2), MOD)



AS 60601.2.54:2018

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- Australasian College of Physical Scientists and Engineers in Medicine
- Australian and New Zealand College of Anaesthetists
- Australian Chamber of Commerce and Industry
- Australian College of Perioperative Nurses
- Australian Radiation Protection and Nuclear Safety Agency
- Australian Society of Anaesthetists
- Certification Body Australia (Certification Interests Australia)
- College of Biomedical Engineering, Engineers Australia
- Department of Defence (Australian Government)
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Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment to supersede AS/NZS 3200.2.7:1999, *Medical electrical equipment Part 2.7: Particular requirements for safety—High voltage generators of diagnostic X-ray generators*.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to specify particular basic safety and essential performance requirements for medical electrical (ME) equipment and ME systems for radiography and radioscopy. The minimum safety requirements specified in this Standard are considered to provide for a practical degree of safety in the operation of ME equipment for radiography and radioscopy.

This Standard amends and supplements the general Standard IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*.

This Standard is an adoption with national modifications, and has been reproduced from, IEC 60601-2-54:2018 (ED. 1.2), *Medical electrical equipment — Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*. [Appendix ZZ](#) lists the variations for the application of this Standard in Australia and New Zealand.

As this document has been reproduced from an International Standard, the following applies:

- (a) In the source text “this particular Standard” should read “this Australian Standard”.
- (b) A full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy**

FOREWORD

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- 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.

DISCLAIMER

This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-54 bears the edition number 1.2. It consists of the first edition (2009-06) [documents 62B/735/FDIS and 62B/750/RVD], its amendment 1 (2015-04) [documents 62B/929/CDV and 62B/956/RVC], its amendment 2 (2018-06) [documents 62B/1089/FDIS and 62B/1097/RVD] and its corrigenda 1 (March 2010) and 2 (June 2011). The technical content is identical to the base edition and its amendments.

This Final version does not show where the technical content is modified by amendments 1 and 2. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-2-54 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

IEC 60601-2-54 has been developed for use with the third edition of IEC 60601-1 (2005). It replaces and supersedes IEC 60601-2-7 and IEC 60601-2-32, as well as parts of IEC 60601-2-28:1993, all of which were developed to amend earlier editions of IEC 60601-1 and consequently no longer apply to this particular standard.

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

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendments 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.

INTRODUCTION

This particular standard has been prepared to provide, based on IEC 60601-1:2005 (third edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. While the previously existing standards for such equipment were dedicated to components and subsystems, this particular standard addresses the system level of X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, ASSOCIATED EQUIPMENT and ACCESSORIES. Component functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for RADIOGRAPHY and RADIOSCOPY. Requirements for additional provisions for ME EQUIPMENT for interventional applications are covered by IEC 60601-2-43.

INTRODUCTION TO AMENDMENT 1

The purpose of this first amendment to IEC 60601-2-54:2009 is to introduce changes to reference the first amendment (2012) to IEC 60601-1:2005. As neither IEC 60601-2-54:2009 nor this amendment refers to specific elements of IEC 60601-1-2, the introduction of a dated reference to the latter document has been removed. In addition, a number of technical errors have been corrected.

INTRODUCTION TO AMENDMENT 2

The purpose of this second amendment to IEC 60601-2-54:2009 is to introduce changes which take the current state of the art into account. Therefore, X-RAY EQUIPMENT specified for DIRECT RADIOSCOPY is no longer in the scope of this document. The normative references were also updated in this amendment, and editorial clarifications and new terms and definitions were added. Provisions for QUALITY CONTROL PROCEDURES to be recommended by the MANUFACTURER are emphasized. Specific attention is paid to EXAMINATION PROTOCOLS in a new subclause which differentiate between adult and paediatric applications, in particular for X-RAY EQUIPMENT without an AUTOMATIC CONTROL SYSTEM. In addition, fixed periods for termination of LOADING after release of the RADIATION control by the OPERATOR are stipulated for RADIOSCOPY.

A new subclause on electronic documentation of EXAMINATION PROTOCOLS is introduced. It recommends providing access to electronic documentation containing relevant parameters of the PRE-PROGRAMMED EXAMINATION PROTOCOL. In another new subclause, the creation of basic documentation of the RADIATION DOSE STRUCTURED REPORT (RDSR) according to IEC 61910-1 is recommended. Furthermore, the subclause describing the LAST IMAGE HOLD RADIOGRAM has been revised and requires that the last image in RADIOSCOPY be displayed rather than provide just a means to display it.

This amendment recommends providing a graphical DISPLAY of the position of the BEAM LIMITING DEVICE blades on the IMAGE DISPLAY DEVICE in the subclause "Indication on the X-RAY EQUIPMENT".

Finally, the requirement for providing means to limit the FOCAL SPOT TO SKIN DISTANCES for radiosopic X-RAY EQUIPMENT differentiates between MOBILE and FIXED EQUIPMENT and extends, in the latter case, the minimum distance in possible clinical applications.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS intended to be used for projection RADIOGRAPHY and INDIRECT RADIOSCOPY. IEC 60601-2-43 applies to ME EQUIPMENT and ME SYSTEMS intended to be used for interventional applications and refers to applicable requirements in this particular standard.

ME EQUIPMENT and ME SYSTEMS intended to be used for bone or tissue absorption densitometry, computed tomography, mammography or dental or radiotherapy applications are excluded from the scope of this International Standard. The scope of this International Standard also excludes radiotherapy simulators.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ME EQUIPMENT and ME SYSTEMS for RADIOGRAPHY and RADIOSCOPY.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE OPERATORS of X-RAY EQUIPMENT are used to audible signals as required in this particular standard rather than to the concepts of IEC 60601-1-8. Therefore IEC 60601-1-8 does not apply.

¹⁾ The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 72.

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60336, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60580:2000, *Medical electrical equipment – Dose area product meters*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC/TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60806, *Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis*

IEC 62220-1-1:2015, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-1: Determination of the detective quantum efficiency – Detectors used in radiographic imaging*

Amendment:

IEC 60601-1-3:2008 *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013

IEC 61910-1:2014, *Medical electrical equipment – Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*

IEC 62494-1:2008, *Medical electrical equipment – Exposure index of digital X-ray imaging systems – Part 1: Definitions and requirements for general radiography*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, applicable collateral standards and IEC 60788:2004 apply, except as follows:

NOTE An index of defined terms is found beginning on page 72.

*Addition:***201.3.201****DIRECT RADIOGRAPHY**

RADIOGRAPHY in which the permanent recording is effected at an IMAGE RECEPTION AREA

Example: film-screen or film radiography.

201.3.202**DIRECT RADIOSCOPY**

RADIOSCOPY in which the visible images are presented at the IMAGE RECEPTION AREA, or close to it, in the RADIATION BEAM

201.3.203**DOSE AREA PRODUCT**

product of the area of the cross-section of an X-RAY BEAM and the averaged AIR KERMA over that cross-section. The unit is the gray square metre ($\text{Gy}\cdot\text{m}^2$)

201.3.204**ENTRANCE FIELD SIZE**

dimensions of the field in the entrance plane of an X-RAY IMAGE RECEPTOR that can be used for the transmission of an X-RAY PATTERN under specific conditions

201.3.205**INDIRECT RADIOGRAPHY**

RADIOGRAPHY in which the permanent recording is effected after TRANSFER of the information obtained at an IMAGE RECEPTION AREA

Examples: CR systems, digital detector systems, image intensifier systems.

201.3.206**INDIRECT RADIOSCOPY**

RADIOSCOPY in which the images are presented at a location outside the RADIATION BEAM after TRANSFER of the information

201.3.207**INTERLOCK**

means preventing the start or the continued operation of ME EQUIPMENT unless certain predetermined conditions prevail

201.3.208**NOMINAL SHORTEST IRRADIATION TIME**

shortest LOADING TIME for which a required constancy of the controlled RADIATION QUANTITY is maintained

NOTE The IRRADIATION TIME is controlled by a HIGH-VOLTAGE GENERATOR with AUTOMATIC CONTROL SYSTEMS.

201.3.209**SERIAL RADIOGRAPHY**

RADIOGRAPHY in which the information is obtained and recorded in a regular or irregular series of LOADINGS with equal or unequal LOADING FACTORS

201.3.210**EXAMINATION PROTOCOL**

full set of any programmed technical factors, control functions and settings, including image processing settings, designed to optimize the image acquisition and DISPLAY

201.3.211**EXAMINATION PROTOCOL SELECTION CONTROL**

control to select a PRE-PROGRAMMED EXAMINATION PROTOCOL

201.3.212**LAST-IMAGE HOLD RADIOGRAM****LIH RADIOGRAM**

single image obtained by sampling or temporal processing of one or more images from the end of a radioscopy IRRADIATION

Note 1 to entry: This note applies to the French language only.

201.3.213**PRE-PROGRAMMED EXAMINATION PROTOCOL**

single hardware or software setting, or both, which is associated with an EXAMINATION PROTOCOL

201.3.214**RADIOLOGY REPLAY IMAGE SEQUENCE**

series of the most recent images of the most recent RADIOLOGY IRRADIATION-EVENT

201.4 General requirements

Clause 4 of the general standard applies, except as follows

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 * Additional potential ESSENTIAL PERFORMANCE requirements

Additional potential ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.104
Reproducibility of the RADIATION output	203.6.3.2
AUTOMATIC CONTROL SYSTEM	203.6.5
Imaging performance	203.6.7

201.4.10.2 Supply mains for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of X-RAY EQUIPMENT for RADIOGRAPHY and RADIOLOGY if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

Either the APPARENT RESISTANCE OF SUPPLY MAINS or other appropriate SUPPLY MAINS specifications used in a facility shall be specified in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than $\pm 2\%$ of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems may be derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

X-RAY EQUIPMENT is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.7 Electrical input power from the SUPPLY MAINS

Addition:

For ME EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

- a) the RATED MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of the general standard,
- b) the number of phases; see 7.2.1 and 7.2.6 of the general standard,
- c) the frequency, in hertz; see 7.2.1 and 7.2.6 of the general standard,
- d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
- e) the characteristics of OVER-CURRENT RELEASES required in the SUPPLY MAINS.

NOTE These requirements are adapted from 6.1j) of IEC 60601-2-7:1998.

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENT, including as appropriate:

- the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;
- the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;
- the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

NOTE These requirements are adapted from 6.1t) of IEC 60601-2-7:1998.

Additional subclause:

201.7.2.101 Beam limiting device

BEAM LIMITING DEVICES shall be provided with the following markings:

- those required in subclause 7.2.2 of the general standard;

- serial designation or individual identification;
- QUALITY EQUIVALENT FILTRATION of all materials together that are permanently fixed and intercept the X-RAY BEAM.

NOTE These requirements are adapted from 6.1 of IEC 60601-2-28:1993.

201.7.8.1 Colours of indicator lights

Addition:

The indication of X-RAY related states shall be excluded from subclause 7.8 in the general standard. Subclauses 203.6.4.2 and 203.6.4.101 shall apply instead.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall contain instructions for MANUFACTURER-recommended QUALITY CONTROL PROCEDURES and tests to be performed on the X-RAY EQUIPMENT by the RESPONSIBLE ORGANIZATION. These shall include acceptance criteria for each test and frequency for each test.

NOTE The intention is to perform these QUALITY CONTROL PROCEDURES and tests using only the supplied information.

Additionally for X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

- an identification of adjustable or selectable image processing applied to ORIGINAL DATA including the version number or how to determine it;
- a description of the file transfer format of the images acquired with this unit and of any data associated with these images;

The performance of means required to present the images for diagnostic purpose shall be stated according to the INTENDED USE.

If the test or PROCEDURE requires a device-specific TOOL that is only available from the MANUFACTURER, the MANUFACTURER shall make this TOOL available to the RESPONSIBLE ORGANIZATION.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

201.7.9.2.1.101 LOADING FACTORS

In the instructions for use the LOADING FACTORS shall be stated as described below. The following combinations and data shall be stated:

- a) The corresponding NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE CURRENT obtainable from the ME EQUIPMENT when operated at that X-RAY TUBE VOLTAGE.

- b) The corresponding highest X-RAY TUBE CURRENT for RADIOSCOPY and RADIOGRAPHY together with the highest X-RAY TUBE VOLTAGE obtainable from the ME EQUIPMENT when operating at that X-RAY TUBE CURRENT.
- c) The corresponding combination of X-RAY TUBE VOLTAGE for RADIOSCOPY and RADIOGRAPHY, and X-RAY TUBE CURRENT which results in the highest electric power in the high-voltage circuit (see 203.4.101).
- d) The NOMINAL ELECTRIC POWER given as the highest constant electric power in kilowatts which the ME EQUIPMENT can produce/generate, for a LOADING TIME of 0,1 s at an X-RAY TUBE VOLTAGE of 100 kV or, if these values are not selectable, with nearest parameters (see 203.4.101).

The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME.

- e) For ME EQUIPMENT indicating precalculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT.

If the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence.

- f) The NOMINAL SHORTEST IRRADIATION TIME used in AUTOMATIC EXPOSURE CONTROL systems of ME EQUIPMENT.

If the NOMINAL SHORTEST IRRADIATION TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the NOMINAL SHORTEST IRRADIATION TIME is valid shall be stated.

The maximum possible range of the X-RAY TUBE VOLTAGE and/or the X-RAY TUBE CURRENT during IRRADIATIONS, controlled with the AUTOMATIC EXPOSURE CONTROL SYSTEMS, shall be stated in the instructions for use.

NOTE These requirements are adapted from 6.8.2 a) of IEC 60601-2-7:1998.

201.7.9.2.1.102 X-RAY SOURCE ASSEMBLY

The instructions for use shall state the maximum symmetrical RADIATION FIELD of the integrated X-RAY SOURCE ASSEMBLY determined according to IEC 60806.

NOTE This requirement is adapted from 6.8.2 (dd) of IEC 60601-2-28:1993.

201.7.9.2.1.103 Integrated X-RAY IMAGE RECEPTOR

For X-RAY EQUIPMENT provided with an integrated X-RAY IMAGE RECEPTOR, the instructions for use shall contain a description of the particular handling and maintenance of the X-RAY IMAGE RECEPTOR.

Compliance is checked by inspection of the instructions for use.

201.7.9.2.17 ME EQUIPMENT emitting radiation

Replacement:

For X-RAY EQUIPMENT the instructions for use shall provide information as required in 203.5.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 X-RAY SOURCE ASSEMBLY

The technical description of the integrated X-RAY SOURCE ASSEMBLIES shall specify the following, in addition to the data required to be marked according to subclause 7.2 of the general standard:

- a) specification of the REFERENCE AXIS to which the TARGET ANGLE(s) and the FOCAL SPOT characteristics of the X-RAY SOURCE ASSEMBLY refer;
- b) TARGET ANGLE(s) with respect to the specified REFERENCE AXIS;
- c) position of the FOCAL SPOT and its tolerances on the REFERENCE AXIS;
- d) NOMINAL FOCAL SPOT VALUE(s) determined according to IEC 60336 for the specified REFERENCE AXIS.

NOTE These requirements are adapted from 6.8.3 dd) of IEC 60601-2-28:1993.

Additional subclause:

201.7.9.101 Additional statements in ACCOMPANYING DOCUMENTS

Additional requirements for statements in ACCOMPANYING DOCUMENTS (which include instructions for use and technical description) are found in the subclauses listed in Table 201.C.102 of Annex C.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.4 Limitation of voltage, current or energy**201.8.4.3 ME EQUIPMENT intended to be connected to a power source by a plug**

Addition:

201.8.4.3.101 HIGH-VOLTAGE CABLE CONNECTIONS

Detachable HIGH-VOLTAGE CABLE CONNECTIONS shall either be designed so that the use of TOOLS is required to disconnect them or they shall be provided with INTERLOCKS so that at all times when protective covers or HIGH-VOLTAGE CONNECTIONS are removed:

- the ME EQUIPMENT is disconnected from its power supply, and
- capacitances in the high-voltage circuit are discharged within the minimum time necessary to gain access to the high-voltage circuit, and
- the discharged state is maintained.

Compliance is checked by inspection and by measurement.

NOTE These requirements are adapted from Clause 15, item aa) of IEC 60601-2-7:1998.

Additional subclause:

201.8.4.101 Limitation of X-RAY TUBE VOLTAGE

ME EQUIPMENT shall be designed so as not to deliver in INTENDED USE, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE concerned or greater than the NOMINAL X-RAY TUBE VOLTAGE the X-RAY TUBE ASSEMBLY is designed for, whichever is the lower voltage.

NOTE This requirement is adapted from 3.1 of IEC 60601-2-7:1998.

201.8.5 Separation of parts**201.8.5.1 MEANS OF PROTECTION (MOP)**

Additional subclause:

201.8.5.1.101 Additional limitation of voltage, current or energy

Provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE This may be achieved for example

- by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between high-voltage and low-voltage circuits;
- by provision of a voltage limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path becomes discontinuous.

Compliance is checked by inspection of design data and construction.

NOTE These requirements are adapted from 15bb) of IEC 60601-2-7:1998.

201.8.5.4 WORKING VOLTAGE

Addition:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

NOTE This requirement is adapted from 20.4 I) of IEC 60601-2-7:1998.

201.8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT**201.8.6.4 Impedance and current-carrying capability**

Addition:

The flexible conductive screen is not to be recognized as satisfying a requirement for a PROTECTIVE EARTH CONNECTION between the devices connected by the cable.

Additional subclause:

201.8.6.101 X-RAY TUBE ASSEMBLY

- a) Accessible high-voltage cables connecting X-RAY TUBE ASSEMBLIES to their associated HIGH-VOLTAGE GENERATOR shall incorporate a flexible conductive screen, having a resistance per unit length not exceeding $1 \Omega \text{ m}^{-1}$, and covered with a non-conductive material capable of protecting the screen against mechanical damage. The screen shall be connected to the conductive ENCLOSURE of the HIGH-VOLTAGE GENERATOR.

Compliance is checked by visual inspection and by measurement.

NOTE These requirements are adopted from Clause 16, item aa) of IEC 60601-2-28:1993.

- b) In all cases, there shall be electrical continuity between the screen of a fitted high-voltage cable and the ACCESSIBLE METAL PARTS of its receptacle on the X-RAY TUBE ASSEMBLY.

Compliance is checked by visual inspection and by measurement.

NOTE These requirements are adopted from Clause 16, item cc) of IEC 60601-2-28:1993.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 *Allowable values

Item c) is amended as follows:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the TOUCH CURRENT under SINGLE FAULT CONDITION shall not exceed 2 mA.

Item d) is replaced by:

For MOBILE X-RAY EQUIPMENT and TRANSPORTABLE X-RAY EQUIPMENT, the allowable values of the EARTH LEAKAGE CURRENT are 2,5 mA in NORMAL CONDITION and 5 mA in SINGLE FAULT CONDITIONS. For PERMANENTLY INSTALLED ME EQUIPMENT, the allowable value of EARTH LEAKAGE CURRENT is 10 mA in NORMAL CONDITION and in SINGLE FAULT CONDITIONS.

Item e) is amended as follows:

For PERMANENTLY INSTALLED ME EQUIPMENT including HIGH-VOLTAGE GENERATORS, the allowable value of EARTH LEAKAGE CURRENT is 20 mA in NORMAL CONDITION and SINGLE FAULT CONDITION.

NOTE These requirements are adapted from 19.3 of IEC 60601-2-7:1998.

201.8.8.3 Dielectric strength

Amendment to the compliance test for high-voltage circuit:

The high-voltage circuit of the ME EQUIPMENT is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s to the full value, which is maintained for 3 min in RADIOGRAPHY and 15 min in RADIOSCOPY.

Addition to the test conditions for high-voltage circuit:

The test for the high-voltage circuit shall be made without an X-RAY TUBE ASSEMBLY connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the ME EQUIPMENT.

If the ME EQUIPMENT can be tested only with the X-RAY TUBE ASSEMBLY connected and if the X-RAY TUBE does not allow the ME EQUIPMENT to be tested with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE, the test voltage may be lower but not less than 1,1 times that voltage.

For ME EQUIPMENT in which the NOMINAL X-RAY TUBE VOLTAGE for RADIOSCOPY does not exceed 80 % of that for RADIOGRAPHY, the test voltage for the high-voltage circuit shall be referred to the value for RADIOGRAPHY, and the test shall be carried out in that mode only.

If during the dielectric strength test there is a RISK of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

During the dielectric strength test, slight corona discharges in the high-voltage circuit are to be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

Additions:

- aa) *HIGH-VOLTAGE GENERATORS or subassemblies thereof, that are integrated with an X-RAY TUBE ASSEMBLY are to be tested with an appropriately loaded X-RAY TUBE;*
- bb) *If such HIGH-VOLTAGE GENERATORS do not have separate adjustment of the X-RAY TUBE CURRENT, the duration of the dielectric strength test is to be reduced to such an extent that the allowable X-RAY TUBE LOAD at the increased X-RAY TUBE VOLTAGE will not be exceeded.*
- cc) *If the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures should be taken to ensure that the values are kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.*

NOTE These requirements are adapted from 20.3 and 20.4 of IEC 60601-2-7:1998.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.2 TRAPPING ZONE

201.9.2.2.4 GUARDS and other RISK CONTROL measures

201.9.2.2.4.4 Other RISK CONTROL measures

Addition:

201.9.2.2.4.4.101 Collision protection

If anti-collision features are provided with the X-RAY EQUIPMENT, the instructions for use shall describe the anti-collision features. In addition the measures provided to prevent unnecessary interruption and to allow continuation of a procedure shall be described.

Means shall be provided or warnings given in the ACCOMPANYING DOCUMENTS, to prevent injuries that could result from collision of power-driven ME EQUIPMENT parts with other moving or stationary items likely to be in proximity.

Compliance is checked by inspection of the instructions for use.

201.9.2.2.5 Continuous activation

Amendment:

The movement of ME EQUIPMENT or ME EQUIPMENT parts which could cause physical injury to the PATIENT or OPERATOR in NORMAL USE shall require the continuous control of the OPERATOR.

The motorized movement of ME EQUIPMENT or ME EQUIPMENT parts which could crush or otherwise cause physical injury to the PATIENT or OPERATOR, and for which the response of the OPERATOR to actuate an emergency stop cannot be relied on to prevent an injury, shall be operated only by continuous actuation of two switches by the OPERATOR. Each switch shall be capable of interrupting independently the movement.

The two switches may be designed into a single control, and one switch may be in a circuit which is common to all motions.

These switches shall be in a location such that possible injury to the PATIENT can be observed by the OPERATOR. At least one set of switches shall be so located as to require the presence of the OPERATOR close to the PATIENT, to observe the moving parts of the ME EQUIPMENT.

The motorized movement of ME EQUIPMENT parts which could indirectly cause physical injury, such as a table angulation which could cause a PATIENT to fall, is not required to be controlled by two switches.

For ME EQUIPMENT designed to be set up or pre-positioned automatically, a control requiring continuous actuation which stops the mechanical motions on release shall be located at the position where movements can be visually observed. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, continuous actuation is not required.

The MANUFACTURER shall identify by RISK MANAGEMENT the motorized movements which could cause the HAZARD.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional test.

201.9.2.2.6 Speed of movement(s)

Addition:

The overtravel of such movement, occurring after actuation of a control to stop the motion, shall not exceed 10 mm in NORMAL USE. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, overtravel may exceed 10 mm.

Except for MOBILE ME EQUIPMENT, when movement of power-driven ME EQUIPMENT towards the PATIENT is within 300 mm of the PATIENT table top, or 100 mm of the table side, the speed should be limited to half the maximum speed. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, the speed limitation is not required.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional test and measurement.

NOTE These requirements are adapted from 22.4.4 of IEC 60601-2-32:1994.

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 Unintended movement

Addition:

Means shall be provided to minimize the possibility of unintended motion, which could result in physical injury to the PATIENT or OPERATOR, in NORMAL USE and SINGLE FAULT CONDITION. The following shall apply:

- a) Where failure, such as welded relay contacts, would result in uncontrolled motion, redundant control or other such protection shall be provided. A failure of one of the redundant controls shall be indicated to the OPERATOR, either directly or by a test according to the instructions for use.
- b) Switching elements shall not be connected on the earthed side of a motion controlling circuit.

Compliance is checked by inspection of the circuit diagram, visual inspection and functional test.

NOTE These requirements are adapted from 22.4.2 of IEC 60601-2-32:1994.

For PERMANENTLY INSTALLED ME EQUIPMENT or PERMANENTLY INSTALLED ME EQUIPMENT parts the following shall apply:

When placement or movement of an object or PATIENT against any motion control can actuate both switches, there shall be a motion disabling switch that permits disabling of the motion controls.

NOTE This switch can be located in the procedure room and not necessarily at the table side. It may be helpful to the OPERATOR to have the motion disabling switch located near the IRRADIATION disabling switch.

The operation of the motion disabling switch shall not, in itself, be capable of initiating motions.

There shall be an indication of the motion disabling switch state at the working position of the OPERATOR.

The location, function and operation of the motion disabling switch shall be described in the instructions for use.

The motion disabling switch shall be separate from the IRRADIATION disabling switch.

The switch should be readily accessible to the OPERATOR and configured to minimize the likelihood of accidental operation.

The configurations shall be considered in the USABILITY ENGINEERING PROCESS.

Compliance is checked by functional tests and by inspection of the instructions for use and the USABILITY ENGINEERING FILE.

201.9.2.3.1.101 Unintended movement during PATIENT loading/unloading

Means shall be provided to prevent unintended movement of ME EQUIPMENT or ME EQUIPMENT parts during PATIENT loading and unloading that could cause injury to the PATIENT or OPERATOR.

Compliance is checked by functional test taking into account the maximum NOMINAL PATIENT weight.

Additional subclause:

201.9.2.3.101 Pressure and force limitation

The pressure or force allowed to be applied to the PATIENT for diagnostic purposes shall be analysed with respect to the body part which may come in contact with the ME EQUIPMENT, to application requirements and the potential for injury. As a general guideline, the pressure on the PATIENT should be limited to 70 kPa maximum and the force to 200 N.

NOTE Higher limits of COMPRESSION DEVICE may be allowed by different local regulations.

For motorized compression movements, means shall be provided which limit the force applied to the PATIENT, according to the values given in the instructions for use.

Compliance is checked by visual inspection, functional test, measurement and inspection of the instructions for use.

NOTE These requirements are adapted from 22.4.3 of IEC 60601-2-32:1994.

201.9.2.3.102 Motion INTERLOCK for COMPRESSION DEVICES

When a compression force is applied to the PATIENT and the movements are not directly controlled by an OPERATOR in the vicinity of the PATIENT, movements which could be hazardous to the PATIENT and are not needed for the examination shall be interlocked. In case override of this INTERLOCK is necessary for the ongoing procedure, provision may be given to override this INTERLOCK through a dedicated control. Visual indication shall be given to the OPERATOR as long as the INTERLOCK override is active.

Information shall be given in the instructions for use warning the OPERATOR against possible RISK resulting from the use of this INTERLOCK override.

Compliance is checked by functional test and by inspection of the ACCOMPANYING DOCUMENTS.

201.9.2.4 Emergency stopping devices

Addition:

201.9.2.4.101 Controls

All power-driven motions which could cause physical injury shall be provided with an emergency stop control. In the event of an emergency stop, means shall be provided for PATIENT access and removal while the ME EQUIPMENT is disabled. If safety can be achieved by other means and if justified in the RISK MANAGEMENT FILE, an emergency stop control is not required.

If in NORMAL USE a power-driven ME EQUIPMENT part is intended or likely to contact the PATIENT, and when appropriate for the designed application, means shall be provided to detect PATIENT contact and stop the motion if the contact could cause physical injury to the PATIENT.

Compliance is checked by functional test and by inspection of the RISK MANAGEMENT FILE.

NOTE These requirements are adapted from 22.4.1 of IEC 60601-2-32:1994.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.3.3 Dynamic forces due to loading from persons

Addition:

NOTE The mass is accelerated for 150 mm, and then decelerates during compression of the 60 mm of foam, resulting in a force equivalent from 2 to 3 times the SAFE WORKING LOAD.

Where mechanical analysis proves that the following alternate static load test is more severe than the dynamic load test specified in the general standard, it is possible to waive the dynamic load test based on RISK MANAGEMENT. If the dynamic load test is passed, the static test may not be necessary.

Prior to performing this test, a PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

For the area of support/suspension where a PATIENT or OPERATOR can sit, adequate multiples of mass (as defined in Figure 33 in general standard) equivalent to SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in instructions for use is applied to the area for at least one minute. Any loss of function or structural damage that could result in unacceptable RISK constitutes a failure.

201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

Additional subclause: